IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE DIRECT PURCHASER ANTITRUST LITIGATION	)	Civil Action No. 06-52 (GMS)
IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	)	Civil Action No. 06-71 (GMS)

MEMORANDUM

I. INTRODUCTION

On June 5, 2006, the plaintiffs[1] filed two Consolidated Class Action Complaints (the "Complaint") asserting claims against AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktiebolaget Hassle (collectively, "AstraZeneca") for: (1) declaratory and injunctive relief under section 16 of the Clayton Act for alleged violations of Section 2 of the Sherman Act; (2) monopolization under state law; (3) unfair and deceptive trade practices under state law; and (4) unjust enrichment. (D.I. 17.) On June 28, 2006, AstraZeneca moved to dismiss the Complaint or, in the alternative, to stay the action pending the resolution of a related

[1]The plaintiffs are comprised of Direct Purchaser Plaintiffs and End Payor Plaintiffs. The Direct Purchaser Plaintiffs allege that they are pharmaceutical product wholesalers and pharmacies, and include the following parties: Meijer, Inc., Meijer Distribution, Inc. on behalf of themselves and all others similarly situated, American sales Co., and Rochester Drug Co-Operative, Inc. The End Payor Plaintiffs allege that they are health and welfare plans, self-insured employers, and other entities and individuals who have paid all or a portion of the cost of Toprol-XL® prescriptions. This group of plaintiffs include the following parties: Meijer, Inc., Meijer Distribution, Inc., Mark S. Merado, District 1119P Health and Welfare Plan, Neil Lefton, Mary Anne Gross, International Association of Fire Fighters Local 22 Health & Welfare Fund, American Federation of State County and Municipal Employees District Council 47 Health and Welfare Fund, United Food and Commercial Workers Union Local 1776 and Participating Employers Health and Welfare Fund, AF of L AGC Building Trades Welfare Plan and Sheet Metal Workers Local 441 Health & Welfare Plan, United Union of Roofers Waterproofers and Allied Workers Local 74 Health and Pension Fund, United Union of Roofers Waterproofers and Allied Workers Local 203 Health and Pension Fund, Plumbers and Pipefitters Local 572 Pension Fund, National Joint Powers Alliance, Dorothy Ferguson, and Thelma Clement. For ease of reference the Direct Purchaser and End Payor Plaintiffs will be collectively referred to as the "plaintiffs" or the "Class."

patent litigation that was on appeal before the United States Court of Appeals for the Federal Circuit. (D.I. 24.) At that time, the court administratively stayed these actions, awaiting the opinion from the Federal Circuit.

On July 23, 2007, the Federal Circuit affirmed the district court's summary judgment decision that the patents at issue were invalid, and vacated the grant of summary judgment on the issue of inequitable conduct, remanding for trial. *See Metoprolol Succinate Patent Litig. v. KV Pharm. Co.*, 494 F.3d 1011, 1021 (Fed. Cir. 2007). Subsequently, on remand, the parties settled the underlying patent litigation and the case was dismissed. On August 22, 2008, AstraZeneca filed a letter confirming the parties' resolution of the underlying patent litigation. (D.I. 36.) At that time, the court lifted the administrative stay.

Presently before the court, is AstraZeneca's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the court will deny the motion to dismiss.

II. SUMMARY OF STATUTORY FRAMEWORK

The provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") govern the generic drug approval process. Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Amendments were modified by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066 (amended 2003). Herein, all references to the Hatch-Waxman Amendments and its regulatory framework include the scope of the provisions as later modified.

The Hatch-Waxman Amendments intend to balance two important public policy objectives: (1) prescription drug manufacturers need meaningful market protection incentives to encourage the development of new drugs; and (2) once the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid

availability of lower priced generic versions of the innovator drug. *See, e.g., Nova Pharmaceutical Corp. V. Shalalai,* 140 F.3d 1060, 1068 (D.C. Cir. 1998). The Hatch-Waxman Amendments modified the Federal Food, Drug, and Cosmetic ("FD&C") Act and created section 505(j). This section established the abbreviated new drug application ("ANDA") approval process, which permits generic versions of previously approved innovator drugs to receive Food and Drug Administrative (the "FDA" or the "Agency") approval without submission of a full new drug application ("NDA"). Specifically, the ANDA refers to a previously approved NDA and relies upon the FDA's finding of safety and effectiveness for that drug product. The timing of an ANDA approval, however, is in part contingent on the innovator drug's patent protections.

