IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: WELLBUTRIN XL ANTITRUST LITIGATION	:	CIVIL ACTION
	:	NO. 08-2431 (direct)
	:	NO. 08-2433 (indirect)

MEMORANDUM

McLaughlin, J. May 11, 2012

TABLE OF CONTENTS

Page

I. Legal and Factual Background. 2

A. The Drug Approval Process and Regulatory Framework. . 2

B. The Citizen Petition Process. 4

C. Wellbutrin IR, Wellbutrin SR, and Wellbutrin XL. . . . 5

D. *Noerr-Pennington* Immunity and the Sham Exception. . . 7

E. Standard of Proof as to Objective Baselessness. . . 11

II. Overview. 13

III. Biovail's Conduct. 15

A. The *Anchen* Lawsuit. 15

B. The *Watson* Lawsuit. 26

C. The *Abrika* Lawsuit. 28

D. The *Impax* Lawsuit. 43

E. The Citizen Petition. 50

IV. GSK's Conduct. 82

A. The *Impax* and *Watson* Lawsuits. 84

B. Biovail's Citizen Petition. 86

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Wellbutrin XL is a once-a-day antidepressant containing the active pharmaceutical ingredient bupropion hydrochloride. It is produced by Biovail Corporation, Biovail Laboratories, Inc., and Biovail Laboratories International SRL[1] (together, "Biovail"), and distributed by SmithKline Beecham Corporation and GlaxoSmithKline, PLC (together, "GSK"). The plaintiffs, direct and indirect purchasers of Wellbutrin XL, have sued Biovail and GSK for illegally conspiring to prevent generic versions of Wellbutrin XL from entering the American market by filing sham patent infringement lawsuits and a citizen petition with the Food and Drug Administration ("FDA"), and entering into agreements with generic companies to settle the lawsuits.

Biovail and GSK now each move for summary judgment, arguing that their conduct is protected from antitrust liability

[1] The Biovail defendants have changed their names or corporate structures following a merger. See Notice of Change of Names of Biovail Defs. (08-cv-2431 ECF No. 407; 08-cv-2433 ECF No. 375). For the sake of continuity, the Court will continue to refer to these defendants collectively as "Biovail."

under the Noerr-Pennington doctrine, and that the settlement agreements are not independently actionable. GSK also argues that it had no involvement in some of the allegedly anticompetitive conduct and, therefore, cannot be held conspiratorially liable for it. The Court will grant the motions as to the four lawsuits and the citizen petition, and defer decision as to the settlement agreements until a future date.

I. Legal and Factual Background[2]

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

Under the first procedure, the applicant files a New Drug Application ("NDA"), which must contain examples of the proposed labeling for the drug as well as clinical data demonstrating the drug's safety and efficacy. Among other

[2] The facts here are undisputed unless otherwise noted. The Court will frequently cite to the following documents: Biovail Stmt. (ECF No. 413/ECF No. 381); GSK Stmt. (ECF No. 411/ECF No. 379); Pls.' Stmt. Resp. (ECF No. 431/ECF No. 394); Pls.' Stmt. (ECF No. 430/ECF No. 393). Where the Court refers to ECF numbers in this memorandum, the first number listed corresponds to the docket entry in 08-cv-2431, and the second corresponds to 08-cv-2433. The Court will cite Biovail exhibits as "BX," GSK exhibits as "GX," and plaintiffs' exhibits as "PX."

things, the NDA must also contain 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." The FDA publishes the names of approved drugs and their associated patents in what is commonly known as the "Orange Book." 21 U.S.C. § 355(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). Under the Hatch-Waxman Act, companies seeking to manufacture and market a generic version of a previously approved pioneer drug (known as the "listed drug") need not file an NDA. Instead, they are 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, 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). 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 (1) the date that the first filer begins to market its drug or (2) 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).

B. The Citizen Petition Process

Federal regulations provide that an interested person may petition the FDA to "issue, amend, or revoke a regulation or

order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25. A citizen petition must describe the FDA action requested, include a statement of the factual and legal grounds on which the petitioner relies, and certify that the petition includes "all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition." 21 C.F.R. § 10.30(a). Within 180 days of receiving the petition, the FDA must furnish a response to the petitioner either approving, denying, or providing a tentative response that indicates why the agency has been unable to reach a decision on the petition.[3] Id. § 10.30(e)(2).

C. Wellbutrin IR, Wellbutrin SR, and Wellbutrin XL

Buproprion hydrochloride, an active pharmaceutical ingredient for treating 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

[3] In 2007, Congress amended the FDCA to provide that the FDA shall not delay approval of an ANDA on account of a pending citizen petition unless the FDA determines that "a delay is necessary to protect the public health." Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 914, 121 Stat. 823, 954 (2007) (codified as amended at 21 U.S.C. § 355(q)(1)(A)(ii)). The 2007 amendments occurred after Biovail filed its citizen petition and are not applicable to this case.

active ingredient and is taken three times a day. The FDA approved Wellbutrin IR on the basis of human clinical trials that demonstrated the safety and efficacy of buproprion hydrochloride and set the maximum recommended daily dose at 450 mg/day. Clinical data indicated an increase in seizure risk above that recommended daily dose. Biovail Stmt. ¶¶ 77-78; Pls.' Stmt. Resp. ¶¶ 77-78; GSK Stmt. ¶ 1; Pls.' Stmt. Resp. ¶ 1.

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 bioequivalence to Wellbutrin IR. The maximum recommended daily dose for Wellbutrin SR is also 450 mg/day. Biovail Stmt. ¶ 79; Pls.' Stmt. Resp. ¶ 79.

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. ¶ 3; Pls.' Stmt. Resp. ¶ 3.

Previous patents had covered bupropion hydrochloride tablets that contained "stabilizers," which are ingredients that prevent bupropion hydrochloride from degrading. Biovail Stmt. ¶ 1; Pls.' Stmt. Resp. ¶ 1. The '341 patent's summary of the invention, however, describes a controlled release tablet

comprising:

(i) a core comprising bupropion hydrochloride and conventional excipients, free of stabilizer; and
(ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer.

'341 Patent (BX 1) (emphasis added).

On October 26, 2001, Biovail and GSK entered into an agreement to develop a once-a-day extended release bupropion hydrochloride tablet that practiced the '341 patent. 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. In August 2002, GSK filed an NDA for Wellbutrin XL and included the '341 and '327 patents for listing in the Orange Book. The FDA approved the NDA for Wellbutrin XL in August 2003 on the basis of bioequivalence to Wellbutrin IR and SR. Thereafter, GSK began to market the drug to great commercial success. As with Wellbutrin IR and SR, the recommended daily dose for Wellbutrin XL was 450 mg/day, although the adult target dose is 300 mg/day. Biovail Stmt. ¶¶ 2, 80; Pls.' Stmt. Resp. ¶¶ 2, 80; GSK Stmt. ¶ 7; Pls.' Stmt. Resp. ¶ 7.

D. *Noerr-Pennington* Immunity and the Sham Exception

A party who petitions the government for redress is generally immune from antitrust liability. Professional Real

Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 56 (1993); Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir. 1999). Under what is known as the Noerr-Pennington doctrine, the First Amendment protects the right to petition all types of government entities, including the right to bring legitimate disputes to the courts for judicial resolution. Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670 (1965); California Motor Transp. Co. v. Trucking Unltd., 404 U.S. 508, 510 (1972).

Noerr-Pennington immunity, however, is not absolute. It is subject to a "sham" exception for activities that are a "mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor." PRE, 508 U.S. at 56 (citing Noerr, 365 U.S. at 144). The sham exception is applicable not only to lawsuits but also to administrative petitions.[4] Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119,

[4] The Third Circuit has applied the sham exception to petitions to the Department of Commerce and the U.S. International Trade Commission. Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 123 (3d Cir. 1999). However, it does not appear to have decided whether the sham exception applies to FDA citizen petitions.

Biovail does not dispute that the sham exception applies to its citizen petition. See Biovail Br. 47. The Court therefore does not address the argument considered and rejected by the court in In re Prograf Antitrust Litigation that the sham exception to Noerr-Pennington immunity is unavailable in the FDA citizen petition context. See In re Prograf Antitrust Litig., No. 11-md-2242, 2012 WL 293850, at *5 (D. Mass. Feb. 1, 2012).

123 (3d Cir. 1999); In re: DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 686 (2d Cir. 2009). In PRE, the Supreme Court set forth a two-tiered definition of the sham exception. The first prong is concerned with the objective merit of the lawsuit or petition at issue, and the second focuses on the antitrust defendants' subjective intentions.

Under the first prong of the test, the party invoking the sham exception, here the plaintiffs, must show that the defendants' conduct is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." PRE, 508 U.S. at 60. Put another way, "[i]f an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail." Id. The existence of probable cause to institute proceedings is an absolute defense to antitrust liability.[5] Cheminor Drugs, 168 F.3d at 122 (citing PRE, 508

In that case, the antitrust defendant cited Kottle v. Nw. Kidney Centers for the proposition that the sham exception does not apply because the FDA resembles a political entity more than a judicial body. See Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1062 (9th Cir. 1998) ("Only when administrative officials must follow rules is it meaningful to ask whether a petition before an agency was 'objectively baseless' . . . ."). The Prograf court rejected the application of Kottle. 2012 WL 293850, at *5; see also In re Flonase Antitrust Litig., 795 F. Supp. 2d 300, 310 n.11 (E.D. Pa. 2011).

[5] The Supreme Court compared the notion of probable cause here to the same notion in the common law tort of wrongful civil

U.S. at 62-63).

Loss on the merits of the underlying proceeding, although instructive, is not determinative on the issue of objective baselessness. See PRE, 508 U.S. at 65 (holding that a copyright action in which the party lost on summary judgment was not sham litigation); FilmTec Corp. v. Hydranautics, 67 F.3d 931, 937 (Fed. Cir. 1995). The PRE Court specifically warned courts to "resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." 508 U.S. at 61 n.5 (internal citations and quotation marks omitted). Where there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law. PRE, 508 U.S. at 63.

Only if an action is objectively baseless may a court proceed to the second prong of the sham exception definition. Under the subjective second prong, a court should examine whether the baseless suit or petition "conceals an attempt to interfere

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proceedings, frequently called "malicious prosecution." PRE, 508 U.S. at 62, 62 n.7. In PRE, the Court also cited the standard from Federal Rule of Civil Procedure 11 in finding that the defendant's copyright action was "warranted by existing law" or, at the very least, "based on an objectively good faith argument for the extension, modification, or reversal of existing law." Id. at 65. Justice Souter's concurrence cautioned, however, against "transplanting every substantive nuance and procedural quirk of the common-law tort of wrongful civil proceedings into federal antitrust law." Id. at 67 (Souter J., concurring).

directly with the business relationships of a competitor through the use of the governmental process - as opposed to the outcome of that process - as an anticompetitive weapon." PRE, 508 U.S. at 61 (internal quotation marks and citations omitted).

E. Standard of Proof as to Objective Baselessness

The parties dispute whether the plaintiffs must establish objective baselessness using a preponderance of the evidence standard or a clear and convincing evidence standard. The Court of Appeals for the Federal Circuit has not published a decision that explicitly sets forth the standard of proof for showing that a lawsuit or petition was objectively baseless in the sham exception context.[6]

In C.R. Bard, Inc. v. M3 Sys., Inc., the Federal Circuit cited with approval Handgards, a Ninth Circuit case that required clear and convincing evidence of bad faith to invoke the sham exception. 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) (citing Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282 (9th Cir. 1984)). However, Handgards predates PRE's division of the sham exception

[6] "Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998); see also Honeywell Int'l Inc. v. Univ. Avionics Sys. Corp., 488 F.3d 982, 1000-01 (Fed. Cir. 2007); In re Wellbutrin SR Antitrust Litig., No. 05-396, 2006 WL 616292, at *11 (E.D. Pa. Mar. 9, 2006).

inquiry into objective and subjective prongs, and C.R. Bard did not explicitly adopt the clear and convincing evidence standard for the objective baselessness prong. The only Federal Circuit decision to do so in the Noerr-Pennington context is unpublished. Mitek Surgical Prods., Inc. v. Arthrex, Inc., 230 F.3d 1383 (Fed. Cir. 2000) (unpublished table disposition).

Nevertheless, the Federal Circuit has imposed a clear and convincing evidence standard in other contexts where the parties must establish objective baselessness under PRE. See, e.g., 800 Adept, Inc. v. Murex Secs. Ltd., 539 F.3d 1354, 1370 (Fed. Cir. 2008); Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH, 524 F.3d 1253, 1263-64 (Fed. Cir. 2008). The issue in those cases was whether state tort claims against patent holders were preempted by federal patent law. Preemption turned on whether the patent holder acted in "bad faith" in the publication or enforcement of its patent. Part of the bad faith analysis required clear and convincing evidence that the patent holder's infringement allegations were objectively baseless, as defined in PRE. Murex, 539 F.3d at 1369-70.

The Federal Circuit has not clarified in a published decision whether the clear and convincing evidence standard required to show objective baselessness in preemption cases also applies in the sham exception context. However, both the unpublished Mitek table disposition and other district court

decisions suggest that a clear and convincing evidence standard of proof may be appropriate.[7] See Teva Pharms. USA, Inc. v. Abbott Labs., 580 F. Supp. 2d 345, 362 (D. Del. 2008) (requiring clear and convincing evidence of objective baselessness); In re Relafen Antitrust Litig., 346 F. Supp. 2d 349, 360 (D. Mass. 2004) (same). Nevertheless, the Court need not decide in this case whether a clear and convincing evidence or a preponderance of the evidence standard is the proper standard in the context of a sham exception claim because the Court's decision on summary judgment would be the same under either standard.

