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

In re WELLBUTRIN SR ANTITRUST LITIGATION	:	**CIVIL ACTION**
	:	**NO. 04-5525**
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS	:	
SHEET METAL WORKERS LOCAL 441 HEALTH AND WELFARE PLAN, et al.	:	**CIVIL ACTION**
	:	**NO. 04-5898**
v.	:	
GLAXOSMITHKLINE, PLC, et al.	:	
MEDICAL MUTUAL OF OHIO, INC.	:	**CIVIL ACTION**
v.	:	**NO. 05-396**
GLAXOSMITHKLINE PLC and SMITHKLINE BEECHAM CORP.	:	

MEMORANDUM AND ORDER

Kauffman, J. **March 9, 2006**

The Motion to Dismiss now before the Court concerns four distinct actions: SAJ Distributors, Inc. v. Smithkline Beecham (04-Cv-5525), Meijer, Inc. v. Glaxosmithkline PLC (04-Cv-5643), Sheet Metal Workers Local 441 Health & Welfare Plan v. Glaxosmithkline PLC (04-Cv-5898) and Medical Mutual of Ohio, Inc. v. Glaxosmithkline PLC (05-Cv-396). In each of those actions, Plaintiffs allege that Defendants Glaxosmithkline and its subsidiary Smithkline Beecham Corporation (together "GSK") have acted unlawfully to block the marketing of generic versions of GSK's depression drug Wellbutrin SR, in violation of federal antitrust laws.

SAJ Distributors, Inc. v. Smithkline Beecham and Meijer, Inc. v. Glaxosmithkline PLC[1] are putative class actions, both brought on behalf of a class of direct purchasers, a term which the complaints define as "all persons or entities in the United States that purchased Wellbutrin SR directly from GSK during the period of January 24, 2002 to a date to be determined." See Class Action Complaint (04-Cv-5525) ("the Saj Complaint") ¶ 108. Sheet Metal Workers Local 441 Health & Welfare Plan v. Glaxosmithkline PLC is also a putative class action; the plaintiffs therein, however, seek to represent the class of "indirect purchasers," which is defined as "all persons and entities in the United States who, at any time from July 1, 2001 to the present purchased Wellbutrin SR, Zyban and/or their generic equivalents in the United States for purposes other than resale." See Class Action Complaint (04-Cv-5898) (the "Sheet Metal Complaint") ¶21. In the final action, Medical Mutual of Ohio, Inc. v. Glaxosmithkline PLC, the plaintiff is a "third-party payor for Wellbutrin SR." See Plaintiff's Original Complaint (05-Cv-396) (the "Medical Mutual Complaint") ¶¶ 7-8.

Now before the Court is GSK's Motion to Dismiss the Complaints. For the reasons that follow, the Motion will be granted in part and denied in part.

I. BACKGROUND

These actions arise from GSK's efforts to use certain patents it has obtained to prevent its competitors from marketing generic versions of the depression drug Wellbutrin. Accepting the allegations of the Complaints as true, the pertinent facts are as follows.

A. *GSK's Bupropion Patents*

GSK's predecessor secured the first of the Wellbutrin patents, which was issued as U.S. Patent No. 3,819,706 (the "'706 Patent"), in 1974. That patent was for a substance known as bupropion hydrochloride ("bupropion"), which was known to act as an antidepressant. Sheet Metal Complaint ¶ 45. Medical Mutual Complaint ¶ 25. In the mid-1980's, the United States

[1] These actions have been consolidated. See SAJ Distributors, Inc. v. Smithkline Beecham, No. 04-5525 (E.D. Pa. Jan. 27, 2005).

Food & Drug Administration ("FDA") granted GSK's predecessor[2] approval to manufacture, market and sell bupropion under the brand name Wellbutrin. Sheet Metal Complaint ¶ 46. Wellbutrin was designed to release more than 75 percent of the bupropion contained in each tablet within approximately forty-five minutes of ingestion. For that reason, it was generally prescribed to be taken three to four times per day. Id. ¶ 47.

The '706 Patent expired in mid-1991. Soon thereafter, GSK developed a sustained release version of bupropion, which uses an excipient known as hydroxypropyl methycellulose ("HPMC") to issue the bupropion into the gastrointestinal tract at sustained intervals.[3] This sustained release mechanism reduces the number of doses necessary, such that a typical user of the sustained release bupropion need only take one or two doses per day. Id. ¶ 49.