The NDA for an innovator drug must include information about patents related to that drug product. The FDA publishes patent information on approved drug products in the Agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." To be properly listed in the Orange Book, the patent must meet two statutory requirements: (1) the patent must "claim the drug" or "a method of using such a drug;" and (2) the patent must be such that a "claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b) and 355(c)(2). The FD&C Act requires that an ANDA contain a certification for each patent listed in the Orange Book for the innovator drug that states one of the following: (1) that the required patent information relating to such patent has not been filed ("Paragraph I Certification"); (2) that such patent has expired ("Paragraph II Certification"); (3) that the patent will expire on a particular date ("Paragraph III Certification"); or (4) that such patent is invalid or will not be infringed by the drug, for which approval is being sought ("Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

A certification under Paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under Paragraph III indicates that the ANDA may be approved on the patent expiration date. A Paragraph IV certification begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent. The ANDA applicant who files a Paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a Paragraph IV certification may be sued for patent infringement. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within forty-five days of the receipt of notice, the FDA cannot grant final approval to the ANDA for at least thirty months from the date of the notice. 21 U.S.C. § 355(j)(5)(B)(iii). This thirty-month stay applies unless the court reaches a decision earlier in the patent infringement case, or otherwise orders a longer or shorter period for the stay. (Id.)

The statute provides an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a Paragraph IV certification and running the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a Paragraph IV certification to a listed patent is eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent

invalid, unenforceable or not infringed, whichever is first. These two events--first commercial marketing and a court decision favorable to the generic--are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

III. BACKGROUND

AstraZeneca manufactures and markets metoprolol succinate under the brand name Toprol-XL®. Toprol-XL® is an extended release drug approved by the FDA for the treatment of hypertension, angina, and congestive heart failure. (D.I. 1 at 5.) AstraZeneca owns two United States patents related to the drug: (1) U.S. Patent No. 5,001,161 (the "'161 patent"); and (2) U.S. Patent No. 5,081,154 (the "'154 patent").[2] (Id.)

A. Invention, Ownership, and AstraZeneca's Metoprolol Succinate Patents

Because the court writes solely for the parties, only those facts relevant to this decision are included. For a full recitation of additional facts related to issues of the ownership and invention of AstraZeneca's patented metoprolol succinate-based drug, AstraZeneca's '154 and '161 patents, the parties and facts involved in the underlying patent infringement litigation, and the Federal Circuit's rationale in affirming the invalidation of AstraZeneca's metoprolol succinate patent, please see *Metoprolol Succinate Patent Litigation v. KV Pharmaceutical Co.*, 494 F.3d 1011 (Fed. Cir. 2007).

In *Metoprolol Succinate Patent Litig.*, the Federal Circuit affirmed the district court's determination that AstraZeneca's metoprolol succinate patent is invalid for double patenting and remanded the question of whether AstraZeneca engaged in inequitable conduct before the PTO. 494 F.3d 1011, 1017-21 (Fed. Cir. 2007). In arriving at its holding, the Federal Circuit examined the district court's factual findings related to the invention and ownership of AstraZeneca's

[2] The '161 patent issued on March 19, 1991, and claims a "sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." The '154 patent issued on January 14, 1992, and claims the composition of metoprolol succinate itself. (D.I. 25 at 5.)

patented metoprolol succinate-based prescription drug. *Id.* From this examination the court determined that: (1) disagreement existed as to the issue of inventorship at the time the '154 and '161 patents were sought; and (2) AstraZeneca failed to disclose to the PTO that issues of inventorship were unresolved during the prosecution of the two patents. *Id.* at 1014.

