UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION	
IN RE: DDAVP INDIRECT PURCHASER ANTITRUST LITIGATION	05 Cv. 2237 (CLB) ***Memorandum and Order***
THIS DOCUMENT RELATES TO: ALL ACTIONS	

Brieant, J.

Before the Court in this consolidated anti-trust class action litigation, are two motions to dismiss the Direct and Indirect Purchasers' separate class action Complaints. By joint motion filed May 1, 2006 (Doc. No. 32), Defendants Ferring B.V. and Ferring Pharmaceuticals ("Ferring") and Aventis Pharmaceuticals move to dismiss the Complaints for failure to state a claim. By motion also filed May 1, 2006 (Doc. No. 35), Defendant Aventis separately moves for the same relief. Opposition papers were filed separately by the Direct and Indirect Purchasers on June 16, 2006 and reply papers were filed July 17, 2006. Oral argument on the motions was heard on July 21, 2006. No motion for class certification has been filed.

This case is presented as a nationwide class action, alleging violations of federal and state antitrust law, as well as unfair and deceptive trade practices. The Direct and Indirect Purchaser Plaintiffs filed their respective class action Complaints against Defendants after this Court held

that a patent held by Ferring for desmopressin acetate ("DDAVP") tablets was unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO").[1]

The following facts are either undisputed or presumed true for purposes of these motions only. Plaintiffs' claims arise from the manufacture and marketing of DDAVP, an antidiuretic, and its generic equivalents, called desmopressin acetate. Ferring is a privately held company under the laws of the Netherlands, which developed the drug and manufactured it. Ferring is the owner and assignee of U.S. Patent No. 5,407,398 entitled "DDAVP Antidiuretic and Method Therefor" ("'398 patent"). The '398 patent issued on September 10, 1991. Aventis is a Delaware Corporation licensed to market and sell the invention of the '398 patent in the United States. Aventis is also the holder of an approved new drug application ("NDA"), No. 019-955, for desmopressin acetate tablets which are marketed in the United States under the product name DDAVP®.

Plaintiffs allege that Defendants Ferring and Aventis unlawfully maintained a monopoly in the relevant market by: 1) procuring the '398 patent through fraud and/or inequitable conduct before the PTO; 2) by improperly listing the patent in the United States Food and Drug Administration's ("FDA") publication of approved "Reference Listed Drugs" called the *Orange*

[1] The Federal Circuit affirmed. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1192 (Fed. Cir. 2006) ("*Ferring I*"). A motion for rehearing or rehearing *en banc* was denied. *See Ferring B.V. v. Barr Labs.*, Inc., 2006 U.S. App. LEXIS 10765 (Fed. Cir. 2006); *see also Ferring B.V. v. Barr Labs., Inc.*, 2006 U.S. App. LEXIS 10811 (Fed. Cir. 2006). A Petition for a Writ of Certiorari was filed with the Supreme Court on September 11, 2006, an extension having been granted by Chief Justice Roberts, and certiorari was denied by the United States Supreme Court on October 30, 2006.

Book, so as to be able to assert patent infringement claims against potential competitors; 3) by instituting and prosecuting a "sham" patent infringement litigation against Barr and Teva in order to delay FDA approval of and market entry of generic DDAVP tablets; and 4) by filing a "sham" citizen petition with the FDA in an effort to further delay final FDA approval of generic desmopressin acetate tablets.

Plaintiffs allege that Defendants unreasonably restrained, suppressed and eliminated competition in the market for DDAVP and its generic equivalents, by illegally obtaining and maintaining a monopoly. The Complaints are substantially similar, but the Indirect Purchaser Plaintiffs also make claims and seek damages under the antitrust and consumer protection statutes of 23 different states. All Plaintiffs allege that as a result of Defendants' conduct, Plaintiffs and proposed Class Members paid up to hundreds of millions of dollars more for DDAVP at "supra-competitive" prices, than they would have if competing and/or generic versions of the drug had been available. Plaintiffs allege that Defendants' purpose in proceeding with earlier patent infringement litigation (in this Court) was in order to invoke the thirty-month Hatch-Waxman stay, despite knowledge that the '398 patent had been procured by fraud and was unenforceable.