II. Overview

Between September 2004 and May 2005, four different generic companies - Anchen, Abrika, Impax, and Watson - filed ANDAs with the FDA, each seeking approval of a generic version of

[7] The plaintiffs argue that the proper burden of proof is the preponderance of the evidence standard for civil cases, but cite only one case, which predates PRE, in support of this proposition. See Litton Sys., Inc. v. Am. Tel. & Tel. Co., 700 F.2d 785, 813 (2d Cir. 1983) ("We see no reason to impose any higher burden of proof on the antitrust plaintiff asserting sham than would ordinarily be applicable in any civil issue."). To the extent that non-Federal Circuit law from before PRE is relevant, the Court notes that case law from other circuits adopted a clear and convincing evidence standard. See Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288 (9th Cir. 1984) (requiring clear and convincing evidence of bad faith prosecution of patent suit); MCI Commc'ns. Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1155 (7th Cir. 1983) (approving jury instructions that emphasized the clear and convincing evidence standard, on account of the First Amendment concerns at issue).

Wellbutrin XL. In each case, Biovail filed a lawsuit against the generic company, claiming infringement of the '341 patent.[8] With respect to most of the generic products, the lawsuits were filed within 45 days of receiving the generic companies' paragraph IV notices, thus triggering the 30-month statutory stay on ANDA approval. GSK joined Biovail in the lawsuits against Anchen and Abrika, but later withdrew. Biovail Stmt. ¶ 2; Pls.' Stmt. Resp. ¶ 2; GSK Stmt. ¶ 9; Pls.' Stmt. Resp. ¶ 9.

On December 20, 2005, Biovail filed a citizen petition (the "Citizen Petition") with the FDA. GSK did not join the filing. The FDA issued its final response granting in part and denying in part Biovail's Citizen Petition on December 14, 2006, the same day that it approved Anchen's ANDA. Citizen Petition (BX 96); FDA Final Resp. (BX 108); Anchen Approval Ltr. (GX 42). Shortly thereafter, the defendants reached a series of agreements with Anchen, Impax, Watson, and another generic pharmaceutical company, Teva Pharmaceuticals, that settled or otherwise disposed of the Anchen, Impax, and Watson patent infringement lawsuits and set a schedule for generic entry. Biovail also separately

[8] The Orange Book also listed the '327 patent as covering Wellbutrin XL. Infringement of the '327 patent was asserted in the Anchen, Abrika, and Watson lawsuits, but claims relating to the '327 patent were eventually dropped from each of the cases. See BX 12 (Anchen); BX 13 (Abrika); BX 14 (Watson). The Court does not understand the plaintiffs to be challenging conduct relating to the '327 patent as a violation of the antitrust laws.

settled the Abrika lawsuit.

The plaintiffs allege that the defendants' lawsuits and the Citizen Petition constituted an illegal conspiracy to delay entry of generic versions of Wellbutrin XL in violation of the Sherman Antitrust Act. The defendants contend that their conduct is immune from antitrust liability under the Noerr-Pennington doctrine. The plaintiffs also contend that the agreements disposing of some of the lawsuits independently violated the antitrust laws, even if the lawsuits themselves were not sham litigation.

The Court will grant the defendants' motions for summary judgment as to the four patent infringement lawsuits and the Citizen Petition because they do not fall within the sham exception to Noerr-Pennington immunity. The Court does not decide today whether the settlement agreements independently violated the antitrust laws, as that issue is still being briefed. The Court will omit the settlement agreements from the recitation of facts and discussion of law below.

III. Biovail's Conduct

A. The *Anchen* Lawsuit

1. Facts as to *Anchen*

On September 21, 2004, Anchen Pharmaceuticals, Inc. filed an ANDA with the FDA, seeking permission to sell a generic

version of Wellbutrin XL. Anchen provided Biovail and GSK with its paragraph IV notice by cover letter dated November 12, 2004, claiming that its product did not infringe the '341 patent. Anchen's paragraph IV notice claimed non-infringement because its "tablet core contains a stabilizing amount of hydrochloric acid" and hence was not "free of stabilizer," the term used in the '341 patent. Anchen also provided selected portions of its ANDA to Biovail and GSK. Biovail Stmt. ¶¶ 3-5; Pls.' Stmt. Resp. ¶¶ 3-5.

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 ingredients other than hydrochloric acid were shown in the ANDA to add up to 100.0% of the finished product. See Biovail Br. Exs. A, B. A list in the ANDA that compared the Anchen product to Wellbutrin XL did not include hydrochloric acid as an ingredient in Anchen's product. Biovail Br. Ex. C.

On November 16, 2004, four days after Anchen sent its paragraph IV notice, Stan Hull, senior vice president of GSK, emailed Carol Chapuis, a Biovail vice president, proclaiming the "need to get aligned on our main messages and position" regarding

the ANDA. Ms. Chapuis's response referenced a Joint Steering Committee meeting to expand on the topics that Mr. Hull mentioned. PX 380.

Shortly after receiving Anchen's paragraph IV notice, Biovail and GSK reached a Common Interest Agreement with respect to their common legal interest in potential infringement of the '341 and '327 patents by Anchen or filers of additional ANDAs and paragraph IV notices, and regarding any litigation in response thereto. The Common Interest Agreement related to the paragraph IV certifications of Anchen, Abrika, and Impax, and to the Anchen and Abrika lawsuits. Stip. of Parties Concerning Defs.' Common Interest Claims ¶ 1 (ECF No. 363/ECF No. 347).

On December 21, 2004, within 45 days of receiving Anchen's paragraph IV notice, Biovail and GSK jointly initiated a patent infringement action against Anchen in the Central District of California. The lawsuit triggered the 30-month statutory stay under Hatch-Waxman. The case was assigned to the Honorable James V. Selna. Anchen answered the complaint, denying infringement and asserting counterclaims for non-infringement and invalidity. Biovail Stmt. ¶¶ 8-9; Pls.' Stmt. Resp. ¶¶ 8-9; Anchen Compl. (BX 2). After GSK moved to withdraw as a plaintiff, the Anchen court approved the parties' stipulation of GSK's withdrawal from the suit on April 25, 2005. Biovail continued the lawsuit following GSK's withdrawal. GSK Stmt. ¶¶ 43, 44; Pls.' Stmt. Resp. ¶¶ 43,

44.

During the claim construction portion of the litigation, Biovail argued that in the '341 patent, the term "free of stabilizer" should be construed to mean that "the core lacks an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride . . . ." Biovail Prelim. Cl. Constr. Br. 9 (BX 17). By contrast, Anchen argued that the term "free of stabilizer" should mean "not united with, attached to, combined with, or mixed with . . . any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination." Anchen Opening Cl. Constr. Br. 11-12 (BX 18).

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." Am. Order on Cl. Constr. Hr'g 5 (PX 182). See also Order Clarifying Court's Cl. Constr. 2 (BX 19). Regarding Biovail's claim construction argument, Judge Selna's order stated:

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

Am. Order on Cl. Constr. Hr'g 9 (PX 182).

Following Judge Selna's ruling on claim construction, the parties filed cross-motions for summary judgment. 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. Biovail Stmt. ¶¶ 19, 21; Pls.' Stmt. Resp. ¶¶ 19, 21; Tentative Summ. J. Order (BX 34).

However, after oral argument, Judge Selna granted Anchen's motion for summary judgment on August 1, 2006. Judge Selna denied Biovail's motion for reconsideration, then entered judgment on August 25, 2006. Biovail appealed to the Federal Circuit, challenging both the claim construction and summary judgment orders. Biovail Stmt. ¶¶ 22-24; Pls.' Stmt. Resp. ¶¶ 22-24; PX 216.

Following full briefing and after holding oral argument on September 5, 2007, the Federal Circuit granted Biovail's motion to withdraw its appeal on June 11, 2008. Order Granting Mot. to Withdraw (BX 38).

2. Analysis as to *Anchen*

The Anchen lawsuit centered around the term "free of stabilizer," which appears in each claim in the '341 patent. See '341 Patent (BX 1). Anchen argued for a plain reading of the term and contended that its generic product did not infringe the

'341 patent because it contains hydrochloric acid, a commonly used stabilizer. Biovail argued on claim construction that "stabilizer" should be construed to have a functional component. Separately, Biovail argued that Anchen's ANDA described and sought approval to market a product that did not contain a stabilizer, and that Biovail was entitled to rely on the representations in the ANDA. The Court finds that the plaintiffs have not met their burden of showing that the Anchen lawsuit was objectively baseless.

a. Claim Construction

On the claim construction question, Biovail put forth a colorable argument in the underlying proceeding that "stabilizer" should have been construed as a functional term – something that actually stabilizes the tablet. First, as a matter of plain meaning, the Court does not find Biovail's argument that a stabilizer ordinarily means something that actually provides stability to be unreasonable. Second, the Manual of Patent Examining Procedure provides for the patentability of functional limitations, which it defines as "an attempt to define something by what it does, rather than by what it is." MPEP § 2173.05(g) (BX 117). Various courts, including the Federal Circuit, have read patent terms containing the suffix "-er" to contain a functional limitation. For example, in Kim v. ConAgra Foods,

Inc., the Federal Circuit interpreted "potassium bromate replacer" as a composition that actually replaces, or performs the same function as potassium bromate. 465 F.3d 1312, 1318 (Fed. Cir. 2006). See also, e.g., Allergan, Inc. v. Watson Labs., Inc., No. 09-511 (D. Del. Dec. 8, 2010), Cl. Constr. Order 3 n.10 (BX 118) (interpreting "release controlling polymer" to mean that the polymer must actually function to control the rate of release); Profile Prods. LLC v. Encap, LLC, No. 09-92, 2009 U.S. Dist. LEXIS 60282, at *11 (W.D. Wis. July 15, 2009) (requiring a "binder" to "actually bind" as opposed to merely having the ability to bind). Thus, the '341 patent attempted to distinguish itself from two prior patents because those earlier formulations "require[d] a stabilizer to achieve sufficient stability," whereas the '341 patent did not. '341 Patent col. 1 ll. 22-24 (BX 1) (emphasis added).

Based on the above, the Court cannot say that it was objectively baseless to argue on claim construction that a stabilizer must actually function to stabilize the tablet as opposed to merely having the ability to stabilize. The Anchen court (and, later, the Abrika and Impax courts) eventually rejected Biovail's proposed claim construction. The court instead construed "free of stabilizer" to mean that "the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." Am. Order on Cl. Constr.

Hr'g 5 (BX 182). However, although the outcome is instructive, the Court does not find it determinative in this case. See PRE, 508 U.S. at 65.

b. Anchen's ANDA

More importantly, Biovail had a colorable legal argument that (1) Biovail was entitled to rely on the representations in the ANDA when initiating suit, and that (2) Anchen had an obligation under FDA regulations and guidance to quantify even residual amounts of HCl if the ingredient tended to stabilize the final tablet.

An infringement inquiry triggered by an ANDA filing is focused on the product that is likely to be sold following FDA approval. Because the potentially infringing drug has not yet been marketed when the patent holder files suit,[9] the inquiry is a hypothetical one that asks the fact finder to determine whether the drug that will be sold upon approval of the ANDA will infringe the asserted patent. Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1248-49 (Fed. Cir. 2000). Thus, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description

[9] The infringement provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), states that it is an act of infringement to submit an ANDA that describes a drug claimed in a patent. Thus, the patent holder may sue before the product goes to market.

of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002); see also Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) (inquiry is "properly grounded in the ANDA application and the extensive materials typically submitted in its support"). In Anchen, whether the ANDA directly addressed the issue of infringement turned on whether Anchen was required to quantify hydrochloric acid in its ANDA.

FDA regulations require ANDA applicants to include a list of 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 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 8 (BX 25). 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. BX 132 at GSKWXL0054379-80. 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. BX 131 at GSKWXL0072506.

The instruction to quantify the target amount of each component does not apply, however, to "processing agents." 2003 FDA Guidance 9 (BX 25). The FDA guidance does not clearly define "processing agent." Biovail presented expert testimony that processing agents are components that appear in the finished tablet only at residual levels and have no function to perform in the finished tablet. See Fleischer WBXL Rpt. ¶ 14 (BX 24); Lin Rpt. ¶¶ 11, 17 (BX 27). The plaintiffs do not expressly set forth their own definition of "processing agent" or explain why hydrochloric acid is a processing agent. However, citing expert testimony from both sides, the plaintiffs argue that the FDA only wants to know whether a drug is stable, and that the FDA does not require stabilizing agents present in such small trace amounts to be quantified. Kaplan Dep. 48-49 (PX 147) ("FDA policy is such that if the ingredient is not more than one percent it need not be quantified."); Lin Dep. 67-68 (PX 148).

The Court need not decide in this case whether the FDA rules, regulations, and the 2003 guidance required Anchen to

quantify the amount of hydrochloric acid on a per unit basis - only whether it was objectively baseless to argue that they did. Notwithstanding the expert testimony cited by the plaintiffs regarding FDA policy, the text of the 2003 guidance itself is not inconsistent with Dr. Fleischer's and Biovail's definition of a processing agent. 2003 FDA Guidance 8 (BX 25). The guidance states that "[t]he function . . . of each component in the formulation should be stated," but qualifies that "[c]omponents that are used in the manufacture of the drug product and do not appear in the finished drug product except at residual levels . . . should be identified as processing agents." Id. One plausible reading of this language is that processing agents have no function to perform in the final tablet, because if they did, the function would need to be stated. Therefore, it was not objectively baseless to contend that if hydrochloric acid tended to stabilize the chemical integrity of the final product, it was not a "processing agent" and, thus, needed to be quantified on a per unit basis.[10]

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[10] The Court notes that although Judge Selna later changed his mind, his minute order on summary judgment had tentatively found a genuine issue as to what the FDA's ANDA requirements were as to Anchen. Tentative Summ. J. Order 13-17 (BX 34).

Similarly, although the Court of Appeals did not have the opportunity to opine on the Anchen case, the panel at oral argument repeatedly asked Anchen's counsel questions about whether the FDA required hydrochloric acid to be listed and quantified if it tended to stabilize the product. See, e.g., Biovail Reply Ex. D at 16-17.