B. The Plaintiffs' Current Claims

As indicated in footnote one, the plaintiffs are comprised of Direct Purchasers and End Payors of Toprol-XL®. The plaintiffs claim that since May 5, 2005, AstraZeneca has possessed a complete monopoly on the production, distribution, and sale of the metoprolol succinate-based prescription drugs to the detriment of Class members who have been forced to pay higher prices due to AstraZeneca's market exclusivity. (D.I. 1 at 15.) The plaintiffs specifically claim that AstraZeneca knowingly withheld relevant information from the PTO in order to fraudulently obtain their Typrol-XL® related patents and wrongfully listed these invalid patents in the Orange Book. (D.I. 17 at 2.) Moreover, AstraZeneca allegedly restricted generic manufacturers—including Sandoz, Inc. (formerly known as Eon Labs, Inc.), which ultimately obtained FDA approval after the thirty month patent infringement suit stay expired—from entering the metoprolol succinate-based prescription drug market by filing sham patent infringement litigation suits against such companies. (D.I. 28 at 9); *see also Metoprolol Succinate Patent Litig.*, 494 F.3d at 1015 (noting that AstraZeneca filed patent infringement suits against generic metoprolol succinate manufacturers and ANDA filers, KV, Andrx, and Eon Labs, Inc.). These suits triggered the Hatch-Waxman Amendments' automatic thirty month stay on final FDA approval and, according to the plaintiffs, delayed generic manufacturers from entering the marketplace, because these companies diverted resources from attaining FDA approval to defending the patent infringement litigation suit. (D.I. 28 at 16-19.) In sum, the plaintiffs allege

that AstraZeneca violated Section 2 of the Sherman Act by engaging in anti-competitive conduct to facilitate and successfully secure its monopoly of the metoprolol succinate-based prescription drug market to the detriment of Direct Purchasers and End Payors.

IV. STANDARD OF REVIEW

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). Under Rule 12(b)(6), the court looks at the facts most favorable to the non-moving party. *See, e.g. Calloway v. Green Tree Servicing, LLC,* 607 F. Supp. 2d 669, 673 (D. Del. 2009). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal,* --- U.S. ---, 129 S. Ct. 1937, 1950 (2009). If they do not, the court should dismiss the complaint. *Id.* When the issue of antitrust injury is raised in a motion to dismiss, the court "has an obligation . . . to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d Cir. 1998). In this task, the court must consider the defendants' "conduct as a whole." *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2D 408, 430 (D. Del. 2006) (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2D 686, 699-703 (E.D. Pa. 2004)). The court is not required, however, to credit unsupported conclusions and unwarranted inferences." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

V. DISCUSSION

The plaintiffs contend that AstraZeneca violated Section 2 of the Sherman Act through unlawful anti-competitive conduct including: (1) fraudulently obtaining the '161 and '154 patents by engaging in inequitable conduct before the Patent and Trademark Office (the "PTO")

through deliberate omissions and/or misrepresentations; (2) listing invalid patents in the Orange Book to give rise to claims of patent infringement; and (3) filing sham patent-infringement lawsuits against generic manufacturers to trigger an automatic thirty month stay on final FDA approval of competitive generic drugs. (D.I. 17 at 2.) The plaintiffs allege that AstraZeneca's combined actions prohibited generic competitors from entering the market, delayed ANDA approvals by forcing generic manufacturers to divert resources from FDA approval to patent infringement litigation, and resulted in the class paying "artificially high" prices. (D.I. 1 at 14.)

Conversely, AstraZeneca contends that the statutory framework, rather than its actions, delayed the entrance of generic manufacturers in the metoprolol succinate-based prescription drug market. Specifically, AstraZeneca asserts that because no generic manufacturer received tentative FDA approval during the thirty month stay triggered by its patent infringement suits, such manufacturers were prohibited by federal law and FDA regulations from entering the market. (D.I. 25 at 13.) Therefore, AstraZeneca claims that the plaintiffs' alleged antitrust injury is not attributable to its actions because "the FDA's failure to provide tentative approval [was the] independent cause that fully accounts for the absence of a generic version of metoprolol succinate from the market." (D.I. 29 at 4.) Consequently, AstraZeneca argues that the plaintiffs cannot establish antitrust standing, and the court should dismiss the Complaint.

A. The Statutory Framework and FDA Tentative Approval

The plaintiffs contend that AstraZeneca's conduct in obtaining invalid patents, listing the patents in the Orange Book, and filing sham patent infringement litigation to trigger the Hatch-Waxman Amendment's thirty month stay amounts to a violation of Section 2 of the Sherman Act. (D.I. 28 at 2.) An antitrust plaintiff is barred as a matter of law from asserting its claims if it cannot establish antitrust standing. *Associated Gen. Contractors of Cal.*, 459 U.S. 519, 529-33

(1983); *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 181 (3d Cir. 1997). Antitrust standing requires that the plaintiff establish the existence of an "antitrust injury," defined as an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Further, the nature of the plaintiffs' injury must evidence a "causal connection between the purportedly unlawful conduct and the injury." *West Penn Power*, 147 F.3d at 265. This causal connection, however, does not need to be the "exclusive" cause of the plaintiff's injury. *Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003). Rather, the plaintiff is required to show only "that a violation is a 'material cause' of the claimed injury." *Id.* The determination of antitrust standing involves a "balancing all of the relevant facts." *West Penn Power,* 147 F.3d at 256 (3d Cir. 1998) ("The antitrust standing inquiry is not a black-letter rule, but rather, is 'essentially a balancing test comprised of many constant and variable factors.'") (quoting *Merican, Inc. v. Caterpillar Tractor Co.*, 713 F.2d 958, 964-65 (3d Cir. 1983)).