In August 1993, GSK filed an application with the United States Patent and Trademark Office ("PTO") seeking patent protection for the sustained release bupropion tablets it had developed. Id. ¶ 50. The application was rejected. The patent examiner found that the claim for patent protection was overly broad insofar as it would have covered any sustained release mechanism for bupropion. The patent claims, he wrote, needed to be limited to the specific sustained release agent GSK's predecessor had developed: HPMC. Id. ¶ 52. In response to the PTO's objections, GSK amended its claims "to recite that the tablet required HPMC." Id. ¶ 53. Once these amendments were made, the PTO issued a Notice of Allowability indicating that "the PTO's previous rejection of the claims would be withdrawn based on the addition of the HPMC limitation." Id. ¶ 57.

On June 27, 1995, the PTO issued to GSK Patent No. 5,427,798 (the "'798 Patent") which was entitled "Controlled sustained release tablets containing bupropion." Id. ¶ 58. Plaintiffs allege that at the time the limiting amendments to the patent claims were made, GSK was aware of the existence of other excipients capable of administering bupropion on a sustained release basis, including hydroxypropyl cellulose ("HPC") and polyvinyl alcohol ("PVA").

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[2] The Court will refer to GSK' predecessor and GSK interchangeably.

[3] An excipient is a usually inert substance used as a vehicle for a drug.

Id. ¶ 64.

In October 1996, the FDA granted final approval for Wellbutrin SR, the sustained release version of Wellbutrin. Id. ¶ 66. In mid-1997, GSK brought Wellbutrin SR to market. Several months later, GSK also began marketing Zyban, which is chemically identical to Wellbutrin SR, but marketed for smoking cessation rather than depression.[4] Id. ¶¶ 2, 67.

B. *Attempts to Bring Generic Versions of Wellbutrin to Market*

Ordinarily, a company wishing to market a new drug must seek the approval of the FDA by completing a New Drug Application ("NDA"). However, the enactment of the Drug Price Competition and Patent Term Restoration Act in 1984 (the "Hatch-Waxman Act" or the "Act") carved out an exception to that general rule for manufacturers seeking to market generic drugs. Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j). Under 21 U.S.C. § 355(j), a generic company may file an Abbreviated New Drug Application ("ANDA") which relies on the FDA's previous findings of safety and efficacy. The applicant must include in the ANDA a certification that the proposed generic drug would not infringe existing valid patents by its manufacture, use, or sale. 21 U.S.C. § 355(j)(2)(A)(vii). If the generic applicant claims that a relevant patent is invalid or will not be infringed by its product, it must so certify to the FDA and notify the patent-holder. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as "paragraph IV certification"); 21 U.S.C. § 355(j)(2)(B)(I). The patent-holder then has forty-five days within which to bring a patent infringement suit against the applicant. If the patent-holder brings such a suit, the FDA's approval of the ANDA is automatically delayed for thirty months or until the patent is declared invalid or not infringed ("30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii).

Additionally, the Act provides a significant incentive to generic-drug manufacturers who file the first ANDA ("first filer"): a 180-day period of market exclusivity before subsequent

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[4] Defendant has assigned the two drugs different names purely for marketing purposes. For the twelve months ending June 30, 2002, domestic sales of Wellbutrin SR generated revenues in excess of $1.3 billion. Domestic sales of Zyban were $83 million for the same period.

ANDA filers can enter the market. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period begins to run when the first filer commercially markets the generic drug or when the court declares the existing patent invalid. Id.

Beginning in August 1999, several generic-drug manufacturers, including Andrx Pharmaceuticals ("Andrx"), Eon Labs ("Eon"), Impax Laboratories("Impax"), Excel Pharmaceuticals ("Excel") and Watson Laboratories ("Watson") sought approval to market generic versions of Wellbutrin SR. Each company filed an ANDA pursuant to 21 U.S.C. § 355(j) and gave GSK notice of its intention to introduce a generic version of Wellbutrin SR. GSK's response was the same in each case: it filed a patent infringement suit, thus triggering the 30-month stay of the FDA's approval of the ANDAs. The effect of that stay was to allow GSK to maintain its monopoly over Wellbutrin SR until either the 30 month period had expired or the generic drug manufacturer obtained a judgment of non-infringement.

C. *The Underlying Infringement Suits*

GSK pursued the Eon and Impax infringement suits simultaneously.[5] The issues in the two cases were virtually identical, as both the Eon and Impax drugs used the same excipient – HPC – as a release mechanism. Both Eon and Impax filed summary judgment motions in their respective cases. Eon's motion was decided first: on August 13, 2002, the district court issued a memorandum and order denying summary judgment on the grounds that GSK had raised a genuine issue of fact as to "the foreseeability of HPC as a sustained release agent." Glaxo Wellcome, Inc. v. Eon Labs Mfg., 2002 WL 1874831, at *5 (S.D.N.Y Aug. 13, 2002). Just over a week later, the district court hearing the Impax case reached the opposite result – that Impax was entitled to summary judgment. Glaxo Wellcome, Inc. v. Impax Laboratories, Inc., 220 F. Supp. 2d 1089 (N.D. Cal. 2002). GSK subsequently appealed the adverse judgment to the Federal Circuit.