Anchen's ANDA, as set forth in the facts, did not quantify hydrochloric acid on a per unit basis. The plaintiffs point out that it is industry convention to use a symbol such as "-" or "**" to signify that a component remains in the final pharmaceutical product in a residual, non-zero, but non-numerically quantified amount. Pls.' Br. 46-47. But industry convention would be inapposite if a court sided with Biovail on its argument that Anchen was required to numerically quantify any hydrochloric acid in the product.

Thus, Biovail had at least a colorable legal argument in Anchen that under Abbott Laboratories and the applicable FDA regulations and policy, Anchen's ANDA controlled the infringement inquiry and suggested that the Anchen product was not "free of stabilizer," as ultimately defined by Judge Selna on claim construction. The Court finds that Anchen does not fit the profile of objectively baseless sham litigation.

B. The *Watson* Lawsuit

1. Facts as to *Watson*

Watson Pharmaceuticals filed an ANDA with the FDA on May 19, 2005, seeking permission to sell a generic version of the 150 mg Wellbutrin XL. Watson later requested permission for the 300 mg Wellbutrin XL as well. Watson provided its paragraph IV notices to Biovail and GSK on July 21, 2005 and July 27, 2005,

claiming non-infringement. As with Anchen, Watson claimed that its generic product "will contain a stabilizer, namely hydrochloric acid." Biovail Stmt. ¶¶ 72-73; Pls.' Stmt. Resp. ¶¶ 72-73.

Watson's ANDA, like Anchen's, did not quantify the amount of hydrochloric acid in its product on a per unit basis. Although diluted hydrochloric acid is identified as a "stabilizer," the ANDA indicated a "-" under the column designated "AMOUNT PER TABLET." The composition statement in the ANDA indicated that "[w]ater is removed during processing." Similarly, the percentage of hydrochloric acid was listed as "-" and 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 that compared the generic product to Wellbutrin XL did not include hydrochloric acid as an ingredient in Watson's product. BX 88. Biovail's counsel signed an offer of confidential access with Watson for access to certain portions of Watson's ANDA. PX 320.

On September 6, 2005, Biovail filed a patent infringement suit against Watson in the Southern District of New York. The Honorable Kenneth M. Karas was assigned to the case. On February 26, 2007, while discovery was ongoing, and before reaching the claim construction stage, the Watson lawsuit settled. Biovail Stmt. ¶¶ 74, 76; Pls.' Stmt. Resp. ¶¶ 74, 76.

2. Analysis as to *Watson*

The Watson case, like Anchen, centered around the issue of whether Watson's generic product was "free of stabilizer," according to Watson's representations in the ANDA. Watson and Biovail made the same legal arguments in Watson as Anchen and Biovail did in Anchen. Because the Court finds that the plaintiffs have not met their burden of showing objective baselessness as to Anchen, the Court concludes that the plaintiffs have also not met their burden with respect to Watson.

C. The *Abrika* Lawsuit

1. Facts as to *Abrika*

On September 23, 2004, Abrika Pharmaceuticals, LLLP filed an ANDA with the FDA, seeking permission to sell a generic version of the 150 mg formulation of Wellbutrin XL. On October 1, 2004, Abrika amended its ANDA to seek permission for the 300 mg formulation of Wellbutrin XL as well. Abrika sent its paragraph IV certification to Biovail and GSK on November 12, 2004. The paragraph IV certification informed the defendants that Abrika's product exhibited a different dissolution profile from the one claimed in the '341 patent when tested in 0.1N HCl. Biovail Stmt. ¶¶ 53-55; Pls.' Stmt. Resp. ¶¶ 53-55; Abrika Para. IV Notice 2 (PX 232).

Prior to filing suit, Biovail requested but did not receive access to Abrika's ANDA. On December 21, 2004, Biovail and GSK filed a patent infringement action against Abrika in the Southern District of Florida. The Honorable Cecilia M. Altonaga was assigned to the case. Biovail Stmt. ¶ 56; Pls.' Stmt. Resp. ¶ 56. As in Anchen, GSK later moved to withdraw as a plaintiff in Abrika, which motion the court approved on April 20, 2005. Biovail continued to litigate the case following GSK's withdrawal. GSK Stmt. ¶¶ 28, 31; Pls.' Stmt. Resp. ¶¶ 28, 31.

Abrika's main claim of non-infringement was that its product did not meet the specified dissolution profile in the '341 patent. A dissolution profile is derived from a dissolution test, which involves adding the drug product to a water-based dissolution medium. The dissolution profile will vary depending on the medium and test selected. Because Abrika's product contains what is called an "enteric" coating, it does not dissolve in acidic mediums such as hydrochloric acid (abbreviated as "HCl"). Abrika's product is designed not to dissolve in the acidic stomach, but in the more neutral environment of the small intestine. Biovail Stmt. ¶¶ 58-59, 61; Pls.' Stmt. Resp. ¶¶ 58-59, 61. The claim language in the '341 patent relating to the dissolution profile did not specify or reference the test conditions used to obtain the covered profile.

On claim construction, Abrika argued that the relevant

dissolution medium to use for dissolution profile testing was 0.1N HCl (in which its enteric-coated product does not dissolve) because that medium was the only one mentioned in the patent examples. Thus, Abrika's paragraph IV certifications only provided dissolution profile results obtained using the 0.1N HCl medium. Biovail Stmt. ¶ 62; Pls.' Stmt. Resp. ¶ 62; BX 64; BX 65.

Biovail argued, however, that a proper dissolution medium to use for testing should mimic what occurs in the human body. Thus, Biovail contended, enteric-coated products such as Abrika's drug should be tested under procedures specified in the United States Pharmacopeia ("USP"), a compendium that describes industry standard methods for the testing of pharmaceutical products. The USP's dissolution test for enteric-coated products is called the "pH switch test." BX 76 at 1791. It is undisputed that Abrika provided testing to the FDA that showed that its product fell within the dissolution profile of the '341 patent if tested using the USP's pH switch test. Biovail Stmt. ¶¶ 62-63, 66, 68; Pls.' Stmt. Resp. ¶¶ 62-63, 66, 68; Kaplan Dep. 148 (PX 147).

The proper medium for dissolution profile testing was not a disputed issue in either the Anchen or Impax litigation. Anchen and Impax argued in those suits that the "dissolution profile" claim limitation was indefinite. Both the Anchen and

Impax courts adopted Biovail's proposed USP-based construction of the term "dissolution profile." Biovail Stmt. ¶ 64; Anchen Cl. Constr. Order 14 (BX 114); Impax Cl. Constr. Order 34 (BX 53).

Judge Altonaga disagreed with those courts and adopted Abrika's proposed construction of the term "dissolution profile." Abrika Cl. Constr. Order 15-16 (BX 79). Judge Altonaga found that Abrika's construction "better reflects the disclosures in the specification and more closely conforms to the patentee's own expressed description of his invention." Id. at 26. Regarding Biovail's proposed construction, Judge Altonaga wrote:

> Given the clear guidance of the specification and prosecution history, it is evident that Biovail's construction of the disputed "dissolution profile" limitation is impermissibly broad. Biovail's broad construction of the disputed term finds no support in the intrinsic record.

Id. at 25. In addition, as in Anchen and Impax, Judge Altonaga sided with the generic company on the "free of stabilizer" issue. Id. at 28-29.

The parties settled the Abrika lawsuit in July 2007, prior to any other court decisions in the case, including summary judgment. Biovail Stmt. ¶ 69; Pls.' Stmt. Resp. ¶ 69.

2. Analysis as to *Abrika*

The defendants make two separate arguments as to why they are entitled to summary judgment as to the Abrika litigation. First, they contend that the suit was not

objectively baseless. Second, they argue that the filing of the suit had no impact on the date when Abrika entered the market. Whether the Abrika suit was objectively baseless is a close question, but it is one that the Court need not decide in this case because this suit did not cause the delay in the entry of the Abrika generic product to the market.

a. Objective Baselessness

The issue in the Abrika litigation was whether Abrika's generic product met the dissolution profile in the '341 patent, which answer turned on the claim construction question of what dissolution medium should be used to obtain the dissolution profile. Abrika maintained that testing should be conducted in an acidic medium (0.1N HCl), as set forth in examples in the patent specification and according to prosecution history. Biovail and GSK contended that the USP-based pH switch test applied since Abrika's product was enteric-coated. The Court declines to find at this juncture that the defendants' position on claim construction was objectively baseless.

The defendants argue as a preliminary matter that in the Hatch-Waxman context, they had a reasonable basis to institute suit against Abrika because Abrika did not provide pre-filing access to its ANDA. Biovail Br. 41 (citing Hoffman-La Roche Inc. v. Invamed Inc., 213 F.3d 1359 (Fed. Cir. 2000)).

They contend that they had to sue to confirm that Abrika's product had an enteric coating and that the product infringed the '341 patent if tested using the pH switch test. This argument only holds weight, however, if this Court agrees that the defendants could reasonably expect success on the merits of their claim construction argument as to the term "dissolution profile." The Court therefore considers whether dissolution testing in a 0.1N HCl medium is the only reasonable construction of "dissolution profile."

It is a "bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citation omitted). It is also well-settled that in interpreting an asserted claim, courts look first to intrinsic evidence - e.g., the patent itself, including the language of the claims, the specification, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). There is a heavy presumption that claim terms mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. Resonate Inc. v. Alteon Websys., Inc., 338 F.3d 1360, 1364 (Fed. Cir. 2003). "When intrinsic evidence unambiguously describes the scope of a patented invention, reliance on extrinsic evidence is

improper." Biovail Corp. Int'l v. Andrx Pharm., 239 F.3d 1297, 1300 (Fed. Cir. 2001); see also J.T. Eaton & Co., Inc. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1570 (Fed. Cir. 1997) ("[T]rial testimony regarding the meaning of a claim cannot vary the meaning of a claim that is established either by the claim itself or by the claim as correctly understood by reference to the specification and the file history."). Nevertheless, extrinsic evidence such as expert testimony can help the court determine what a person of ordinary skill in the art would understand claim terms to mean. Phillips, 415 F.3d at 1319.

In Abrika, the claims in the '341 patent in which the dissolution profile limitations appear do not specify the appropriate testing conditions. See, e.g., '341 Patent cl. 1 (BX 1). The examples in the patent specification all either state that the dissolution profile was obtained using the hydrochloric acid medium, or reference the example that did. However, none of the examples specifically concern an enteric-coated product. See, e.g., id., col. 5 ll. 12-13, col. 8 l. 14. As the Abrika court recognized, the construction of the "dissolution profile" claim limitation thus required walking the "fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." Abrika Cl. Constr. Order 14 (BX 79) (citing Phillips, 415 F.3d at 1323). The claim construction analysis also implicated the principle

that

> When a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification. It is established that as a general rule claims of a patent are not limited to the preferred embodiment . . . or to the examples listed within the patent specification.

Glaxo Wellcome, Inc. v. Andrx Pharm., Inc., 344 F.3d 1226, 1233 (Fed. Cir. 2003).

The plaintiffs here rely chiefly on two cases in which the Court of Appeals for the Federal Circuit evaluated claim language that covered a particular test result but was silent on the appropriate testing methodology. In each case, the Federal Circuit examined intrinsic evidence to determine what methodology to use to obtain the claimed test result. In Genentech, the disputed claim term was a numerical figure, "500,000 IU/mg," which measurement varied depending on the assay used for measurement. Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994). As here, the claim language itself was silent on the appropriate assay for measurement. The Genentech court looked at intrinsic evidence - specifically, the patent's prosecution history, which revealed that the 500,000 figure was obtained using a "bovine fibrin plate assay." Id. at 1562-63.

Similarly, in J.T. Eaton, the disputed claim limitation surrounded an adhesive that had to withstand "plastic flow temperature above 120 degrees > F." J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1565 (Fed. Cir. 1997). The

expert witnesses disagreed over the length of time the product needed to be tested at 120 degree heat. In its analysis, the Federal Circuit looked to the patent's prosecution history rather than to conflicting expert testimony to find the testing conditions that were used during the patent reexamination process. Id. at 1570. In doing so, the court stated: "trial testimony regarding the meaning of a claim cannot vary the meaning of a claim that is established either by the claim itself or by the claim as correctly understood by reference to the specification and the file history." Id.

In the instant case, two forms of intrinsic evidence support the contention that the '341 patent only claimed the dissolution profile as tested in a hydrochloric acid medium. First, as noted above, the examples in the specification all recite 0.1N HCl testing conditions.[11] Second, the patent prosecution history reveals that the patentee explained to the patent office that unlike prior art, which was "silent on the dissolution medium and conditions that are used," "[t]he dissolution medium and conditions that are used in the invention is . . . disclosed in example 1, page 8. (It corresponds to gastric juice.)" '341 Patent File History, Amendment 6 (Aug. 11,

[11] Although there are scattered references in the '341 patent to the USP, they do not relate to the dissolution profile testing conditions. See, e.g., '341 Patent col. 3, ll. 28-31 (BX 1).

1999) (PX 7).

Nevertheless, the defendants have a colorable legal argument that Genentech and J.T. Eaton are distinguishable, and that plain meaning supports their claim construction. In those cases, the dispositive claim limitation was a "term unknown to those of ordinary skill in the art at the time the patent application was filed." J.T. Eaton, 106 F.3d at 1570. By contrast, here, the defendants have pointed to non-conflicting expert testimony that persons skilled in the art would know to consult the USP to determine the proper dissolution medium. As noted above, the Federal Circuit has instructed that extrinsic evidence can help the court determine what a person of ordinary skill in the art would understand claim terms to mean. Phillips, 415 F.3d at 1319.

Glaxo Wellcome is instructive. In that case, the issue on claim construction was whether the claim was limited to the grade and weight of hydroxypropyl methylcellulose (HPMC), a release agent, that was set forth in the specification examples. Because the properties and usage of HPMC to control release were "well known" and patentability of the agent turned on characteristics other than its grade or weight, the court found that the claim terms were not limited to the grade and weight recited in the specification examples. 344 F.3d at 1233.