AstraZeneca's contention that generic manufacturers of metoprolol succinate-based prescription drugs were excluded from the market by the statutory framework rather than their actions, is derived primarily from: (1) the Third Circuit's holdings in *West Penn Power* and *Schuylkill Energy Resources*; (2) United States District Courts for the District of Massachusetts, Southern District of Florida, and the Eastern District of New York's interpretations of *West Penn Power* and Hatch-Waxman antitrust standing as requiring tentative FDA approval to satisfy the antitrust injury element; and (3) the nature of the FDA approval process and parameters of the Hatch-Waxman Amendments, wherein generic manufacturers are incentivized to obtain approval expeditiously to capitalize on the first-filer 180-day period of exclusivity. (D.I. 25 at 13-21.) As

discussed below, however, AstraZeneca's contentions are not supported by the relevant case law in the Third Circuit.

1. *West Penn Power, Schuylkill Energy Resources, and the Statutory Framework Analysis*

AstraZeneca asserts that the plaintiffs cannot establish antitrust standing because federal law and the FDA approval process prohibited generic manufacturers from entering the metoprolol succinate-based prescription drug market. More specifically, AstraZeneca points to the fact that the FDA had not granted tentative approval to any generic manufacturer of the drug during the thirty month stay and concludes from this fact that it was the statutory framework which precluded market competition. In support of this contention, AstraZeneca cites the Third Circuit's holdings in *West Penn Power* and *Schuylkill Energy Resources, Inc.* and argues that these cases render the plaintiffs' antitrust standing insufficient for lack of causation.

In *West Penn Power*, the City of Pittsburgh (the "City") filed an antitrust action alleging that two power companies had entered into a pre-merger agreement in restraint of trade, and that such merger would "lessen competition or tend to create a monopoly." *West Penn Power*, 147 F.3d at 258. The Third Circuit held that the City failed to establish an antitrust injury, because the ability to compete in the market was contingent on the decision of the Pennsylvania Utilities Commission (the "PUC"), rather than the actions of the defendants. In sum, the court concluded that "the fact that no competition existed was the result of the regulatory structure" and, therefore, that the City failed to establish the causation element of antitrust standing. *Id.* at 262-63. Similarly, the court in *Schuylkill Energy Resources* dealt with the same regulatory framework in which the PUC—not the market competitors—decided which power companies could enter the market and what rates were established. *Schuylkill Energy Res.*, 113 F.3d at 414. In *West Penn Power*, however, the Third Circuit recognized that the case arose "in a factual

context which is substantially different from that of most antitrust cases," and accordingly noted that its "ruling [was] fact specific to the current climate in which the instant facts developed, namely, in the era of 'regulated electric utility monopolies.'" *West Penn Power*, 147 F.3d at 263-69. Accordingly, *West Penn Power* and *Schuylkill Energy Resources* are distinguishable.

AstraZeneca also relies on holdings of the United States District Courts for the District of Massachusetts, the Southern District of Florida, and the Eastern District of New York, to support its contention that the Hatch-Waxman Amendments and the FDA statutory regulatory framework are the cause of antitrust injury in the patent arena when generic manufacturers are precluded from the market. (D.I. 25 at 13-16.) Specifically, AstraZeneca cites cases in which these courts concluded that: (1) the market exclusivity of a brand-name prescription drug manufacturer is directly attributable to the regulatory structure; and (2) the ability of generic manufacturers to obtain tentative approval during the thirty month patent infringement suit stay is dispositive in assessing antitrust standing. *See, e.g.*, *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004) (explaining that "without tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury" and concluding that *West Penn Power* dictates that "[i]n a regulated industry, the failure to get needed regulatory approval may 'cut[] the causal chain and convert[] what might have been deemed antitrust injury in a free market into only a speculative exercise'") (citation omitted); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 240-41 (E.D.N.Y. 2003) (identifying the FDA's grant of tentative approval as an indicator that a generic manufacturer and Paragraph IV filer "was at least a potential competitor"); *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 62 (D. Mass. 2003) (holding that prior to receiving tentative FDA approval, injury to generic manufacturers and/or purchasers is "entirely speculative"); *Bristol-Myers Squibb Co.*

v. Copley Pharm., Inc., 144 F. Supp. 2d 21, 24 (D. Mass. 2000) (recognizing that *West Penn Power* dealt with the antitrust standing issue in "the utilities context," but concluding that without tentative FDA approval requisite elements of antitrust standing cannot be met).