In November 2003, while the Impax appeal was pending before the Federal Circuit, Eon

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[5] For standing reasons, Plaintiffs' claims are based only on the Eon and Impax actions.

announced that it was taking steps to bring its generic version of Wellbutrin SR to market, a move which was now possible because the thirty-month stay triggered by GSK infringement action had expired. GSK responded by moving for a Temporary Restraining Order ("TRO"), which was granted on November 26, 2003, and then extended on December 12, 2003. See Glaxo v. Eon, No. 00-9089 (S.D.N.Y. Nov. 26, 2003) and (S.D.N.Y. Dec. 12, 2003) (attached as Exhs. 24 and 25 to GSK's Memorandum in Support of Motion to Dismiss ("GSK's Memo")). While the TRO was still in place, the district court held a bench trial. At the conclusion of the trial, the district court converted the TRO into a preliminary injunction. Id. No. 00-9089 (S.D.N.Y. Dec. 29, 2003). Several days later, Eon moved to stay the injunction, which the district court denied on January 7, 2004. The court explained that it was keeping the injunction in place in order to "preserve the status quo," i.e., GSK's monopoly over Wellbutrin SR, until the court was able to render a final decision on the merits. See Id., No. 00-9089 (S.D.N.Y.) (trial tr. Jan. 7, 2004 at 17-19).

Eon immediately appealed the preliminary junction to the Federal Circuit. The turnaround was short. On January 12, 2004, the Federal Circuit entered an Order staying the preliminary injunction. Eon, App. No. 04-1169 (Fed. Cir. Jan. 12, 2004) (attached as Exh. 28 to GSK's Memo). Eon promptly began shipping its product.

On January 29, 2004, the Federal Circuit decided GSK's appeal in the Impax case. As noted above, the district court in that case had granted Impax summary judgment. The Federal Circuit affirmed that decision. See Glaxo Wellcome, Inc. v. Impax Labs, Inc., 356 F.3d 1348 (Fed. Cir. 2004). The Federal Circuit's decision against GSK in Impax had an obvious bearing on proceedings in the Eon matter, where the issues were nearly identical. Recognizing this, GSK voluntarily dismissed the Eon action. The dismissal took place before the trial judge rendered a decision on the merits.

D. *The '994 Patent*

GSK obtained U.S. Patent No. 4,687,660 (the "'660 patent") on August 18, 1987. Saj Complaint ¶ 28. At some point thereafter, the '660 patent was "being reexamined in response to

the discovery of two prior art patents that, when combined" rendered the '660 patent unpatentable. Id. ¶ 80. In order to preserve its monopoly over the subject matter of the '660 patent, GSK applied to have the patent reissued.[6] It succeeded and on July 14, 1992, the '660 patent was reissued as U.S. Patent No. RE33,994 ("the '994 patent"). Id. ¶ 28. The reissued patent "was drawn to pharmaceutical compositions that resulted in a controlled release of bupropion in a simulated gastric buffer. The Saj complaint alleges that GSK fraudulently misrepresented facts material to patentability to obtain the '994 patent." Id. ¶ 76.

E. *The Present Lawsuit*

The gravamen of Plaintiffs' Complaints is that GSK's infringement lawsuits constituted sham litigation in violation of state and federal antitrust laws. They contend that the lawsuits were frivolous, that GSK knew they were frivolous, and that GSK used the litigation to unlawfully extend its monopoly for the period of the stay.[7] To that end, Plaintiffs have brought an assortment of federal and state law claims. The Saj Complaint alleges violations of §2 of the Sherman Antitrust Act, 15 U.S.C. §2 (the "Sherman Act"). The Sheet Metal Complaint seeks injunctive and declaratory relief under § 16 of the Clayton Antitrust Act, 15 U.S.C. § 26 (the "Clayton Act") for violations of §2 of the Sherman Act (count one); in addition, it claims violations of state antitrust laws (count two), that GSK is liable for unfair and deceptive trade practices (count three), and unjust enrichment (count four). Finally, like the Sheet Metal Complaint, the Medical Mutual Complaint seeks injunctive relief under § 16 of the Clayton Act based on violations of §2 of the Sherman Act (count one); it also claims violations of state antitrust laws (count two) and state consumer fraud and unjust enrichment laws (count three).

Defendants have moved to dismiss all the Complaints under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted.