Similarly, the plaintiffs in this case do not dispute

that the USP is the industry standard compendium for methods of dissolution testing of pharmaceutical products. Biovail Stmt. ¶ 66; Pls.' Stmt. Resp. ¶ 66. The USP's pH switch test applies

> [w]here the label states that an article is enteric-coated, and a dissolution or disintegration test that does not specifically state that it is to be applied to enteric-coated articles is included in the individual monograph . . . unless otherwise specified in the individual monograph.

BX 76 at 1791. The 0.1N HCl examples in the '341 patent did not concern enteric-coated articles or otherwise specify that the 0.1N HCl medium applied to enteric-coated products. The plaintiff's expert, Dr. Kaplan, conceded that dissolution testing is typically done under conditions that mimic or attempt to mimic what will happen to the drug when ingested. Kaplan Dep. 144 (BX 72). Furthermore, Dr. Kaplan admitted that since an enteric-coated product such as the Abrika product is designed not to dissolve in the acidic stomach, "one of ordinary skill in the art typically employs the dissolution testing methodology described above as a pH-switch protocol."[12] Kaplan Rpt. ¶ 99 (July 20, 2011) (BX 121). See also Kaplan Dep. 145 (BX 72).

Given the above, the Court cannot say as a matter of law that the defendants' USP-based claim construction was objectively baseless. The plaintiffs are correct that courts

[12] Thus, Abrika used the pH switch test as part of its quality control parameters for its enteric-coated product in its ANDA submission. Kaplan Rpt. ¶ 99 (July 20, 2011) (BX 121).

generally consider intrinsic evidence such as the specification and prosecution history before extrinsic evidence such as expert testimony. Vitronics, 90 F.3d at 1582. However, based on the undisputed expert testimony about the testing protocol typically employed to test enteric-coated products, and the stature of the USP in the scientific community, the Court is not persuaded that it was unreasonable to argue that those skilled in the art would interpret "dissolution profile" to incorporate the USP-based pH switch test as a matter of plain meaning.

Furthermore, it is not clear to this Court that the intrinsic evidence unambiguously describes the scope of the invention such that reliance on extrinsic evidence is improper. Andrx, 239 F.3d at 1300. The specification examples say nothing regarding conditions for enteric-coated tablets, and the patentee's reference to "gastric juice" in the prosecution history could reasonably be interpreted to reference the fact that the dissolution medium disclosed in the specification corresponds to tablets that dissolve in the stomach. Cf. Kaplan Dep. 144 (BX 72) (dissolution testing generally attempts to mimic what actually happens to tablets).

The defendants' position finds further support in the fact that both the Anchen and Impax courts adopted Biovail's argument that reliance on the USP to determine the proper dissolution test was proper. Anchen Cl. Constr. Order 14 (BX

114); Impax Cl. Constr. Order 34 (BX 53). The plaintiffs protest that those courts were not actually confronted with the same claim construction arguments as in Abrika. But one of the plaintiffs' arguments in this case is that construing "dissolution profile" without reference to the test conditions set forth in the specification examples results in indefiniteness. Pls.' Br. 63-64. The Anchen and Impax courts each considered the generic companies' argument that Biovail's USP-based dissolution test rendered the claim indefinite. The Anchen court found reliance on the USP to be proper and not indefinite. Anchen Cl. Constr. Order 14 (BX 114). Similarly, the Impax court agreed that one skilled in the art would look to the USP to determine the appropriate dissolution medium, while deferring the question of indefiniteness. Impax Cl. Constr. Order 35 (BX 53).

The Court is therefore not inclined to hold that the Abrika lawsuit was not reasonably calculated to elicit a favorable outcome. Nevertheless, for the reasons below, the Court need not ultimately decide whether the Abrika suit was objectively baseless.

b. Delay

The Court finds that the plaintiffs cannot survive summary judgment as to the Abrika suit because they have not

shown that this suit caused any delay in Abrika's entry into the market.

The elements of an antitrust claim are (1) a violation of the antitrust laws; (2) individual injury resulting from that violation; and (3) measurable damages. In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008). It is not necessary to show with total certainty the exact amount of damages sustained, just that the defendants' anti-competitive acts caused the antitrust injury suffered by the plaintiff. Rossi v. Std. Roofing, Inc., 156 F.3d 452, 483-84 (3d Cir. 1998); Sound Ship Bldg. Corp. v. Bethlehem Steel Co., 533 F.2d 96, 98-99 (3d Cir. 1976) (affirming grant of summary judgment because plaintiff failed to show required causal link between the antitrust transgression and damages suffered).

In this case, the purported antitrust violation is that the Abrika lawsuit was sham litigation that delayed the entry of Abrika's generic product into the market and caused purchasers to pay higher prices. The Hatch-Waxman stay on Abrika's product ended 30 months after the initiation of the Abrika lawsuit, or June 21, 2007. Biovail Stmt. ¶ 71; Pls.' Stmt. ¶ 71. Yet, as the plaintiffs stipulated, absent all of the conduct challenged by the plaintiffs, Abrika would have begun selling its generic products on August 18, 2008. ECF No. 343/ECF No. 335. It is undisputed that Abrika did not actually receive approval for its

300 mg product until August 18, 2008, and that Abrika's 150 mg product did not receive final approval until December 1, 2008. Id. The plaintiffs' expert conceded that "[t]he sole reason that Abrika did not receive [final approval] for its 150 mg dosage strength on August 15, 2008 was . . . the then-unexpired 180-day [first-to-file] marketing exclusivity of another applicant (Anchen)." Blume Rpt. ¶ 102 (BX 87) (internal quotation marks omitted). Plaintiffs thus appear to concede that the Abrika lawsuit itself did not delay the entry of the Abrika generic product.

The plaintiffs' only response in opposition is to argue that the defendants' conduct caused delay in Abrika's FDA approval because they sued Anchen, the first filer. In doing so, defendants triggered a 30-month stay for ANDA approval for Anchen, on top of the 180-day exclusivity period for Anchen as the first-filing generic. Pls.' Br. 72. But Anchen's 180-day exclusivity period is a creature of statute, and this Court has already found above that the Anchen lawsuit was not objectively baseless (and hence entitled to Noerr-Pennington immunity). 21 U.S.C. § 355(j)(5)(B)(iv). The plaintiffs' response pertains to whether the *Anchen* lawsuit caused the plaintiffs' injury, not the Abrika lawsuit. The plaintiffs have not adduced any facts to show that independently of the Anchen lawsuit, the Abrika lawsuit caused any delay or damages. Thus, even if the Court were to

conclude that the Abrika suit was objectively baseless, the plaintiffs' inability to show causation of injury warrants summary judgment in defendants' favor as to the Abrika litigation.

D. The *Impax* Lawsuit

1. Facts as to *Impax*

On November 30, 2004, Impax filed an ANDA with the FDA seeking permission to sell a generic version of the 150 mg formulation of Wellbutrin XL. Impax later amended its ANDA to request permission for a 300 mg strength tablet as well. On January 20, 2005, and January 24, 2005, Impax provided paragraph IV notices to Biovail and GSK, claiming non-infringement. The notices stated that Impax's product "is not a tablet in which the delayed release of a drug is obtained by a controlled release coating (as required by every claim of the '341 patent)." Biovail Stmt. ¶¶ 26, 29-30; Pls.' Stmt. Resp. ¶¶ 26, 29-30; BX 40 at 2; BX 43 at 3.

On March 7, 2005, Biovail filed a patent infringement action against Impax in the Eastern District of Pennsylvania, alleging that Impax's 150 mg generic product infringed the '341 patent. The Honorable Anita J. Brody was assigned to the case. Impax Compl. (BX 44). A month later, Biovail amended its complaint to assert infringement against Impax's 300 mg generic

product as well. Since Biovail did not file its infringement claim against the 300 mg product within the 45-day period prescribed by the Hatch-Waxman Act, Biovail only received a 30-month stay on ANDA approval for Impax's 150 mg product. Biovail Stmt. ¶¶ 31, 33; Pls.' Stmt. Resp. ¶¶ 31, 33.

The parties submitted extensive briefing concerning proper construction of the '341 patent. As in the Anchen lawsuit, the parties disputed the proper construction of "free of stabilizer." The key disputed term, however, was "delayed release tablet." Biovail argued that the phrase did not need to be construed, but if it did, the term should mean "a tablet that exhibits [a particular dissolution profile]" and should not be construed to require a controlled release coating. Biovail Stmt. ¶¶ 35, 37-38; Pls.' Stmt. Resp. ¶¶ 35, 37-38.

Impax's position was that "delayed release tablet" should be construed to mean "a tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer." Impax Cl. Constr. Br. 10 (BX 50). In other words, Impax requested a claim construction that addressed "both the structure (a core and a coating comprising specific components) and the functional characteristics (the coating

controls the release of the active ingredient) of the claimed delayed release tablet." Id.

On May 23, 2006, Judge Brody issued an order on claim construction. As to the term "delayed release tablet," Judge Brody found that although the proper construction of the term was a "close question," Impax's proposed construction was ultimately the correct one when read in light of the patent's specification. Impax Cl. Constr. Order 16, 17 (BX 53). Regarding the term "free of stabilizer," Judge Brody agreed with the Anchen court and rejected Biovail's proposed functional construction. Id. at 28.

Judge Brody denied reconsideration of the claim construction order on August 11, 2006. Shortly thereafter, Impax filed a motion for summary judgment of non-infringement. However, on March 6, 2007, before Judge Brody had a chance to rule on the motion, the parties agreed to settle and dismiss their claims. Biovail Stmt. ¶¶ 48-51; Pls.' Stmt. Resp. ¶¶ 48-51; Joint Stip. of Dismiss. (BX 60).

2. Analysis as to *Impax*

The central issue in the Impax litigation was whether the term "delayed release tablet" should be construed to cover only tablets with the delayed release mechanism in the coating, or whether it should be construed to cover any tablet that exhibited the specified dissolution profile. The plaintiffs do

not dispute that if the Impax court had accepted Biovail's construction of "delayed release tablet," Impax's generic product would have infringed the '341 patent. The Court finds that the plaintiffs have not met their burden of showing that the Impax lawsuit was objectively baseless sham litigation.

"The starting point for any claim construction must be the claims themselves." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). The majority of the claims in the '341 patent explicitly limit coverage to tablets with a particular release mechanism in the coating. For example, Claim 1 claims a delayed release tablet comprising: (1) a core comprising bupropion hydrochloride and excipients and (2) "a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer" that exhibits a specified dissolution profile. '341 patent cl. 1 (BX 1); see also, e.g., id. cls. 26, 28.

By contrast, Claim 30 notably omits the language describing the coating. Claim 30 reads as follows:

> A bupropion hydrochloride delayed release tablet free of stabilizer and free of pore-forming agent, exhibiting a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours,

> from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

'341 patent cl. 30 (BX 1) (emphasis added). The Federal Circuit has articulated that "[w]hen different words or phrases are used in separate claims, a difference in meaning is presumed." Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1143 (Fed. Cir. 2005). See also Phillips, 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms."). Under the claim interpretation principle set forth in Nystrom, this Court cannot say that it was baseless to argue that the omission of the coating language from Claim 30 meant that its coverage was not limited to tablets with the release mechanism in the coating.

The plaintiffs contend that Claim 30's reference to "free of pore-forming agent" only makes sense if Claim 30 required a coating, because pore-forming agents only relate to a coating. Pls.' Br. 77. But under Biovail's proposed claim construction, Claim 30 covers any delayed release tablet that exhibits the specified dissolution profile, whether the release mechanism is in the coating or elsewhere. The appearance of the phrase "free of pore-forming agent" therefore does not control the inquiry.

Biovail's reading of Claim 30 also finds support in the plain meaning of the claim language as understood by one of

ordinary skill in the art. See Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., 262 F.3d 1258, 1268 (Fed. Cir. 2001) (noting a heavy presumption in favor of ordinary meaning). As the trial judge in Impax recognized, the parties agreed that "one skilled in the art would understand a 'delayed release tablet' to be any tablet that does not release its active ingredient immediately." Impax Cl. Constr. Order 14-15 (BX 53). The plain meaning of "delayed release tablet," in other words, does not include a controlled release coating.

Impax's claim construction in the underlying suit relied on the principle that claims "must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315. As many courts have observed, however, the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice. See, e.g., Phillips, 415 F.3d at 1323; Impax Cl. Constr. Order 40 (BX 53).

The "Summary of the Invention" of the '341 patent states that

> The invention . . . provides a new bupropion hydrochloride controlled release composition under the form of a tablet free of stabilizer of any kind . . . . Also, the controlled release is obtained thanks to a semi-permeable release coating, free of (monomeric) pore-forming agent. The tablets of the invention exhibit specific dissolution profiles.

'341 Patent col. 1, ll. 53-59 (BX 1). The "Detailed Description

of the Invention" also states that "[t]he invention consists in a tablet comprising a core and a coating." Id. col. 1, ll. 66-67. The plaintiffs argue that, read in light of the specification, "delayed release tablet" can only be construed to include the coating. Given the competing plain meaning of the term "delayed release tablet" and the omission of coating language from Claim 30, however, the Court is not persuaded that Biovail's proposed claim construction was objectively baseless.

Judge Brody ultimately found that Impax's proposed construction of "delayed release tablet" aligned most naturally with the patent's description of the invention in the specification. However, the Court finds it significant that Judge Brody regarded this dispositive question as a "close question," noting that "both parties' positions were ably presented in their briefs and at oral argument." Impax Cl. Constr. Order 16 (BX 53)(emphasis added). Judge Brody went to considerable lengths to reject Biovail's claim construction in the underlying infringement suit. Such a litigation history simply does not fit the profile of objectively baseless litigation. See GP Indus., Inc. v. Eran Indus., Inc., 500 F.3d 1369, 1375 (Fed. Cir. 2007).