As just noted, the Indirect Purchasers' Complaint includes state claims brought under the antitrust and consumer protection statutes of the Indirect Purchaser States based on illegal monopolization of the DDAVP market. Indirect Purchasers seek disgorgement of Defendants' profits from sales of DDAVP to the extent that Defendants have been unjustly enriched.

The Direct Purchaser Plaintiffs propose the following class:

> All persons and entities in the United States that purchased DDAVP in tablet form directly from one or more of the Defendants at any time from February 18, 2001 through the date on which the anti-competitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants, their parents, subsidiaries and affiliates, employees, and federal government entities.

Direct Purchasers' Consolidated Amended Class Action Complaint ("Direct Purchaser Complaint") at ¶15.

The Indirect Purchasers or Third-Party Plaintiffs propose the following class:

> All persons or entities throughout the United States and its territories who purchased and/or paid for DDAVP or generic versions of DDAVP for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class") during the period from February 25, 2001, through the date on which the anticompetitive effects of Defendants' conduct cease ("the Class Period"). For purposes of the Class definition, persons and entities "purchased" DDAVP if they paid some or all of the purchase price.

Indirect Purchasers' Consolidated Class Action Complaint ("Indirect Purchaser Complaint") at ¶124.

Defendants Ferring and Aventis jointly move to dismiss on the bases that: 1) Plaintiffs lack standing to assert the anti-trust violations claimed; 2) that Indirect Purchaser Plaintiffs' state-law claims are preempted by federal patent law; and 3) that the state law claims suffer from other defects, meriting dismissal. Defendant Aventis also moves separately to dismiss the Complaints on the basis that Plaintiffs have not sufficiently alleged misconduct by Aventis in relation to the antitrust allegations.

Defendants' Joint Motion to Dismiss the Complaint for Failure to State a Claim

Generally, patents can be enforced without violating the Sherman Act and patents are intended in part to keep competition off of the market for a designated period of time. Enforcing a patent to stifle competition could only be actionable if there were a wilful and knowing use of an invalid patent, which violated antitrust laws. Defendants argue that this antitrust suit is an indirect and impermissible attempt to collaterally attack the validity of the patent, while Plaintiffs respond that it is rather a garden variety antitrust claim of monopolization.

Defendants argue that Plaintiffs lack standing to assert the federal and state law claims because they are purchasers and not competitors or would-be competitors of Ferring, and because neither Ferring nor Aventis has ever threatened to enforce the patents against Plaintiff purchasers. They argue that the Court should find that the purchaser-Plaintiffs have no standing, and that "it is entirely reasonable to limit antitrust standing, ... to only those entities directly threatened with the enforcement of a patent." *Reply at 2.*[2]

It is well established that conduct in obtaining and enforcing a patent is immune from antitrust allegations, as a form of petitioning protected by the First Amendment. In *Walker Process*, the Supreme Court addressed the issue of "whether the maintenance and enforcement of

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[2] The Court notes the unusual circumstance in this case, that none of the generic manufacturers, originally sued by Ferring for infringement of the '398 patent, asserted antitrust counterclaims. *See April 15, 2005 Transcript at 41-42.* "An antitrust claim premised on stripping a patentee of its immunity under the antitrust laws, is typically raised as a counterclaim by a defendant in a patent infringement suit." *Nobelpharma Ab v. Implant Innovations*, 141 F.3d 1059, 1067 (Fed. Cir. 1998).

a patent obtained by fraud on the Patent Office may be the basis of an action under §2 of the Sherman Act, and therefore subject to a treble damage claim by an injured party under §4 of the Clayton Act," and held that the 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 case are present. *See Walker Process Equip., Inc., v. Food Mach. & Chem Corp.,* 382 U.S. 172, 173 (1965).

The Court of Appeals for the Federal Circuit has held:

> A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process*, or (2) that the infringement suit was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor," *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (holding that *Noerr* "governs the approach of citizens or groups of them . . . to courts, the third branch of Government"). *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 n.6, (1993) (PRE) (declining to decide "whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations").

Nobelpharma, 141 F.3d at 1068 (some citations omitted). That Court has also set forth the following with regard to fraud:

> Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). In *Nobelpharma*, the Court explained:

> In *Walker Process*, the Supreme Court held that in order "to strip [a patentee] of its exemption from the antitrust laws" because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee "obtained the patent by knowingly and willfully misrepresenting facts [] to the [PTO]." 382 U.S. at 177. The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit.