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[6] A reissue patent examination is conducted when requested by the patent holder to remedy a defect in the patent that makes it fully or partially inoperative or invalid. Saj Complaint ¶ 78.

[7] The Saj Complaint alone seeks relief based on GSK's allegedly fraudulent prosecution of the '994 patent.

II. LEGAL STANDARD

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may look only to the facts alleged in the complaint and its attachments. Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994). The Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff. Angelastro v. Prudential-Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir. 1985). A Rule 12(b)(6) motion will be granted only when it is certain that no relief could be granted under any set of facts that could be proved by the plaintiff. Ransom v. Marrazzo, 848 F.2d 398, 401 (3d Cir. 1988).

III. GSK'S IMMUNITY UNDER NOERR-PENNINGTON

The central issue in this Motion to Dismiss is the applicability of the Noerr-Pennington doctrine ("Noerr-Pennington"), which generally provides immunity from antitrust liability to those who petition the government for redress. This immunity serves to protect "from the Sherman [Antitrust] Act a concerted effort to influence public officials regardless of intent or purpose." Mine Workers v. Pennington, 381 U.S. 657, 670 (1965). GSK argues that its infringement suits qualify for Noerr-Pennington immunity and that Plaintiffs' antitrust claims, both state and federal, should be dismissed.

A. *The Sham Exception to Noerr-Pennington*

Plaintiffs acknowledge that lawsuits are ordinarily protected activity under Noerr-Pennington, but argue that the infringement actions at issue here are subject to an exception. The Supreme Court has established a "sham exception" to Noerr-Pennington immunity. "Activity 'ostensibly directed toward influencing government action' does not qualify for ... immunity if it 'is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.'" Professional Real Estate Investors, Inc. v. Columbia Pictures Industry, Inc., 508 U.S. 49, 51 (1993) (quoting Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961)). Plaintiffs contend that the GSK patent infringement suits constitute "sham litigation" and thus fall under the exception.

Accordingly, the Court must determine whether the GSK infringement suits were "protected activity" under Noerr-Pennington or whether, as Plaintiffs claim, they are subject to the "sham litigation" exception. Professional Real Estate is the key case discussing that exception. There, the Supreme Court set out a two-part test: the antitrust defendant's immunity gives way only if the plaintiff demonstrates that (1) the underlying lawsuit on which the antitrust suit is based is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits[;]" and (2) "the lawsuit conceals "an attempt to interfere 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[.]" 508 U.S. at 60-61 (emphasis in original) (quoting Noerr, 365 U.S. at 144 and Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380 (1991)).

The Court analogized the "objectively baseless" standard in the first prong of the test to the concept of "probable cause as understood and applied in the commonlaw tort of wrongful civil proceedings[.]" Id. at 62. "Probable cause to institute civil proceedings," the Court explained, "requires no more than a 'reasonable belief that there is a chance that a claim may be held valid upon adjudication[.]'" Id. (quoting Hubbard v. Beatty & Hyde, Inc., 343 Mass. 258, 262, 178 N.E.2d 485, 488 (1961)). Conversely, in order to overcome Noerr-Pennington immunity, the antitrust plaintiff must demonstrate that the defendant who brought the underlying suit could not have held such a belief. Thus, the first prong of the test, with its emphasis on the reasonable litigant, is concerned with the objective merits of the lawsuit at issue. The second prong, in contrast, focuses on the antitrust defendant's subjective intentions.

GSK contends that Plaintiffs are unable to satisfy the first prong of the test – that, in other words, they cannot establish that the Eon and Impax suits were objectively baseless. The question before the Court is thus whether GSK had probable cause to bring the infringement actions, i.e., whether it could reasonably have believed that its infringement claims might have been "held valid upon adjudication." Id.

B. *The Probable Cause Determination*

The answer to that question plainly depends on (1) the facts GSK faced when it filed the suits, (2) the governing legal principles, and (3) how those principles apply to the facts. See Professional Real Estate, 508 U.S. at 67 (Souter, J., concurring) (stating that the standard is whether "on the undisputed facts and the law as it stood when Columbia filed its suit, a reasonable litigant could realistically have expected success on the merits."); Restatement (Second) of Torts § 675, cmt. a (1977) ("[T]he claimant's mistaken belief in the possible validity of his claim may be a mistake as to the facts upon which the claim is based or a mistake as to the possible validity of his claim under the facts reasonably believed to exist.").