E. The Citizen Petition

1. Facts

On December 20, 2005, Biovail filed a Citizen Petition with the FDA. The Citizen Petition requested that the FDA require any ANDA for a generic version of Wellbutrin XL to satisfy the following four criteria:

(1) All bioequivalence trials should calculate and evaluate parameters based on concentrations of the parent drug and active metabolites [hereinafter the "metabolites evaluation request"];

(2) Any generic formulation should be shown to be bioequivalent to Wellbutrin XL, sustained release and immediate release bupropion [hereinafter the "bioequivalence drift request"];

(3) The bioequivalence studies should be conducted at steady-state evaluating the performance of the dosage form based on AUC, Cmax, Cmin [hereinafter the "steady-state request"]; 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" [hereinafter the "dose dumping request"].

Biovail Stmt. ¶ 91; Citizen Pet. 1 (BX 96).

On June 7, 2006, the FDA issued an interim response to Biovail, stating: "FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials . . . . We will respond to your petition as soon as we have reached a decision on your request." Biovail Stmt. ¶ 92; FDA Interim Resp. (BX 107).

Approximately six months later, on December 14, 2006,

the FDA issued its final response, stating that the Citizen Petition was granted in part and denied in part, as follows. FDA Final Resp. (BX 108).

Request #1: Metabolites Evaluation Request

Biovail's Citizen Petition requested that all bioequivalence trials of generic versions of Wellbutrin XL measure and evaluate parameters based on concentrations of the parent drug as well as three active metabolites (hydroxy-, threo- and erythro-). The Citizen Petition explained that bupropion hydrochloride is extensively metabolized and that the active metabolites "contribute to both the activity and the toxicity of bupropion formulations, and represent the majority of what circulates in blood following doses of bupropion." Citizen Pet. 4 (BX 96). The petition represented that "[t]he metabolites of bupropion play a very significant role in the clinical performance of Wellbutrin XL and any generic version should demonstrate similar results in order to assure that the generic will provide similar effects." Id. at 7.

The NDA for Wellbutrin XL itself had contained bioequivalence testing data for the parent drug as well as for its three metabolites, for comparison to prior formulations of Wellbutrin. BX 99 at 18-19. In its review of the Wellbutrin XL NDA, the FDA Center for Drug Evaluation and Research stated that

"[a]lthough bioequivalence could not be demonstrated for the parent compound . . . consideration should be given to the active metabolites, since they are responsible for more than 90% of the exposure following administration of bupropion." Id. at 1. Thus, the FDA found that "the comparable exposure and the role of the metabolites in the exposure and pharmacologic activity support the approval of the WELLBUTRIN XL formulation." Id.

Prior to Biovail's Citizen Petition, a May 2005 document titled Draft Guidance on Bupropion Hydrochloride had stated that manufacturers of extended release tablets of buproprion hydrochloride should test both bupropion and "[h]ydroxybupropion (active metabolite of bupropion)." The draft guidance contained a notice stating that "once finalized, [it] will represent the [FDA's] current thinking on this topic. It . . . does not operate to bind FDA or the public." 2005 Draft Guidance (PX 732).

In response to Biovail's metabolites evaluation request, the FDA granted the request with respect to the hydroxy-metabolite, finding that it

> contributes meaningfully to the safety and/or efficacy of the drug product. Consequently, we agree that the metabolite, hydroxybupropion, should be measured in bioequivalence testing, and the Agency expects ANDA applicants for generic bupropion HCl extended-release tablets to measure both the parent drug bupropion and the metabolite hydroxybupropion in their BE studies.

FDA Final Resp. 10 (BX 108). However, the FDA denied the request

as to the other two (threo- and erythro-) metabolites, finding that "there is currently insufficient scientific evidence upon which we can reasonably determine" whether it is appropriate to measure the other two metabolites. Id. at 9, 10.

The FDA response noted not only the absence of evidence showing the other two metabolites' contribution to the safety and efficacy of Wellbutrin XL, but also evidence to the contrary. The FDA referenced Wellbutrin XL labeling that explained that these two metabolites were "five-fold less potent than bupropion." In addition, the FDA pointed out that

> [an exhibit attached to the Petition] states that erythrohydrobupropion has only a minor contribution to the overall pharmacological activity due to its low potency.

Id. at 10 n.32 (citation and quotation marks omitted) (emphasis added).

Request #2: Bioequivalence Drift Request

The Citizen Petition requested that any generic version of Wellbutrin XL demonstrate bioequivalence to Wellbutrin XL, SR, and IR. The petition cited

> potential for significant variations . . . between a generic version of a RLD [reference listed drug] and the immediate release version of the drug to which the RLD was shown to be bioequivalent. The relevance and accuracy of data regarding seizure incidence and other side effects is open to question if the generic drug has not been shown to be bioequivalent to the same reference that was relied upon for approval of the RLD.

Citizen Pet. 6 (BX 96). In response to this request, the FDA

stated:

> [A]n ANDA applicant for generic bupropion HCl extended-release tablets is not required to demonstrate bioequivalence to Wellbturin SR and Wellbturin [IR].
> . . . .
> The fact that there is equivalency information in the approved labeling of Wellbutrin XL does not, as you claim, require the ANDA applicant to independently demonstrate bioequivalence or equivalence to sustained-release and immediate-release formulations of Wellbutrin in addition to the RLD [Wellbutrin XL].

FDA Final Resp. 6 (BX 108).

Request #3: Steady-State Request

The steady-state request was a derivative request. Biovail asked that the testing it requested for the parent drug and active metabolites and for bioequivalence to Wellbutrin XL, SR, and IR be conducted "at steady-state." Citizen Pet. 1 (BX 96).

In response to the steady-state request as to bioequivalence drift, the FDA stated that the request was "irrelevant" because the FDA did not agree with the bioequivalence drift request. FDA Final Resp. 12 (BX 108). As to the steady-state request regarding the parent drug and metabolites, the FDA stated that "based on our experience and expertise . . . a single-dose study is the preferred approach – not a multiple-dose study." Id.

Request #4: Dose Dumping Request

Dose dumping is the "[u]nintended, rapid drug release in a short period of time of the entire amount or a significant fraction of the drug contained in a modified release dosage form." It can pose a "significant risk to patients, either due to safety issues or diminished efficacy or both." BX 104 at 1. Alcohol can induce dose dumping in some modified release (also known as controlled release) drug products. Biovail Stmt. ¶ 25; Pls.' Stmt. Resp. ¶ 25.

On October 26, 2005, approximately two months before Biovail filed its Citizen Petition, the FDA's Advisory Committee for Pharmaceutical Sciences held a meeting in which doctors presented information about the potential for alcohol-related dose dumping in controlled release formulations. They discussed the need for testing and for a general "regulatory decisional framework to minimize risk of alcohol-induced dose dumping." See PX 92 at 9-35; id. at 21-22. One speaker testified that the Center for Drug Evaluation and Research was conducting ongoing in vitro testing on existing controlled release products to see whether alcohol could undermine the controlled release characteristics of the products. Id. at 13-15.

Although the FDA was investigating alcohol-related dose dumping in controlled release formulations, it is undisputed that as late as November 2005 (one month before the Citizen Petition

was filed), the FDA did not require ANDA applicants to submit dose dumping data on all controlled release drugs. Indeed, for Wellbutrin XL, a controlled release drug, the FDA granted tentative approval of Anchen's ANDA on November 14, 2005 without requesting or receiving data on alcohol-related dose dumping. FDA Tentative Approval Ltr. (BX 105). Specifically, the FDA concluded that the Anchen drug was "safe and effective for use as recommended in the submitted labeling" and stated that it was only "unable to grant final approval to your ANDA at this time because of the patent issue." Id.

Biovail filed the Citizen Petition containing the dose dumping test request for generic Wellbutrin XL products on December 20, 2005. Citizen Petition (BX 96). On September 11, 2006, the Deputy Director of the Division of Bioequivalence of the FDA sent a memo to the Citizen Petition docket as well as to several ANDA applicants for generic versions of Wellbutrin XL. The memo referenced Biovail's Citizen Petition and stated that a working group of scientists had "developed an in vitro test to evaluate the potential for dose-dumping in the presence of alcohol (in vitro dose-dumping test)." In early 2006, the Office of Generic Drugs ("OGD") had asked all ANDA applicants for generic versions of Wellbutrin XL to conduct the in vitro dose-dumping study. BX 109; see also BX 110 (Anchen response to OGD request, dated February 23, 2006); BX 111 (FDA deficiency letter

to Anchen, requesting in vitro dose-dumping study results, dated July 25, 2006).

In its final response to Biovail's dose dumping test request on December 14, 2006, the FDA stated:

> FDA asked ANDA applicants for generic bupropion HCl extended-release tablets to submit data from in vitro dissolution studies using various concentrations of ethanol in the dissolution medium to evaluate the possible interaction between alcohol and the excipients in both Wellbutrin XL and generic bupropion HCl extended-release tablets. FDA will evaluate the results of the in vitro data submitted by the ANDA applicants and consider these results when determining whether to approve each ANDA.

FDA Final Resp. 13 (BX 108).

2. Analysis

Biovail makes four separate arguments in favor of summary judgment as to the Citizen Petition: (1) First, that because the dose dumping request was granted, and the metabolites evaluation request was granted in part, the entire petition is immunized from antitrust liability under the Noerr-Pennington doctrine; (2) Second, that any competitive harm is immune from antitrust liability because it resulted from government decision; (3) Third, that even if the entire petition is not immunized, the unsuccessful requests were not objectively baseless; and (4) Finally, that even if the unsuccessful requests were objectively baseless, the plaintiffs have not shown that they caused any delay. The Court addresses each argument in turn.

a. Mixed Sham and Non-Sham Petitions

(1) Did the Citizen Petition Contain Successful Requests?

The Court finds that Biovail's dose dumping request and hydroxy- metabolite evaluation request were successful and, thus, non-sham by definition under PRE.

"A successful effort to influence governmental action . . . certainly cannot be characterized as a sham." PRE, 508 U.S. at 58. Thus, the PRE Court declared that "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." Id. at 61 n.5. The FDA, in its final response to the Citizen Petition on December 14, 2006, stated that it asked ANDA applicants for generic Wellbutrin XL for dose dumping test data, and would evaluate and consider the results when determining whether to approve each ANDA. FDA Final Resp. 13 (BX 108). Indeed, the record shows that in early 2006, after Biovail filed the Citizen Petition, the FDA had asked ANDA applicants for generic versions of Wellbutrin XL to conduct a dose dumping study.[13] BX 109; see also BX 110 (Anchen response to OGD request, dated February 23, 2006); BX 111 (FDA deficiency letter to Anchen, requesting in vitro dose dumping study results,

[13] The FDA also requested that GSK conduct dose dumping testing for Wellbutrin XL itself in October 2006. See PX 487 at GSKWXL50373034 (referencing correspondence from October 13, 2006).

dated July 25, 2006). The FDA also granted Biovail's request for hydroxy- metabolite testing, noting that it "contributes meaningfully to the safety and/or efficacy of the drug product." FDA Final Resp. 10 (BX 108).

The plaintiffs contend, however, that petitioning the FDA to do something it has already done or to act on an issue about which it is already aware cannot be characterized as successful or objectively reasonable. They argue that PRE requires a causal connection between the petition and the favorable outcome in order for the petition to be objectively reasonable as a matter of law. Pls.' Br. 90. The plaintiffs' reading of PRE goes too far.

PRE does not define success in the context of a citizen petition, but it does state that the petition must be calculated to "elicit" a favorable outcome or to "influence" governmental action. 508 U.S. at 58, 60. However, this Court does not read PRE to have imported concepts of legal and factual causation into the objective baselessness analysis. The PRE standard for objective baselessness is a forward-looking standard from the point in time when the suit or petition was filed. In setting forth the standard, the Supreme Court used the language of expectancy:

> [T]he lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable

> outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail.

508 U.S. at 60 (emphasis added). To examine post hoc whether it was the petition that caused the government to reach a certain outcome would be contrary to the forward-looking language in PRE.[14]

In support of their proposed causal connection requirement, the plaintiffs rely chiefly on In re Flonase Antitrust Litigation.[15] 795 F. Supp. 2d 300, 315 (E.D. Pa. 2011). In that case, the brand manufacturer requested through a citizen petition that the FDA reconsider its endorsement of something called the geometric mean ratio method. The manufacturer, the antitrust defendant, argued that the FDA's ultimate endorsement of a different method over the geometric

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[14] The plaintiffs have not elaborated upon whether, in their view, the petition must be the but-for or proximate cause, or whether the petition must be the sole cause of the favorable outcome, or just one contributing cause. Nor have they cited any case law discussing the proper standard.

[15] In addition, the plaintiffs cite two paragraphs in the report of the defendants' expert, Douglas Sporn, for the proposition that the Citizen Petition had no impact on the FDA's policy and practice regarding alcohol-related dose dumping. Pls.' Br. 100 (citing Sporn Rpt. ¶¶ 94, 95 (PX 80)). But the Court does not read Mr. Sporn's report as an expert admission that the Citizen Petition had no impact on the FDA's policy and practice on dose dumping. Rather, Mr. Sporn appeared to be commenting on the impact of the Citizen Petition as to the timing of FDA action - that is, opining that the Petition did not cause the delay in ANDA approval, which is an element of the plaintiffs' affirmative antitrust case. Sporn Rpt. ¶¶ 94, 95 (PX 80).

mean ratio method implied that its request succeeded on the merits. The Flonase court rejected the argument, finding that "[a]bsent evidence connecting the FDA's change in position to [manufacturer's] criticism, the FDA's action[s] are minimally probative, if probative at all, of the substantive merits of [manufacturer's] criticisms." 795 F. Supp. 2d 300, 315 (E.D. Pa. 2011). Similarly, in Louisiana Wholesale Drug. Co., Inc. v. Sanofi-Aventis, the court stated that "if [plaintiffs] can establish the [defendant] never intended or could reasonably expect to affect FDA labeling policy with respect to the five ANDAs, and filed the Petition solely to delay or impede the approval of generics, Noerr-Pennington immunity will be unavailable." La. Wholesale Drug Co., Inc. v. Sanofi-Aventis, No. 07-7343, 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008).