The positioning of tentative FDA approval as the dispositive factor in patent antitrust cases, however, is questionable in view of case law in the Third Circuit and elsewhere. Specifically, the plaintiffs cite three cases within the Third Circuit in which district courts rejected arguments identical to those AstraZeneca asserts here, namely, that tentative approval is a prerequisite for antitrust standing and that the statutory framework—rather than the patentee's actions—caused the antitrust injury. (D.I. 28 at 12); *see, e.g.*, *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (denying the patentee's motion to dismiss based on the conclusion that the patentee caused antitrust injury by "triggering . . . the 30-month stay" and rejecting premise that the statutory framework caused injury); *Bristol Meyer-Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (rejecting the patentee's argument that the statutory framework rather than company actions prevented generic companies from entering market and concluding that such an argument "ignores the reality of Hatch-Waxman. There is no dispute that by suing the generic defendants under the Hatch-Waxman Act, the patentee provoked the automatic moratorium of FDA approval of the generics' ANDAs . . ."); *Warner Lambert Co. v. Purepac Pharm. Co.*, No. Civ.A. 98-02749, 2000 WL 34213890 (D.N.J. Dec. 22, 2000) ("[T]he generic manufacturer's injury does not merely result from the 'structure of the regulatory industry,' but from the decision of the pioneer manufacturer to bring suits," because this action delayed final FDA approval and "temporarily foreclosed" market competition.).

In addition, the plaintiffs point to one case from each of the Seventh Circuit and the D.C. Circuit where those courts reached similar conclusions. *See Xechem Inc. v. Bristol-Meyers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004) (identifying ANDA filing, rather than receipt of tentative approval, as antitrust standing requirement); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (disagreeing with district court's conclusion that the plaintiff's "injury . . . was caused . . . by the lack of FDA approval of its generic version . . . and by the delay period prescribed by the Hatch-Waxman Amendments"). These cases, coupled with the Third Circuit's restriction of its *West Penn Power* holding to the factual scenario presented in that case, would seem to limit the applicability of *West Penn Power* to the Hatch-Waxman Amendments. Because the absence of tentative approval does not resolve the question of whether AstraZeneca engaged in anti-competitive conduct, the court will deny AstraZeneca's motion to dismiss on this ground.

2. *Tentative FDA Approval Within the Statutory Framework*

As an extension of its first argument, AstraZeneca further contends that the plaintiffs cannot establish antitrust standing because they are unable to prove that it directly delayed or inhibited the ability of generic manufacturers to obtain tentative FDA approval while the thirty month stay was in effect. (D.I. 29 at 4.) To this end, AstraZeneca cites case law showing that generic manufacturers can—and have—received tentative approval from the FDA during a thirty month stay. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902 (6th Cir. 2003) (noting that the FDA tentatively approved a generic company's ANDA during the thirty month stay and stipulated that the application would be "finally approved as soon as it was eligible"); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1369, 1372 n.2 (Fed. Cir. 2002) (observing that Andrx received tentative approval of its ANDA from the FDA pending the expiration of thirty

month stay).

In addition, AstraZeneca challenges the plaintiffs' assertion that patent infringement suits divert the generic manufacturer's resources from seeking FDA approval to the litigation by noting that Sandoz, Inc. continued to seek FDA approval during the course of the thirty month stay and the underlying patent infringement suit in this case. (D.I. 29 at 9.) Further, AstraZeneca argues that the plaintiffs' premise that generic manufacturers divert resources from obtaining FDA approval is unfounded because the 2003 Hatch-Waxman Amendments incentivize first-filer generic ANDA applicants to obtain approval despite a stay. (D.I. 29 at 8.). Specifically, the Amendments provide that if the ANDA first-filer fails to obtain tentative or final FDA approval within thirty months after filing, that the manufacturer forfeits its 180-day period of post-approval exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Based on the Amendments, AstraZeneca concludes that the thirty month stay triggered by its patent litigation would not—and did not in this case—cause the generic manufacturers to delay seeking approval due to pending litigation. (D.I. 29 at 9-10.)