Because this is a Motion to Dismiss, the Court must base the probable cause determination on the facts alleged in Plaintiffs' Complaints. That is, the Court must assume that the facts GSK confronted when it initiated the Eon and Impax cases are those Plaintiffs have alleged in the Complaints. GSK contends that the Court need not accept the allegations in the Complaints as true at this stage. It urges the Court to make factual findings that deviate from the allegations in the Complaints based on trial transcripts and opinions from the underlying infringement actions, of which, it argues, the Court may take judicial notice. See GSK's Memo at 24.

GSK is correct that the Court may take judicial notice of the opinions filed in the underlying actions; however, the scope of that notice is subject to important limitations. The Court may take judicial notice only of the "existence of the opinion, which is not subject to reasonable dispute over its authenticity." Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir. 1999). The Court may not, however, make factual findings in this case based on the facts recited in the opinions of other courts. Id.

It follows that for the purposes of this Motion to Dismiss, GSK cannot invoke the record in the underlying infringement actions to challenge factual allegations in the Complaints. The Court's probable cause analysis must therefore be based exclusively on the allegations in Plaintiffs' Complaints, regardless of whether those allegations are consistent with the factual findings of other courts. Jarrow Formulas, Inc. v. Int'l Nutrition Co., 175 F. Supp. 2d 296, 311

(D. Conn. 2001) ("Here, all that is required is that the complaint allege facts, which, if proven, show that the defendant is not entitled to Noerr-Pennington immunity under the sham litigation exception."); Skinder-Strauss Assocs v. Mass. Continuing Legal Educ., Inc., 870 F. Supp. 8, 10 (D. Mass. 1994) ("Because [the defendant's] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6).")

The next question in the probable cause inquiry is how those facts would have been analyzed under the governing law. The Court must, in other words, consider whether GSK could reasonably have believed that the facts as Plaintiffs have alleged them gave rise to a claim for infringement against Eon and Impax.

It is thus necessary to examine GSK's theory of infringement. As noted above, GSK argued in the lawsuits that the Eon and Impax drugs infringed on the '798 patent. The '798 patent was limited to drugs that used the excipient HPMC as a release agent for bupropion. Because the Eon and Impax drugs employ a different excipient, HPC, as a release agent, GSK was foreclosed from claiming literal infringement. Instead, it was forced to rely on the doctrine of equivalents.

The doctrine of equivalents is essentially an expansion of the intellectual property rights of a patent holder; it allows a claim not only for those ideas described by the literal terms of the patent, but any "equivalents" as well. Festo Corp. v. Shoketsu Kinzoku Kogyo Kbushiki Co., 535 U.S. 722, 732 (2002) ("Festo VIII"). An equivalent is a product or process developed by a would-be competitor of the patent-holder which makes "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and [absent the doctrine of equivalents] outside the reach of law." Graver Tank & Mfg. Co. V. Linde Air Products Co., 339 U.S. 605, 607 (1950).[8]

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[8] The Supreme Court has explained that estoppel doctrine is essential if patents are to serve their purpose of providing an incentive for innovation: "If patents were always

GSK argues that its infringement suits against Eon and Impax were not a sham because it had a good faith argument based on the doctrine of equivalents: namely, that while the Eon and Impax drugs do not literally infringe the '798 patent, they are equivalents to the claimed subject matter, and consequently infringe by equivalence.

Plaintiffs, on the other hand, contend that GSK's reliance on the doctrine of equivalents is "objectively baseless." Their argument is rooted in a limitation to equivalence protection which courts have termed "the doctrine of prosecution history estoppel." The doctrine of prosecution history estoppel becomes relevant when a patent application fails to meet a statutory requirement for patentability, and is consequently rejected by the PTO. If "the patentee responds to the rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent." Festo VIII, 535 U.S. at 727. Here, Plaintiffs contend that GSK's decision to amend its original formulation of the '798 patent so as to narrow the claim to a drug that used HPMC as its sustained release mechanism estopped GSK from arguing for the "equivalence" of drugs like Eon's and Impax's, which deploy other sustained release agents. Accordingly, they argue, the doctrine of prosecution history estoppel would have proven an insuperable barrier to the Eon and Impax suits.

GSK responds that the law governing prosecution history estoppel was unsettled at the time it filed the suits. The resulting ambiguity, it argues, left open the possibility that the narrowing amendments did not bar GSK from claiming the Eon and Impax drugs as equivalents. In order to test that assertion, the Court must examine the state of the law at the time GSK filed the infringement suits. During the 1980's and 1990's, the Federal Circuit articulated two competing and inconsistent rules as to the scope of the doctrine of prosecution history estoppel. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki, 234 F.3d 558, 574 (Fed. Cir. 2000)

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interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying." Festo VIII, 535 U.S. at 732.