Even if Flonase and Louisiana Wholesale Drug were binding case law, this Court does not read them to require a showing of causation. The instant case is also distinguishable in that here, there is evidence connecting the FDA's favorable action to Biovail's Citizen Petition - at least with respect to the dose dumping request. In its September 11, 2006 memorandum to the Citizen Petition docket and to additional ANDA applicants, the FDA specifically referenced the Biovail Citizen Petition when it noted that the Office of Generic Drugs had asked ANDA applicants for dose dumping test data in early 2006. BX 109.

The plaintiffs argue that as a policy matter, the lack of a causal connection requirement is an unworkable standard in that it "allows brand companies to file abusive petitions with impunity, simply by including a request that the FDA adopt a policy or practice that it knows that the FDA has already adopted (or was developing)." Pls.' Br. 101. However, the plaintiffs' position is equally unworkable from a public policy standpoint, especially as applied to policies or procedures still in development. FDA regulations permit the filing of citizen petitions to issue, amend, or revoke a regulation, or to take or refrain from taking any other form of administrative action. 21 C.F.R. § 10.30. The plaintiffs ask this Court to strip citizen petition requests that were granted by the FDA from Noerr-Pennington immunity merely because the FDA was already aware of the concerns discussed therein. But to do so would discourage companies from attempting to shape the development of and contribute to the discourse surrounding FDA policies once the FDA becomes aware of an issue.

In this case, the undisputed facts indicate that the FDA had not yet adopted a policy of requesting dose dumping data before Biovail filed its Citizen Petition. The FDA had held a meeting to discuss the dose dumping problem and to consider developing a "regulatory decisional framework to minimize risk of alcohol-induced dose dumping." See PX 92 at 9-35; id. at 21-22.

But although the FDA was generally aware of dose dumping, it had not specifically required applicants for generic bupropion hydrochloride to submit testing. Indeed, the FDA granted tentative approval to Anchen in November 2005, one month before the Citizen Petition was filed, without requesting or receiving dose dumping data. See FDA Tentative Approval Ltr. (BX 105).

Similarly, the FDA had not issued a final guidance on hydroxy- metabolite testing. The FDA had in place a draft guidance from May 2005 that requested hydroxy- metabolite testing for generic extended release bupropion hydrochloride products. But the draft guidance was non-binding and not final by it own terms:

> This draft guidance, once finalized, will represent the Food and Drug Adminsitration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

2005 Draft Guidance (PX 732) (emphasis added).

The Court finds that the FDA's awareness about the dangers of dose dumping and the May 2005 draft guidance regarding hydroxy- metabolite testing do not mean that those two requests were not "reasonably calculated to elicit a favorable outcome." The outcomes were not yet set in stone, and even if they were, 21 C.F.R. § 10.30 permits citizen petitions to amend or revoke regulations. To characterize these granted requests as sham

requests and eliminate Noerr-Pennington immunity merely because the FDA was already aware of the concerns brought up therein would unreasonably curtail the First Amendment right to petition the government and influence policy.

(2) Is a Mixed Petition Immune?

Biovail argues that if a citizen petition includes more than one request, the entire petition is not a sham if at least one of the requests has objective merit. The question of whether a single petition containing a mix of sham and non-sham requests merits Noerr-Pennington immunity is an interesting one, but the Court need not decide it in this case.

Biovail cites two cases for the proposition that a single non-sham claim or request keeps the entire lawsuit or petition from being a sham. In the first case, In re Flonase Antitrust Litigation, the court examined a citizen petition that, as here, made multiple requests to the FDA. The Flonase court wrote, without analysis, that "conduct is not a sham if at least one claim in the petition has objective merit." 795 F. Supp. 2d 300, 312 (E.D. Pa. 2011) (citing Dentsply Int'l, Inc. v. New Tech. Co., No. 06-272, 1996 U.S. Dist. Lexis 19846 (D. Del. Dec. 19, 1996)). In other words, "[i]f Plaintiffs cannot show that all of these requests were objectively baseless, they fail to carry their burden under PRE, and the [Citizen] Petition will be

protected by Noerr-Pennington immunity." Id. (emphasis added). However, the Flonase court was not confronted with a case with mixed sham and non-sham requests.

The second case, Dentsply, was the unpublished case relied upon by the Flonase court. In Dentsply, patent holders brought patent infringement and trade secrets claims against defendants, who in turn filed antitrust counterclaims alleging sham litigation. The court stated that "if plaintiffs prevail on one of their counts [in their lawsuit], the sham aspect of the antitrust counterclaim must fail." No. 96-272, 1996 U.S. Dist. Lexis 19846, at *9 (D. Del. Dec. 19, 1996). "[C]ourts have indicated that litigation will not be considered a 'sham' so long as at least one claim in the lawsuit has objective merit." Id.

The court in In re: Wellbutrin SR Antitrust Litigation disagreed and, in doing so, explained at length why the legal authority on which Dentsply relied does not strongly support the proposition that a single meritorious count in a lawsuit will defeat a sham litigation antitrust claim. 749 F. Supp. 2d 260, 263-64 (E.D. Pa. 2010). The Court finds the analysis in Wellbutrin SR persuasive. In that case, the manufacturer had filed two patent infringement claims based on two separate patents in a single patent suit. In the antitrust case based on the underlying patent suit, Judge Stengel granted summary judgment with respect to one patent, finding that the

manufacturer had probable cause to file that infringement claim, but denied summary judgment with respect to the other. Judge Stengel then rejected the manufacturer's argument on a renewed motion for summary judgment that the assertion of at least one non-sham claim immunized the entire lawsuit from antitrust liability under Noerr-Pennington. Judge Stengel held that the one non-sham claim in the lawsuit was "sufficient to cause antitrust damage because it resulted in the continuation of [the manufacturer's] 30 month patent protection stay after the [sham] claim was dismissed." See id. at 266-67.

The parties have not pointed to, and this Court has not found, binding authority on the issue of whether petitions with a mix of sham and non-sham requests can be considered objectively baseless as a whole. This Court is inclined to find that they can. As Judge Stengel pointed out in Wellbutrin SR, it is theoretically possible that a sham claim in a lawsuit or sham request in a petition can cause antitrust damage above and beyond the delay caused by the non-sham claim - i.e., that the injury will exceed the portion of the conduct that is protected by Noerr-Pennington immunity. As a matter of policy, it would create poor incentives if tacking one meritorious claim onto any number of baseless ones that delay adjudication or resolution could automatically immunize the whole lawsuit or petition from antitrust liability as a matter of law.

Nevertheless, as set forth below, the Court need not opine on this question because the plaintiffs have not shown any evidence that the unsuccessful and arguably sham requests in the Citizen Petition actually delayed FDA approval of the generic ANDAs any further than the delay caused by the successful requests.

b. Government Action Immunity

Biovail argues that because the Citizen Petition did not trigger any automatic delay by statute or regulation, any decision to delay action on ANDA approval was the FDA's alone, and injury flowing from such a government decision is immune to private antitrust liability. Biovail Br. 53-54. In support, Biovail cites the applicable federal regulations, which provide:

> (d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under § 10.30 . . . , will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless . . . . (1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

21 C.F.R. § 10.35 (2005) (emphasis added). The Court is not persuaded that Biovail's Citizen Petition is immunized from antitrust liability based on any delay that may be attributable to the FDA. Nevertheless, the Court need not ultimately decide this question.

The Sherman Act does not prohibit an anticompetitive restraint imposed by a state as an act of government. Parker v. Brown, 317 U.S. 341, 352 (1943); Noerr, 365 U.S. at 136. This so-called Parker or state action immunity protects the states' act of governing and expresses the principle that "the antitrust laws regulate business, not politics." Mass. Sch. of Law. v. ABA, 107 F.3d 1026, 1035 (3d Cir. 1997). The doctrine is grounded in principles of federalism and respect for state sovereignty, and relies heavily on the clarity of the state's goals and actions. Mariana v. Fisher, 338 F.3d 189, 201 (3d Cir. 2003); A.D. Bedell Wholesale Co., Inc. v. Philip Morris Inc., 263 F.3d 239, 254 (3d Cir. 2001).

Conflicts similar to those created by state regulation and policy can arise in the context of federal regulation. Some statutes explicitly preclude application of antitrust law. See Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264, 270-71 (2007) (listing examples). Where statutes are silent, however, courts must determine whether they implicitly preclude application of the antitrust laws, which determination turns on the relation between the antitrust laws and the regulatory program set forth, and the specific conduct at issue. Id. at 271.

Biovail argues that 21 C.F.R. § 10.35 (2005) exempts it from antitrust liability because it is the FDA Commissioner that

determines whether a stay or delay is in the public interest. However, "[r]epeal of the antitrust laws by implication is not favored and not casually to be allowed. Only where there is a plain repugnancy between the antitrust and regulatory provisions will repeal be implied." Gordon v. NYSE, Inc., 422 U.S. 659, 682 (1975) (internal quotation marks and citation omitted). See also United States v. Phila. Nat'l Bank, 374 U.S. 321, 350-51 (1963); Essential Commnc'ns Sys., Inc. v. Am. Tel. & Tel. Co., 610 F.2d 1114, 1117 (3d Cir. 1979). Absent express immunity conferred by Congress, immunity will be implied

> only if Congress has clearly supplanted the antitrust laws and their model of competition with a differing competitive regime, defined by particularized competitive standards and enforced by an administrative agency, and has thereby purged an otherwise obvious antitrust violation of its illegality.

United States v. NASD, Inc., 422 U.S. 694, 742-43 (1975) (emphasis added). See also Harrison Aire, Inc. v. Aerostar Int'l, Inc., 316 F. Supp. 2d. 186, 211 (E.D. Pa. 2004).

Biovail has not argued that Congress has clearly supplanted the antitrust laws in this case. Nor has Biovail otherwise cited any cases in the pharmaceutical context that find that FDA delay in ANDA approval entitles filers of citizen petitions to immunity from the antitrust laws. Moreover, as a factual matter, Biovail has not linked the delay in this case to any particular FDA decision or action, as opposed to inaction. Biovail points to the FDA's interim response, which states that

the "FDA has been unable to reach a decision on [the Citizen Petition] because it raises complex issues requiring extensive review and analysis by Agency officials." FDA Interim Resp. (BX 107). But even if the interim response constitutes an FDA decision to delay, the response hardly rises to the standard set forth in NASD, which confers immunity only if Congress has supplanted federal antitrust law with a "differing competitive regime." NASD, 422 U.S. at 722-23. In any case, the plaintiffs have pointed to testimony indicating that such interim FDA responses are typically boilerplate answers issued before the FDA has even reviewed and considered the petition. The FDA issues such responses to comply with regulations requiring a response to citizen petitions within six months. Morrison CP Rpt. ¶¶ 20-22 (PX 67); 21 C.F.R. § 10.30(e)(2). According to the plaintiffs' expert, FDA delay in ANDA approval is commonly a result of FDA backlog, limited resources, and the need to create a record in defense of anticipated litigation by brand companies. Morrison CP Rpt. ¶¶ 20-22 (PX 67); Morrison CP Rebuttal Rpt. ¶ 15 (PX 73).

Lastly, the Court notes that as a policy matter, adopting Biovail's position would essentially mean that no pharmaceutical company could be liable for antitrust injury as a result of a citizen petition - no matter how frivolous - because the FDA is the one delaying ANDA approval. Nevertheless, the Court need not decide whether Biovail is entitled to immunity

that produces such sweeping immunity because the plaintiffs have not shown that the unsuccessful requests delayed ANDA approval beyond the delay stemming from the successful requests.

c. The Unsuccessful Requests

Because the Court does not find at this time that the Citizen Petition is immunized by the inclusion of two successful requests or by government action, the Court considers whether the remaining unsuccessful requests were objectively baseless under the PRE standard. However, as with the questions examined above, the Court need not ultimately decide whether the unsuccessful requests were objectively baseless because the plaintiffs have not shown that they caused antitrust injury above and beyond the delay caused by the successful, non-sham Citizen Petition requests.

(1) The Metabolites Evaluation Request as to the Other Two Metabolites

Biovail's Citizen Petition requested that the FDA require generic versions of Wellbutrin XL to provide bioequivalence data for the parent drug and all three active metabolites.[16] Citizen Petition 7 (BX 96). Biovail argues that the metabolites evaluation request as to the threo- and erythro-

[16] The Court considered the request as to the hydroxy-metabolite, which the FDA granted, above.

metabolites was reasonable because it is unknown whether bupropion or its active metabolites cause bupropion's antidepressant effect and produce the seizure risk associated with higher dosages of bupropion. Biovail Br. 59-60. Based on the summary judgment record, the Court cannot find at this time that Biovail had probable cause to request that the FDA require generic companies to measure the threo- and erythro- metabolites.

Bioequivalence testing is usually limited to the parent drug - in the case of Wellbutrin XL, bupropion hydrochloride. The applicable FDA guidance on bioequivalence studies recommends testing metabolites only in cases where a metabolite "may be formed as a result of gut wall or other presystemic metabolism" and "contributes meaningfully to safety and/or efficacy." FDA Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Admin. Drug Prods. 18 (Mar. 2003) (BX 126). In May 2005, the FDA issued a draft guidance on bupropion hydrochloride that recommended testing of the parent drug and the hydroxy-metabolite. The draft guidance was silent as to the threo- and erythro- metabolites. 2005 Draft Guidance (PX 732).