Nobelpharma, 141 F.3d at 1068-1069.

As held in *Walker Process*, "[i]t must be remembered that we deal only with a special class of patents, i.e., those procured by intentional fraud." *Walker Process,* 382 U.S. at 172. A finding of *Walker Process* fraud "must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1071.

The '398 patent now stands as unenforceable for inequitable conduct, but that misconduct has not been shown to rise to the level of fraud, so as to lead to invalidity.

> Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword. ...[T]he remedies for inequitable conduct, while serious enough, only include unenforceability of the affected patent or patents and possible attorney fees. See 35 U.S.C. §§ 282, 285 (1994). Simply put, Walker Process fraud is a more serious offense than inequitable conduct.

Id. at 1070.

Fraud "must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." *Id at 1071.* In contrast, "a conclusion of inequitable conduct may be based on 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.* Fraud requires a higher threshold of both intent and materiality than does a finding of inequitable conduct and must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance. *Id. at 1070-1071.*

The Court's findings in the prior litigation of inequitable conduct and unenforceability do not arise to the *Walker Process* requirements of fraud and invalidity. At the very least, an additional component of scienter must be shown to render actions fraudulent that might otherwise be found merely inequitable. This Court did not determine that fraud was perpetrated on the PTO, nor that but for the omissions found, the patent would not have issued. Nor could it have done so on the complete record presented in *Ferring I.*[3]

Fraud must be pleaded with particularly, under Rule 9(b) of the Federal Rules of Civil Procedure ("FRCP"). Plaintiffs did not do so, and cannot do so, consistently with the record in *Ferring I.* For this reason alone, granting the motions to dismiss is appropriate.

The Court now considers in the interest of completeness whether these plaintiffs are "proper" antitrust plaintiffs, having standing to state a *Walker Process* claim.

> The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a

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[3] In her dissent in *Ferring I*, Judge Newman noted that the record "does not indicate sufficient culpability to require a finding of intent to deceive." *Id* at p. 1205.

consequence of a superior product, business acumen, or historic accident.

United States v. Grinnell Corp., 384 U.S. 563, 570-571 (U.S. 1966).

Our Court of Appeals has held:

> To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact.

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.), 2006 U.S. App. LEXIS 22154, *93 (2d Cir. 2006)(citations and quotations omitted).

The harm alleged by Plaintiffs in this case is in a monopoly, which kept generic versions of DDAVP off of the market and resulted in overcharges to Plaintiffs. Plaintiffs have not alleged and cannot, that they did compete or would have competed with Defendants, nor that have they been sued or threatened with an infringement lawsuit by Defendants. Rather, they allege that they have paid higher prices for desmopressin acetate by virtue of Defendant's misconduct before the PTO and subsequent actions, which prevented the lower prices, which would have ensued from generic competition.

In *Associated General*, the Supreme Court discussed the standards for establishing standing to bring a Section 2 Sherman Act claim under Section 4 of the Clayton Act. In regard to "antitrust standing," it stated:

> The label "antitrust standing" has traditionally been applied to some of the elements of this inquiry. As commentators have observed, the focus of the doctrine of "antitrust standing" is somewhat different from that of standing as a constitutional doctrine. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action.

Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 535 n.31 (U.S. 1983)(citations omitted). In a subsequent case, the Supreme Court noted:

> A showing of antitrust injury is necessary, but not always sufficient, to establish standing under § 4, because a party may have suffered antitrust injury but may not be a proper plaintiff under § 4 for other reasons. Thus, in *Associated General Contractors* we considered other factors in addition to antitrust injury to determine whether the petitioner was a proper plaintiff under § 4.

Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 110 (U.S. 1986)(citations omitted). Our Court of Appeals summarized the factors of *Associated General* as:

> (1) the causal connection between the alleged antitrust violation and the harm to the plaintiff; (2) the existence of an improper motive; (3) whether the injury was of a type that Congress sought to redress with the antitrust laws; (4) the directness of the connection between the injury and alleged restraint in the relevant market; (5) the speculative nature of the damages; and (6) the risk of duplicative recoveries or complex apportionment of damages.