("Festo VII") (acknowledging inconsistency). The more prevalent of the two was known as the flexible bar rule, according to which the doctrine of prosecution history estoppel extends only to subject matter the patent holder relinquished during the prosecution. Under that approach, a court would determine whether a patent holder is estopped from claiming his competitor's product as an equivalent by looking to the subject matter the patent holder surrendered when it adopted the narrowing amendments. If the competitor's product falls within the surrendered subject matter, estoppel applies. See Litton Sys., Inc. v. Honywell, Inc., 140 F.3d 1449, 1455-57 (Fed. Cir. 1998) (holding that "an estoppel only bars recapture of that subject matter actually surrendered during prosecution."); Hughes Aircraft Co. v. United States, 140 F.3d 1470, 1476-77 (Fed. Cir. 1998) (holding that in order to determine the scope of the estoppel, there must be a determination as to the exact "subject matter the patentee actually surrendered.").

The second approach, known as the "complete bar rule," treated a narrowing amendment adopted by the patent holder to act as a complete bar to claiming equivalents. See, e.g., Kinzenbaw v. Deere Co., 741 F.2d 383, 391 (Fed. Cir. 1984). That is, once the patent holder adopts the narrowing amendments, the patent is effectively limited to its literal terms and the patent holder may no longer claim infringement by equivalence.

The Federal Circuit attempted to resolve the uncertainty with its decision in Festo VII, which expressly adopted the complete bar rule. Festo VII, 234 F.3d at 574. The flexible bar rule, it explained, was not workable and could not be consistently applied. The bright-line approach represented by the complete bar rule was the only feasible option. Id. The matter did not end there, however. The Supreme Court granted certiorari, and, on May 28, 2002, in a unanimous decision, reversed, holding that, despite the Federal Circuit's misgivings, the flexible bar rule is the correct approach. See Festo VIII, 535 U.S. 722, 737 (holding that the estoppel doctrine's "reach requires an examination of the subject matter surrendered by the narrowing amendments.") Thus, held the Court, so long as the competitor's product falls within "the territory between the original claim and the amended claim[,]" the patent-holder is barred from bringing an infringement claim. Id. at 740.

The law governing the application of the flexible bar rule, i.e., how a court determines what subject matter the patent holder's amendments surrender, has also undergone important changes. At the time GSK filed its infringement suits, "the standard for determining whether subject matter has been relinquished is whether one of ordinary skill in the art would objectively conclude from the prosecution history that an applicant surrendered it." Litton Sys., Inc. v. Honywell, Inc., 140 F.3d 1449, 1462 (Fed. Cir. 1998) (citing Marl I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995)). Then, in Festo VIII, the Supreme Court provided new guidance on the question. It held that "the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question." 535 U.S. at 740. However, the patentee can rebut that presumption by establishing that one of the following situations applies: "The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question; or there [is] some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." Id. at 740-41.

As noted above, GSK's argument is that the changes in the law governing prosecution history estoppel show that at the time it filed the infringement suits, the law had not yet solidified to the point that it was clear that GSK was estopped from claiming the Eon and Impax drugs as equivalents. Uncertainty in the law by itself, however, is not sufficient to create probable cause. Rather, for probable cause to exist, the range of the uncertainty must extend far enough to render viable a legal rule that would allow the plaintiff to prevail. That is not the case here.

GSK filed its infringement suit against Impax on September 28, 2000. Its suit against Eon was filed two months later on November 29, 2000, the same day that the Festo VII decision was announced. At that point, there was still some uncertainty as to whether the flexible bar rule or the complete bar rule was the governing law. Nevertheless, it was clear that, at the very least, the doctrine applied to all subject matter the patent holder had relinquished via narrowing amendments during prosecution. The only outstanding question was whether the scope of estoppel would reach further.

Thus, at the time the suits were filed, any reasonable litigant would have understood that if the Eon and Impax drugs fell within the subject matter GSK relinquished by adopting the narrowing amendments, GSK would not be able to claim them as equivalents. The only remaining question therefore is whether by narrowing its claim in response to the patent examiner's objections, GSK surrendered the right to claim as equivalents tablets that used excipients other than HPMC to administer the bupropion over time.

The facts Plaintiffs have alleged, which the Court must assume to be true for the purposes of this Motion, compel an affirmative answer to that question. According to the Complaints, GSK's initial patent application for sustained release bupropion was rejected for lack of enablement. The PTO examiner found that HPMC was "critical for the controlled and/or sustained release and should be incorporated into the independent claims. The disclosure of a single species does not provide a basis for disclosing a generic concept." See Sheet Metal Complaint at ¶ 52; Saj Complaint at ¶ 35; Medical Mutual Complaint at ¶ 33. The examiner's conclusion thus was that GSK was entitled to protection only for the specific means of achieving the sustained release bupropion that it had devised, namely the excipient HPMC. Sheet Metal Complaint ¶ 56. In response to the examiner's findings, GSK "submitted narrowing amendments to the patent examiner. These amendments narrowed the scope of the claims from covering all pharmaceutical means for achieving a specified release rate of bupropion to covering only HPMC, the single controlled release means divulged in the patent disclosure." See Saj Complaint at ¶ 37; Sheet Metal Complaint at ¶¶ 53-55.