The record shows, at best, a lack of scientific consensus and clarity as to the threo- and erythro- metabolites' contribution to the safety and efficacy of bupropion hydrochloride. Biovail relies chiefly on research conducted by and an expert report prepared by Dr. Sheldon Preskorn. In a 1991

article, Dr. Preskorn wrote that the "mechanism of action responsible for bupropion's antidepressant properties is unknown." Sheldon H. Preskorn, "Should Bupropion Dosage Be Adjusted Based Upon Therapeutic Drug Monitoring?," 27 Psychopharmacology Bull., 637, 637 (1991) (BX 101). The plaintiffs' expert, Dr. Kaplan, agreed that the "role of the metabolites in the overall activity of the drug" is unknown. Kaplan Dep. 388-89 (PX 147). In a later 1998 study, Dr. Preskorn and a colleague concluded:

> In comparing the pharmacological potency of the metabolites with their expected concentrations at therapeutic doses of bupropion, [the hydroxy- and threo- metabolites] would be expected to appear to contribute to bupropions [sic] overall antidepressant effects.

W. Dale Horst & Sheldon H. Preskorn, "Mechanism of Action and Clinical Characteristics of Three Atypical Antidepressants," 51 J. Affective Disorders 237, 241 (1998) (BX 102) (emphasis added). See also Preskorn Rpt. ¶ 34 (BX 125) ("[T]here is evidence that at least the hydroxy and threo metabolites contribute to the effects on norepinephrine and dopamine neurotransmission."). However, as noted in the FDA's final response, Wellbutrin XL's own labeling explained that the threo- and erythro metabolites were "five-fold less potent than bupropion." In addition,

> [an exhibit attached to the Citizen Petition] states that erythrohydrobupropion has only a minor contribution to the overall pharmacological activity due to its low potency.

FDA Final Resp. 10 n.32 (BX 108) (citation and quotation marks

omitted) (emphasis added).

On the issue of drug safety, Dr. Preskorn noted that because most studies conducted during the development of bupropion hydrochloride measured only the parent drug and not the metabolites, there was an "inadequate database to establish the relationship between [levels of bupropion and/or its metabolites] and the occurrence of seizures." Preskorn, "Should Bupropion Dosage Be Adjusted," at 641 (BX 101). Nevertheless, Dr. Preskorn concluded in his report that "high levels of bupropion and/or its metabolites are the likely cause of bupropion's seizure risk." Preskorn Rpt. ¶ 35 (BX 125). The plaintiffs' expert, Dr. Kaplan, testified that the role of the metabolites in the bupropion seizure risk is unknown. Kaplan Dep. 388-89 (PX 147).

The record above demonstrates, at best, what appears to be scientific uncertainty as to whether and to what degree the threo- and erythro- metabolites contribute to the efficacy of or detract from the safety of Wellbutrin XL. Biovail argues that since the data is insufficient to determine which of the parent drug and the metabolites (or combination thereof) causes bupropion's antidepressant effect and seizure risk, it was not objectively baseless to ask that generic versions of Wellbutrin XL be required to provide testing data as to the parent drug and all three metabolites. Indeed, the NDA for Wellbutrin XL itself had contained bioequivalence testing data for the parent drug,

bupropion, as well as for its three metabolites. BX 99 at 18-19. And the FDA had relied in part on "the comparable exposure and the role of the metabolites in the exposure and pharmacologic activity" in approving the Wellbutrin XL formulation. Id. at 1.

It may be that where there is scientific uncertainty as to the effect that the metabolites have on safety and efficacy, it would be prudent to ask that they be measured and tested. The FDA's subsequent treatment of generic versions of Wellbutrin XL supports such an outlook.[17] But under the applicable FDA bioequivalence guidance when the Citizen Petition was filed, metabolite testing was only recommended where metabolites contribute meaningfully to safety and/or efficacy. In addition, as noted above, the 2005 FDA draft guidance specific to bupropion hydrochloride recommended testing only as to the parent drug and the hydroxy- metabolite. Biovail did not provide any factual or legal support in its Citizen Petition to deviate from either guidance. Nor did Biovail point to any evidence demonstrating affirmatively that the threo- and erythro- metabolites contribute meaningfully to safety or efficacy; Biovail merely pointed out a

[17] In October 2008, the FDA's Division of Bioequivalence wrote to Teva Pharmaceuticals regarding a proposed generic version of 300 mg Wellbutrin XL. In that letter, the FDA recommended measuring the parent compound as well as all three active metabolites in a study for individuals who complained of suffering from adverse events or lack-of-effect when switching from Wellbutrin XL to Teva's generic equivalent. BX 103 at TEVA_WXL00483-84. This information was not available to Biovail at the time the Citizen Petition was filed, however.

lack of clarity on the subject.

Thus, given the relevant FDA guidance and draft guidance, the Court cannot find that Biovail could realistically expect success on the merits of the metabolites evaluation request as to the threo- and erythro- metabolites. Nevertheless, as will be explained below, the Court need not ultimately decide the question of whether this request was objectively baseless.

(2) Bioequivalence Drift Request

The Court understands Biovail's basic argument with respect to bioequivalence drift to be as follows: (1) Wellbutrin IR is the only Wellbutrin formulation proven in human clinical trials to be safe and effective; (2) Wellbutrin XL was bioequivalent to Wellbutrin IR, but studies showed that XL exposed the patient to 11% less bupropion over time than Wellbutrin IR;[18] (3) hypothetically, a generic version of Wellbutrin XL could expose patients to less buproprion over time than XL; (4) hypothetically and mathematically, the compounded effect of the generic product being only mostly equal to Wellbutrin XL, which was only mostly equal to Wellbutrin IR, means that the generic version of XL could potentially not be

[18] See BX 99 at 86 (showing an AUC ratio of 0.89 for Wellbutrin XL as compared with IR). The AUC is a measurement of the extent to which a drug stays in the body and for how long. An AUC ratio of 0.89 for Wellbutrin XL means that XL's AUC is 11% lower than that of IR. Fleischer Rpt. ¶ 13 (BX 124).

bioequivalent to IR. Biovail Br. 56-57. The Court cannot find at this time that the bioequivalence drift request in the Citizen Petition was not objectively baseless.

The Hatch-Waxman Act, FDA regulations, and FDA guidance only require generics to prove bioequivalence to the reference listed drug ("RLD") - in this case, Wellbutrin XL. See 21 U.S.C. §§ 355(j)(2), (j)(8); 21 C.F.R. § 314.94; FDA Guidance for Indus., Bioavailability and Bioequivalence Studies for Orally Admin. Drug Prods. 2 (Mar. 2003) (BX 126). Biovail argues, however, that the FDA has discretion to establish bioequivalence requirements for any particular drug, and that Wellbutrin's unique approval history rendered the bioequivalence drift request in the Citizen Petition objectively reasonable. Based on the current record, the Court does not find the argument persuasive.

The bioequivalence drift request appears to be purely based on hypothetical postulations and mathematical possibilities, as opposed to clinical evidence. Cf. Biovail Corp. v. U.S. FDA, 519 F. Supp. 2d 39, 49 (D.D.C. 2007) (declining to award injunctive relief based on the "speculative nature" of Biovail's allegations and on the basis of "hypothetical mathematics"). Biovail has pointed to no studies or evidence supporting its hypothetical outcome. Most importantly, Biovail does not appear to dispute the plaintiffs' argument that actual bioequivalence data for several of the

generic versions of Wellbutrin XL showed no evidence of bioequivalence drift. The plaintiffs claim this data was produced to Biovail in the early stages of the underlying patent lawsuits, and before Biovail filed the Citizen Petition. See Pls.' Br. 94; Kaplan Rpt. ¶ 13 (PX 75); Pls.' Stmt. ¶ 364. Biovail does not counter those facts or make any argument as to why it was realistic to expect the FDA to grant the bioequivalence drift request based on hypothetical arguments in the face of actual data.

Moreover, the plaintiffs have cited a GSK analytical document that states the following:

> Clinical Conclusions:
> - No safety issues associated with potentially higher concentrations that may result from [bioequivalence] drift
> - No efficacy issues associated with potentially lower concentrations that may result from [bioequivalence] drift

"Wellbutrin XL and Generic Entry" at GSKWXL00086996 (PX 655); see also id. at 0087029 ("No known safety or efficacy concerns from resultant values and dispersion around these values."). In other words, even assuming the existence of bioequivalent drift, GSK concluded that there were no safety or efficacy issues for the generic products. The Court also finds GSK's assessment of industry practice and precedent to be informative. According to GSK:

> Industry and Agency Precedents:
> - It is common practice in the industry to rely on serial bioequivalence demonstrations to qualify new formulations . . .

- No precedent for successfully arguing against this practice as regulatory standard.

Id. at 0087001 (emphasis added). It is unclear whether Biovail was aware of GSK's positions on the bioequivalence drift argument, and the Court does not impute such knowledge to Biovail in today's decision. Nevertheless, the existence of scientific conclusions from a major pharmaceutical company regarding the lack of clinical ramifications of bioequivalence drift for the safety and efficacy of generic Wellbutrin XL informs the Court's thinking that there was no realistic expectation of success on the merits of the bioequivalence drift request. However, as will be explained below, the Court need not ultimately decide whether the bioequivalence drift request was objectively baseless in this case.

(3) Steady-State Request

The parties agree that the steady-state request was largely derivative of the bioequivalence drift test. See Biovail Br. 59; Pls.' Br. 98. In other words, the baselessness of this request appears to turn largely on whether the underlying bioequivalence requests were baseless. Because the Court need not decide the objective merit of either the metabolites evaluation test or the bioequivalence drift test, the Court does not now consider whether the steady-state request was objectively baseless.

d. Delay

An antitrust plaintiff must prove a causal connection between the antitrust violation and actual damages suffered. See In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008); Rossi v. Std. Roofing, Inc., 156 F.3d 452, 483-84 (3d Cir. 1998). In this case, the plaintiffs' theory of antitrust injury is that the Citizen Petition delayed ANDA approval, thus postponing generic entry and permitting the brand manufacturers to maintain monopoly prices of Wellbutrin XL. Having found that two of the Citizen Petition requests were successful non-sham requests entitled to Noerr-Pennington immunity, however, this Court must examine whether the plaintiffs have put forth evidence of injury attributable to the unsuccessful (and arguably sham) requests.

Martha Bennett, the expert proffered by the plaintiffs to opine on the delay caused by the petition, testified that the FDA could "tackle multiple requests simultaneously rather than sequentially." Bennett Dep. 238 (BX 113). When asked how long the FDA took to resolve the dose dumping issues in the Citizen Petition, Ms. Bennett testified that:

> from December of '05 when the petition was submitted to December of '06 when FDA responded to the petition [was] the length of time it took them to resolve those issues.

Id. at 240. As the plaintiffs point out, Ms. Bennett's testimony

could reasonably be interpreted as merely stating the obvious - in other words, that the amount of time the FDA took to respond to each of the requests was the amount of time that the FDA took. Nevertheless, the testimony that follows is significant on the issue of delay:

> Q: If the citizen petition had been limited to the dose dumping and metabolite issues, how long would it have taken FDA to resolve it?
> . . . .
> A: I don't know.
> Q: Can you state to any professional certainty that it would have taken any less time than it actually took to resolve the citizen petition?
> A: No. I don't know.

Id. at 242-43. This excerpt speaks directly to the plaintiffs' expert's lack of knowledge as to what delay was attributable to the Citizen Petition independent of the successful, non-sham requests. The plaintiffs have not pointed to any other evidence in the record from which a jury could reasonably conclude that the FDA would have approved the ANDAs earlier if the Citizen Petition had been limited to the successful, non-sham requests. In other words, even if the unsuccessful requests were sham petitions not entitled to Noerr-Pennington immunity, the plaintiffs have not met their burden to show causation of anticompetitive injury. Because the plaintiffs have not raised a genuine issue of material fact as to whether the unsuccessful and allegedly sham requests caused any delay beyond the non-sham requests, the Court grants summary judgment as to the Citizen

Petition.

IV. GSK's Conduct

Antitrust co-conspirators are jointly and severally liable for all damages caused by the conspiracy to which they were a party. In re Cotton Yarn Antitrust Litig., 505 F.3d 274, 284 (4th Cir. 2007) (citation omitted); Wilson P. Abraham Const. Corp. v. Texas Indus., Inc., 604 F.2d 897, 904 n.15 (5th Cir. 1979). Both a conspiracy claim under section 1 of the Sherman Act and a conspiracy to monopolize claim under section 2 of the Sherman Act require the existence of agreement or concerted action. See Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc., 602 F.3d 237, 254 (3d Cir. 2010). To show agreement or concerted action, antitrust plaintiffs must produce evidence allowing a jury to reasonably infer "a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement." Id.

Direct proof of an express agreement is not required, but antitrust law limits the range of permissible inferences from ambiguous evidence. The Supreme Court has held that conduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy. To withstand a motion for summary judgment, a plaintiff must present evidence that tends to exclude

the possibility that the alleged conspirators acted independently. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 588 (1986); Cosmetic Gallery, Inc. v. Schoeneman Corp., 495 F.3d 46, 51 (3d Cir. 2007). The plaintiff must show that "the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed [them]." Matsushita, 475 U.S. at 588.

Thus, the Third Circuit has observed that "courts generally reject conspiracy claims that seek to infer an agreement from communications despite a lack of independent evidence tending to show an agreement and in the face of uncontradicted testimony that only informational exchanges took place." In re Baby Food Antitrust Litig., 166 F.3d 112, 133 (3d Cir. 1999). Furthermore, "[p]roof of opportunity to conspire, without more, will not sustain an inference that a conspiracy has taken place." Petruzzi's IGA Supermkts. Inc. v. Darling-Delaware Co., Inc., 998 F.2d 1224, 1235 (3d Cir. 1993) (citation omitted).

Here, the plaintiffs have failed to proffer evidence from which a jury may reasonably infer that GSK and Biovail together conspired to delay generic entry by filing the Impax and Watson lawsuits and the Citizen Petition, in light of the competing inference of independent action. In other words, even if the Court were to find that the plaintiffs survive Biovail's

motion for summary judgment, the plaintiffs have not met their burden to show that GSK can be held conspiratorially liable for Biovail's conduct as to Impax, Watson, and the Citizen Petition.