While it is clear that Sandoz did indeed amend its ANDA during the patent infringement suit, AstraZeneca's assertion that its efforts at seeking FDA approval were not slowed due to the litigation and thirty month stay is not based on any factual findings. Though decided before the 2003 Amendments and inclusion of the forfeiture provision, two district courts in the Third Circuit have recognized that generic manufacturers may divert resources from FDA approval to patent litigation—resulting in a delay in receiving tentative approval. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (concluding that it is "reasonable to infer [that] generic companies direct[] resources away from FDA approval and toward the defense of the infringement actions and, furthermore, that this reallocation of funds

result[s] in a delay of FDA approval" even if the patent infringement suit is baseless); *Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (recognizing that where patent infringement suits are brought against Paragraph IV filers, "the generic companies are better served to direct their resources toward defense of the infringement action" than toward obtaining tentative FDA approval because "approval would be meaningless in the absence of a favorable court ruling"). As it is not clear at this stage whether Sandoz diverted resources in this case, or whether the FDA's grant of tentative approval was slowed as a result of diverted resources, the court cannot resolve this issue on a Rule 12(b)(6) motion. Thus, the court will deny this aspect of AstraZeneca's motion to dismiss.

B. The Plaintiffs' Claims Regarding the Entirety of AstraZeneca's Conduct

In addition to the above allegations, the plaintiffs argue that AstraZeneca violated Section 2 of the Sherman Act through unlawful anti-competitive conduct by: (1) engaging in *Walker Process* fraud before the PTO; (2) knowingly listing invalid patents in the Orange Book; and (3) initiating sham patent infringement litigation against generic manufacturers in order to trigger the mandatory thirty month stay on final FDA approval. (D.I. 17 at 2.) The plaintiffs allege that these combined actions precluded generic competitors from entering the market, delayed ANDA approvals, and resulted in the class paying "artificially high" prices. (D.I. 1 at 14.)

1. *The Plaintiffs' Walker Process Claim*

The plaintiffs allege that AstraZeneca: (1) defrauded the PTO into issuing the '161 and '154 patents through inequitable conduct inclusive of deliberate omissions and/or misrepresentations; and (2) that AstraZeneca listed invalid patents in the Orange Book. (D.I. 17 at 2.) Since the plaintiffs filed their initial Complaint, the Federal Circuit addressed the latter

claim, holding in *Metoprolol Succinate Patent Litig.* that the '154 patent is invalid.[3] 494 F.3d 1011, 1021 (Fed. Cir. 2007). The Federal Circuit, however, remanded the issue of AstraZeneca's inequitable conduct before the PTO to the district court. 494 F.3d at 1021.

The plaintiffs allege that AstraZeneca's omissions and misrepresentations before the PTO were deliberate and, thus, amounted to *Walker Process* fraud. (D.I. 17 at 2.) The Federal Circuit has characterized the *Walker Process* claim as "a more serious offense than inequitable conduct."[4] *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). That is, a *Walker Process* claim must be based on "independent and clear evidence of deceptive intent together with a clear showing of reliance" by the PTO. *Id.* A finding of *Walker Process* fraud can result in the offending party being subject to antitrust liability. *Id.* at 1070.

In *Metoprolol Succinate Patent Litig.*, the Federal Circuit determined that the district court incorrectly "equat[ed] the presence of an incentive [to deceive the PTO] with an intent to deceive," and concluded that the inequitable conduct issue must be remanded because a genuine

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[3] AstraZeneca did not appeal the district court's finding of invalidity with respect to its '161 patent, and has since requested that it be removed from the Orange Book (D.I. 25 at 8.)