HPC, the excipient that the Eon and Impax generic drugs use to achieve sustained release, "had been recognized as a release controlling substitute excipient for HPMC since before the prosecution of the application that would issue as the '798 patent." See Saj Complaint at ¶ 38. "GSK knew that HPC was a substitute for HPMC" when it agreed to the narrowing amendments. See Saj Complaint at ¶ 43; Sheet Metal Complaint at ¶ 64.

These facts render immaterial the changes in the law governing how a court determines what subject matter a patent holder has surrendered during patent prosecution. Under both the

Federal Circuit test that governed when the infringement suits were filed and the three factor test announced in Festo VIII that succeeded it, the allegations in the Complaints place the Eon and Impax drugs squarely within the relinquished subject matter.

Accordingly, the Court finds that any reasonable litigant confronting the facts Plaintiffs have alleged at the time the infringement suits were filed would have concluded that GSK would be estopped from claiming infringement by equivalence. Without a viable argument for infringement by equivalence, GSK could not reasonably have expected success on the merits. Thus, for the purposes of this Motion to Dismiss, GSK's infringement actions against Eon and Impax must be considered objectively baseless.

C. *The Effect of GSK's Limited Success in the Eon Suit*

GSK also argues that regardless of whether the underlying infringement suits are objectively baseless under the facts Plaintiffs have alleged, the success GSK enjoyed in the Eon action precludes a finding that the infringement suits were objectively baseless. In effect, GSK is asking the Court to adopt a per se rule that any action which achieves a certain "measure of success" – in this case, surviving summary judgment motion and securing a preliminary injunction – is, as a matter of law, not "objectively baseless."

To be sure, several courts appear to have adopted the rule GSK is proposing. See, e.g., Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag, 207 F. Supp. 2d 221, 224 (S.D.N.Y. 2002) (summary judgment denied and claims found not baseless because claims went unchallenged until trial); Harris v. Custom Builkders, Inc. v. Hoffmeyer, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993) (finding that an "action that is well enough grounded, factually and legally, to survive a motion for summary judgment is sufficiently meritorious to lead a reasonable litigant to conclude that they had some chance of success on the merits.")

However, the controlling authority is the Federal Circuit, whose decisions govern "all antitrust claims premised on the bringing of a patent infringement suit." Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069 (Fed. Cir. 1998). Thus, it is to the Federal Circuit that the Court must look for guidance as to the merits of GSK's proposed per se rule, and

the Federal Circuit has explicitly rejected it. In Filmtec Corp. v. Hydranautics, the panel held that the "court hearing the antitrust claim must make its own assessment of the objective merits of the predicate suit," regardless of how the case fared before the previous court. 67 F.3d 931, 937 (Fed. Cir. 1995) (quoting Boulware v. Nevada Dep't of Human Resources, 960 F.2d 793, 799 (9th Cir. 1992)). Thus, "preliminary success on the merits does not necessarily preclude a court from concluding that litigation was baseless." Id. at 938. See also In re Relafen Antitrust Lit., 346 F. Supp. 2d 349, 362-65 (D. Mass. 2004) (holding that a plaintiff's surviving summary judgment does not prove as a matter of law that his case was not objectively baseless).

Furthermore, the per se rule GSK proposes is inconsistent with Professional Real Estate, where the Court made clear that the "objectively baseless" determination depends on the reasonable expectations of the party alleged to have brought the frivolous suit. By employing the language of "expectations" the Court was indicating that the analysis should focus on what the litigant knew or reasonably could have known at the time the suits were filed, not on the results of the suits. Professional Real Estate, 508 U.S. at 61 n. 5. The analysis, in other words, must be prospective not retrospective, and therefore should be limited to the law and the facts as they existed when the decision to file suit was made. Id. at 67 (Souter, J., concurring) (stating that the standard is whether "on the undisputed facts and the law as it stood when Columbia filed its suit, a reasonable litigant could realistically have expected success on the merits."). Accordingly, the Court rejects GSK's proposed per se rule that the success it enjoyed in the Eon case precludes a finding that the action was objectively baseless.

D. *Conclusion*

Accepting the allegations of the Complaints as true, which the Court must do at this stage of the proceedings, GSK's Motion to Dismiss based on Noerr-Pennington immunity will be denied.