A. The *Impax* and *Watson* Lawsuits

1. Facts

GSK was not a party to the Impax or Watson lawsuits, though it received Impax's paragraph IV certification on January 21, 2005 and Watson's in July of 2005. PX 247 (Impax); PX 264 (Watson 150 mg); PX 265 (Watson 300 mg). GSK and Biovail's Common Interest Agreement encompassed Impax's paragraph IV certification. Stip. of Parties Concerning Defs.' Common Interest Claims ¶ 1 (ECF No. 363/ECF No. 347).

Before the Impax lawsuit was filed, GSK's outside counsel communicated directly with Impax regarding their paragraph IV notification and requested access to Impax's ANDA. GSK's outside counsel, Jason Leif, was tasked with reviewing the Impax ANDA and paragraph IV certification, did so, reached a conclusion as to whether the Impax generic would infringe Wellbutrin XL, and communicated that conclusion to GSK. See PX 249; PX 250; PX 251; PX 252; PX 253; PX 254; Leif Dep. 142-44, 151 (PX 137).

GSK and Biovail employees exchanged at least one email regarding Impax's paragraph IV certification. PX 418 (email from

GSK to Biovail attaching Impax certification). On February 28, 2005, about a week before the Impax suit was filed, Kenneth Cancellara, Biovail's general counsel, sent an email to GSK's outside counsel, Jason Lief, indicating that

> On the Impax Notice, I [Mr. Cancellara] have not yet heard from GSK (Carol Ash) on a conference call with their expert. I do not want to let the 45-day clock expire without consciously dealing with the issue.

PX 423. Mr. Leif recalled that he did communicate at some point with Biovail's counsel regarding the Impax paragraph IV notice. Id. at 162-63 (PX 137).

As to Watson, Mr. Leif reviewed Watson's paragraph IV notice, reached a conclusion regarding whether the Watson generic infringed Wellbutrin XL, and communicated his conclusion to GSK. However, he testified that he did not recall that there were discussions regarding Watson with either Biovail or its counsel. Leif Dep. 190-92 (PX 137). GSK's then CEO, Jean Pierre Garnier, testified that GSK decided not to sue the newer generics coming on the market (i.e., Impax and Watson). Garnier Dep. 141 (PX 129).

2. Analysis

The facts set forth above relating to GSK's involvement in Impax and Watson do not tend to exclude the possibility that Biovail and GSK acted independently once each received the Impax and Watson paragraph IV notices.

The record is consistent with a theory that GSK independently reviewed the paragraph IV notices and the ANDAs, came to a legal conclusion about infringement, and decided not to sue Impax and Watson. GSK's outside counsel recalled discussions with Biovail's counsel only regarding Impax, and no such discussions regarding Watson. To infer concerted action from the mere existence of the Common Interest Agreement as to the Impax paragraph IV certification and discussions between the defendants' counsel would be an exercise in speculation. See Warren Distrib. Co. v. InBev USA LLC, No. 07-1053, 2008 WL 4371763, at *4 (D.N.J. Sept. 18, 2008) ("The fact that a joint defense agreement was signed is not evidence of the conspiracy plaintiffs allege existed."). At best, the above evidence is equally consistent with informational exchange or independent action, which is not enough for the plaintiffs to survive GSK's motion for summary judgment as to these two lawsuits.

B. Biovail's Citizen Petition

1. Facts

a. Bioequivalence Drift

In April 2004, David Stout, GSK's President of U.S. Pharmaceutical Operations, emailed several other GSK employees addressing reports that up to four companies intended to file generic versions of Wellbutrin XL in the next twelve months. In

the email, Mr. Stout sketched the outline of a bioequivalence drift argument that later appeared in Biovail's Citizen Petition:

> If one product is approved on a bioequivalence basis, can another product be approved based on bioequivalence to that product or should they have to prove bioequivalence to the standard product. If you are allowed to continue to approve provducts [sic] based on bioequivalence to any other product that has been approved on that basis, you could end up with a product that is no where near the standard for which all clinical work was based.
>
> How do we get these arguments in front of the FDA? Citizens [sic] petition? We need to act fast!

PX 347. In response, David Wheadon, GSK's Senior Vice President of U.S. Regulatory Affairs, said he would "recommend going to FDA and making the public health argument that you outlined." GSK's then CEO, Jean-Pierre Garnier, requested to be copied on the FDA submission. PX 348.

On May 4, 2004, Brian Crombie, the CFO and Senior Vice President of Biovail wrote in an email:

> David stout of gsk in a conference today said that a generic to Wellbutrin XL would have to prove bioequivilence [sic] to a three times a day IR not to XL to get approved and that that would be very challenging. Is that true?

Greg Szpunar, Biovail's head of research and development, responded: "Doesn't make sense to me. If Xl is in the orange book, with no patent, the comparator would be XL." PX 349.

An internal GSK teleconference was scheduled for May 17, 2004 to discuss bioequivalence standards for generic Wellbutrin XL - specifically, whether there are "unique considerations for bupropion that might argue for bioequivalence

to IR to reduce 'bioequivalence drift.'" PX 350. GSK's Project Management Board ("PMB"), a governance body chaired by a GSK commercial leader and a research and development team leader, held a meeting in May 2004 to discuss a defense strategy for Wellbutrin XL. Bioequivalence drift was an "urgent agenda item" at the meeting. PX 352.

In an email to Mr. Stout (GSK's President of U.S. Pharmaceutical Operations) dated May 26, 2004, Dan Burch, GSK's Senior Vice President of Neurosciences, wrote: "I will get something organized soon to update you [on the issues raised at the May PMB meeting]. I am going to discuss this with Biovail. Are you or any others outside of JDC team members already in discussions with them about this?" PX 355. On the same day, Mr. Burch emailed a GSK employee to ask "[w]ho is the best person for me to call in Biovail to discuss work around issue?" PX 356.

GSK employees continued to discuss the bioequivalence drift argument internally, and circulated a draft outline for a presentation to GSK's PMB on June 30, 2004. PX 357. On June 22, 2004, a GSK PMB Briefing Document stated the following:

> The team has concluded that there are no safety or efficacy concerns associated with . . . 'bioequivalence drift'
> . . . .
> It is common practice in GSK and the industry to rely on serial bioequivalence demonstrations to qualify new formulations . . . . Finally, we are aware of no precedent for a company successfully arguing against this as a regulatory standard.

PX 368. The briefing document ended with the following proposal:

"Not recommending further action at this time." Id. Slides from the internal GSK PMB meeting on June 30, 2004 reflected the above conclusions. PX 369.

At his deposition, Dan Burch (GSK's Senior Vice President of Neurosciences) testified that when he gave the presentation at the GSK PMB meeting, he "knew there was no clinical ground to stand on . . . [and] was just trying to show . . . why we wouldn't even consider this or recommend this." Burch Dep. 152 (PX 121). He cited the lack of clinical support as the primary reason why he did not think GSK should ask the FDA to require generic companies to demonstrate bioequivalence to Wellbutrin IR. Id. at 152-53.

Similarly, Mr. Stout (GSK's President of U.S. Pharmaceutical Operations) testified at his deposition that the bioequivalence drift argument "would not fly at the FDA and, therefore, we had no basis to go the FDA." Stout Dep. 115 (PX 119). Although Mr. Stout could not recall specific discussions, he testified that he was "sure" both that GSK discussed bioequivalence drift with Biovail and that he communicated GSK's conclusions on the bioequivalence drift argument to Eugene Melnyk at Biovail. See id. at 108-09, 135, 253, 258.

In an internal GSK email dated December 9, 2004, a GSK employee provided answers to various questions that Mr. Stout had posed regarding generic versions of Wellbutrin XL. Among them

was the following question and answer, which related to the metabolites evaluation request that later appeared in Biovail's Citizen Petition:

> [Question:] Biovail is curious if we have any information on metabolites that might form the basis of a challenge to the standard bioequivalence testing/standards. In other words, is there any reason to believe that a different formulation of Wellbutrin XL might have a different metabolite profile due to differences in absorption patterns, excipients, etc.
> . . . .
> [Answer:] [F]rom a PK perspective, there isn't any reason to believe that a different formulation will have a different metabolite profile. We've seen this in our own work with Wellbutrin IR, SR and XL, which were all formulated to give bioequivalence of the parent drug, and then shown to be bioequivalent for the (major) metabolites as well.
>
> <u>This information is available internally, but has not been shared with Biovail, and it is our recommendation not to share metabolite data with Biovail.</u>

PX 406 (emphasis added).

On December 1, 2005, several senior GSK managers, including Mr. Burch and Mr. Stout, participated in another internal GSK teleconference with the subject "Wellbutrin XL and Generic [Bioequivalence]." PX 681. Eight days later, an internal GSK email chain referenced a meeting between GSK's David Stout and Biovail's Eugene Melnyk and Doug Squires to occur on December 12, 2005. PX 434. GSK employees were asked if anything needed to be communicated to Mr. Stout regarding the meeting with Biovail. In response, one GSK employee asked: "have they [Biovail] filed a citizens [sic] petition on XL." PX 434. Another internal GSK teleconference regarding "Wellbutrin XL and

Generic [Bioequivalence]" occurred on December 16, 2005, again involving GSK senior management like Mr. Burch and Mr. Stout. PX 682.

That same day, on December 16, 2005, Keith Muir, GSK's Director of Clinical Pharmacology, wrote:

> David Stout said that he wanted a Citizen's Petition prepared by the end of next week with a Clin Pharm scientific rationale for more rigorous BE [bioequivalence] requirements for Wellbutrin XL than for Wellbutrin SR. So I will be working on this for the better part of Monday and Tuesday.

PX 436; see also PX 435 (email from Keith Muir with similar text and referencing a draft "1 page summary of the strategy").

Biovail filed its Citizen Petition on December 20, 2005. On December 21, 2005, GSK's legal counsel, Bill Zoffer, sent a letter to Kenneth Cancellara, the Senior Vice-President and Chief Legal Officer at Biovail. The purpose of the letter was to

> confirm the outcome of conversations David Stout of GSK had with Eugene Melnyk and Douglas Squires [of Biovail] on December 12, 2005, and then briefly in follow up on December 13.
>
> Those discussions touched upon Biovail's efforts to explore and develop scientific issues related to appropriate review criteria for prospective generic copies of Wellbutrin XL, and the possibility of principled advocacy with FDA along those lines.
>
> This is to confirm the position that David Stout communicated in the follow up call: GSK does not wish to participate in or be associated with any such Biovail explorations, deliberations, strategizing, decision-making, or ultimate advocacy with FDA.

PX 280 (emphasis added). On December 23, 2005, GSK's Bill Zoffer circulated Biovail's Citizen Petition internally to various GSK team members. PX 438.

In response to Bill Zoffer's letter above, Biovail's Kenneth Cancellara answered by letter on January 9, 2006. Mr. Cancellara disputed Mr. Zoffer's characterizations of the discussions between GSK's David Stout and Biovail's Eugene Melnyk and Douglas Squires:

> [I]t is more accurate to state that Biovail explained to Mr. Stout its obligations to examine emerging scientific issues as they relate to Biovail's current and future products, including Wellbutrin XL. Since Wellbutrin XL is marketed by GSK, you are correct in stating that our two Companies have a shared interest in the overall safety, quality and integrity of the product.
> . . . .
> Biovail does not seek the participation of GSK's executives or scientists in this examination and did not indicate that such was being sought. Indeed, during Mr. Stout's telephone conference with Dr. Squires, it was Mr. Stout who sought and initiated the interaction between GSK and Biovail scientific and technical staff. This interaction, I understand, has now taken place.

PX 281.

At his deposition, Biovail's Douglas Squires testified:

> Q: Had there been collaboration between GSK and Biovail regarding the Citizen Petition before the Citizen Petition was complete?
>
> A: No, not that I recall.

Squires Dep. 104 (PX 120).

2. Analysis

The facts set forth above regarding GSK and the Citizen Petition are, at the very least, equally consistent - if not more consistent - with a theory that GSK and Biovail independently pursued the filing of a citizen petition with the FDA.

The fact that GSK benefitted from Biovail's Citizen Petition is not, by itself, sufficient to show concerted action. In SigmaPharm, Inc. v. Mutual Pharm. Co., Inc., one company filed a citizen petition requesting that the FDA require certain labeling information from generic competitors that would implicate a method for which the company held a co-exclusive license with another company. The court held that the citizen petition was "non-inculpatory, self-interested action." "That either or both companies would seek to impede competitors does not alone suggest a conspiracy . . ." SigmaPharm, Inc. v. Mutual Pharm. Co., Inc., 772 F. Supp. 2d 660, 671 (E.D. Pa. 2011), aff'd on other grounds, 2011 WL 6145370 (3d Cir. Dec. 12, 2011).

In this case, GSK has pointed to facts suggesting that it independently analyzed the possibility of filing a citizen petition with the FDA, and independently came to the conclusion that there was no clinical basis for the bioequivalence drift argument and the metabolites evaluation request as to the threo- and erythro- metabolites. The evidence suggests that GSK either independently decided not to file a citizen petition, or was in

the process of drafting its own separate petition. At one point, a GSK employee queried whether Biovail intended to file a petition, evincing a lack of knowledge as to the existence or contents of Biovail's Citizen Petition. PX 434. One science document even recommended that GSK not share internal GSK information with Biovail. PX 406. GSK also confirmed with Biovail its unwillingness to participate in Biovail's Citizen Petition via letter. PX 280. Furthermore, Biovail's Douglas Squires testified that he did not recall collaboration between GSK and Biovail on the Citizen Petition before it was complete. Squires Dep. 104-05 (PX 120).

In sum, the plaintiffs have not pointed to sufficient evidence to permit a jury to reasonably infer the existence of concerted action in light of all the evidence pointing to independent action by GSK. Therefore, even if the Court did not grant Biovail's motion for summary judgment, the Court would grant GSK's motion for summary judgment as to the Impax and Watson lawsuits as well as the Citizen Petition.

An appropriate order will follow separately.