[4] Inequitable conduct requires a finding of both materiality and intent. *See Nobelpharma.*, 141 F.3d at 1071. Specifically, the Federal Circuit has established that a party alleging inequitable conduct before the PTO by "failure to disclose" must provide clear and convincing evidence that: (1) the patentee withheld "prior art or information that is material;" (2) the patentee had "knowledge . . . of that prior art or information and of its materiality;" and (3) the "failure of the [patentee] to disclose the art or information resulted from an intent to mislead the PTO." *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). Indeed, a party can satisfy the inequitable conduct standard with evidence of "a lesser misrepresentation or an omission, such as omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner." *Id.* at 1070; *see also Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003) (noting that the current standard for materiality—"information is material to patentability when . . . it refutes, or is inconsistent with, a position the applicant takes . . . asserting an argument of patentability"—was "not intended to constitute a significant substantive break with the previous standard") (citing 57 Fed. Reg. 2021, 2023 (January 17, 1992)). The result of such a finding is the unenforceability of the patent and possible attorney fees. *See Nobelpharma*, 141 F.3d at 1070.

factual dispute remained. The plaintiffs' current claim is based on the same conduct and alleges that AstraZeneca deliberately failed to disclose information regarding the inventorship and ownership dispute to the PTO, because such information would have precluded patentability. (D.I. 1 at 11.) Given the foregoing, and in view of the Federal Circuit's conclusion with respect to the inequitable conduct issue in the underlying patent litigation, the court will deny AstraZeneca's motion to dismiss the *Walker Process* claim.

2. *The Plaintiffs' Sham Patent Infringement Litigation Claim*

The plaintiffs allege that AstraZeneca's violation of Section 2 of the Sherman Act encompassed filing sham patent infringement litigation against generic manufacturers in order to maintain their monopoly of the metoprolol succinate-based prescription drug market. (D.I. 1 at 2.) The Supreme Court articulated the standard for determining whether patent litigation is a sham filing in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993). Specifically, the Court held that a plaintiff alleging sham filing must prove that the suit was: (1) objectively baseless "in the sense that no reasonable litigant could realistically expect success on the merits;" and (2) "motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy." *Professional Real Estate Investors, Inc.*, 508 U.S. at 60-61; *Nobelpharma*, 141 F.3d at 1071. The latter element requires examination of the litigant's subjective intent and directs that the court should "focus on whether the baseless 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." *Nobelpharma*, 141 F.3d at 1071 (quoting *Professional Real Estate Investors*, 508 U.S. at 60-61). Before beginning to assess the patentee's subjective intent, however, the court must first conclude that the suit was objectively baseless to the extent

that the litigant could not have believed that the "suit [was] reasonably calculated to elicit a favorable outcome." *Id.* If the patentee calculated a favorable outcome, the "antitrust claim premised on the sham exception must fail." *Id.* (quoting *Professional Real Estate Investors*, 508 U.S. at 60-61).

The plaintiffs' allegations with respect to this claim rest on their conclusion that AstraZeneca brought patent infringement suits against generic manufacturer ANDA filers despite knowing that their metoprolol succinate patents were invalid. (D.I. 1 at 13.) As previously noted, in *Metoprolol Succinate Patent Litig.*, the Federal Circuit held that the '154 patent was invalid for obvious-type double patenting and the district court held that the '161 patent was invalid. The court also concluded that a genuine factual dispute exists as to whether AstraZeneca intended to deceive the PTO by not disclosing information as to the ownership and inventorship dispute. 494 F.3d at 1020-21. If the plaintiffs can demonstrate that AstraZeneca deliberately failed to disclose relevant information to the PTO and was aware that its metoprolol succinate patents were invalid, its patent infringement suits against generic manufacturers may indeed be "objectively baseless." The court, however, cannot make such a finding at the motion to dismiss stage, because it is fact intensive. Accordingly, the court concludes that the plaintiffs have adequately stated a claim and that the plaintiffs' allegations are sufficient to survive a Rule 12(b)(6) motion.

VI. CONCLUSION

For the foregoing reasons the court will deny AstraZeneca's motion to dismiss. Given this ruling, the court will deny as moot AstraZeneca's request for the court to decline to exercise supplemental jurisdiction over the plaintiffs' state law claims.

Dated: April 13, 2010

CHIEF, UNITED STATES DISTRICT COURT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE DIRECT PURCHASER ANTITRUST LITIGATION	)	Civil Action No. 06-52 (GMS)
IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	)	Civil Action No. 06-71 (GMS)

ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. AstraZeneca's Motion to Dismiss for Failure to State a Claim (06-52 D.I. 17; 06-71 D.I. 24) is DENIED.

2. AstraZeneca's request for the court to decline to exercise supplemental jurisdiction over the plaintiffs' state law claims (06-52 D.I. 17; 06-71 D.I. 24) is DENIED AS MOOT.

Dated: April 13, 2010

CHIEF, UNITED STATES DISTRICT COURT JUDGE