IV. THE WALKER PROCESS CLAIMS

The Saj Complaint claims an additional violation of the Sherman Act based on GSK's allegedly fraudulent prosecution of patent '994 ("Walker Process claim"). See Walker Process

Equip., Inc. v. Food Mach. And Chem. Corp., 382 U.S. 172, 174 (1965) ("[T]he enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 are present."). GSK argues that that claim should be dismissed (1) because the Saj Complaint failed to plead the alleged fraud with the requisite particularity; and (2) for lack of standing.

Rule 9(b) requires that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b). In the Third Circuit, a plaintiff's complaint must set out the circumstances of the fraud with enough particularity to "place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984); In re: Rockefeller Ctr. Prop., Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002). While providing allegations of "date, place or time" is one means of giving the defendant adequate notice, it is not exclusive. "Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." Id.

At oral argument, the Saj Plaintiffs conceded that in its current state, the Walker Process claim did not satisfy the requirements of Fed. R. Civ. P. 9(b). Accordingly, that claim will be dismissed without prejudice.

V. INJUNCTIVE RELIEF

The Medical Mutual and Sheet Metal Complaints do not seek damages for GSK's alleged violations of the Sherman Act, but only injunctive relief under § 16 of the Clayton Antitrust Act. They request that the Court enjoin Defendants from "engaging in future anticompetitive practices concerning the manufacture, distribution or sale of Wellbutrin SR and Zyban." See Medical Mutual Complaint ¶ 99; Sheet Metal Complaint ¶ 131.

GSK argues that these claims should be dismissed because the Complaints fail to allege an antitrust injury cognizable under § 16 the Clayton Act. The Court agrees. "In order to seek

injunctive relief under § 16 [of the Clayton Act], a private plaintiff must allege threatened loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful.'" Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 113 (1986) (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)) (emphasis added). Now that all the infringement suits have terminated in the generic companies' favor, there is no unlawful conduct to be enjoined. Accordingly, the Court finds that the Medical Mutual and Sheet Metal Plaintiffs have failed to allege a claim cognizable under § 16 of the Clayton Act. See In re Relafen Antitrust Lit., 221 F.R.D. 260, 274 (D. Mass. 2004) (holding that antitrust plaintiffs were not entitled to injunctive relief for antitrust claim based on frivolous lawsuits where the suits had already been resolved since "it is difficult to imagine how [the alleged] violation might recur.").

VI. CONCLUSION

For the foregoing reasons, the Court will grant GSK's Motion to Dismiss with respect to the Walker Process Claims in the Saj Complaint and the claims under § 16 of the Clayton Act in the Sheet Metal and Medical Mutual Complaints, all without prejudice.[9] With respect to the remaining claims, GSK's Motion will be denied.

[9] Plaintiffs should generally be given an opportunity to amend claims dismissed pursuant to a 12(b)(6) motion unless such amendment would be "inequitable, futile, or untimely." Alston v. Parker, 363 F.3d 229, 236 (3d Cir. 2004).

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

In re WELLBUTRIN SR ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **ALL ACTIONS**	:	**CIVIL ACTION** **NO. 04-5525**
SHEET METAL WORKERS LOCAL 441 HEALTH AND WELFARE PLAN, et al. **v.** **GLAXOSMITHKLINE, PLC, et al.**	:	**CIVIL ACTION** **NO. 04-5898**
MEDICAL MUTUAL OF OHIO, INC. **v.** **GLAXOSMITHKLINE PLC and SMITHKLINE BEECHAM CORP.**	:	**CIVIL ACTION** **NO. 05-396**

ORDER

AND NOW, this 9th day of March, 2006, upon consideration of Defendants' Motion to Dismiss (docket no. 23 in 04-Cv-5525, docket no. 8 in 04-Cv-5898, docket no. 16 in 05-Cv-396) and the responses thereto and for the reasons stated in the accompanying memorandum, it is **ORDERED** that the Motion is **GRANTED** in part and **DENIED** in part. It is **FURTHER ORDERED** that

(1) The Walker Process claim in the Saj Complaint (04-5525) is **DISMISSED WITHOUT PREJUDICE**.

(2) Count one in the Sheet Metal Complaint (04-5898) is **DISMISSED WITHOUT PREJUDICE**.

(3) Count one in the Medical Mutual Complaint (05-396) is **DISMISSED**

WITHOUT PREJUDICE.

(4) GSK's Motion to Dismiss is **DENIED** as to all other counts.

BY THE COURT:

/s/ Bruce W. Kauffman
BRUCE W. KAUFFMAN, J.