Balaklaw v. Lovell, 14 F.3d 793, 798 (2d Cir. 1994). The Court explained:

> Over time, courts have developed a two-pronged analysis to determine whether a plaintiff has antitrust standing. As a necessary first step, courts must determine whether the plaintiff suffered an antitrust injury. If the answer to that question is yes, they must then determine whether any of the other factors, largely relating to the directness and identifiability of the plaintiff's injury, prevent the plaintiff from being an efficient enforcer of the antitrust laws.

Id.

Although several district courts have addressed the question, there is no precedent binding upon this Court with regard to the specific issue of whether purchaser plaintiffs like

those in this case have standing to assert a *Walker Process* claim. Plaintiffs rely on the holding of *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.)("Remeron")*, 335 F. Supp. 2d 522 (D.N.J. 2004) (Hochbert, J.), in which the United States District Court for the District of New Jersey was faced with a case similar to the case at bar. Direct purchasers of a drug sued the manufacturer under the Sherman and Clayton Acts, claiming that fraud was perpetrated on the PTO by the manufacturer, which then monopolized the market for that drug. The *Remeron* Court concluded that a plaintiff does not have standing to state a *Walker Process* claim unless the defendant had sought to enforce the patent against that plaintiff, or if the plaintiff had a reasonable basis for fearing such an attempted enforcement. *See Id.* at 529. The Court reasoned:

> Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.

Id.

To the same effect, *see In re Ciproflaxin Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005)(Trager, J.) ("*Cipro*"), in which drug manufacturers' agreements settling patent infringement litigation were alleged to prevent competition for an antibiotic in violation of antitrust laws. It was held that non-infringing consumers of patented products have no cause of action to invalidate a patent, and *Walker Process* claims were preempted because they arise out of, and rest on patent law. *See Contra*: *Molecular Diagnostics Labs. v. Hoffmann-La Roche, Inc.*, 402 F. Supp. 2d 276, 280 (D.D.C. 2005)(Kennedy, J.), holding that customer plaintiffs have standing to litigate a *Walker Process* claim.

This Court concludes that the Courts in *Ciproflaxen* and *Remeron* have the better side of the argument. Plaintiffs in *Walker Process* were competitors, and not purchasers. *See Indium Corp. of America v. Semi-Alloys, Inc.*, 566 F. Supp. 1344 (N.D.N.Y. 1983) (*Walker Process* claim dismissed for failure to adequately allege any set of facts that would amount to enforcement, attempted enforcement, or threatened enforcement of defendant's patents vis-a-vis the plaintiff). As herein earlier noted and as noted by Judge McCurn in *Indium Corp.*, the Supreme Court stated explicitly in *Walker Process*: "We have concluded that the *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 case are present." *Indium Corp.*, 566 F.Supp at 1353 (emphasis added), *citing Walker Process.*, 382 U.S. at 174.

In this case, there has been no enforcement of the patent against the customer Plaintiffs. For want of antitrust standing, as an alternative ground, the motions shall be granted.

Plaintiffs' Sham Litigation Claims

Plaintiffs argue, and Defendants deny that even if the Court should find that they lack standing to pursue *Walker Process* claims, they may nonetheless pursue a "sham litigation" claim. Plaintiffs argue that Defendants conducted sham litigation by the filing of the original infringement action against Barr Laboratories, (*Ferring I*) by listing the patent in the Orange Book of patents, and by the filing of a citizen's petition, asking that the FDA require Barr to submit additional tests of bio-equivalence, which Plaintiffs argue was done for delay.

"Under [*Professional Real Estate Investors v. Columbia Pictures Industries*, 508 U.S. 49 (1993)], a sham suit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is objectively baseless. Accordingly, if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial." *Nobelpharma*, 141 F.3d at 1072. "In contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue." *Id.*

Clearly Aventis had the right to bring suit, since it was not privy to the inequitable conduct. The bringing of the suit by Ferring and Aventis was not in subjective bad faith, but rather a standard response to Hatch-Waxman. Every losing litigant in the federal courts does not become a sham litigant merely by losing their case.

The same is true of the citizen petition, which is First Amendment protected activity even though delay of Barr's access to the market was foreseeable.

These claims are also dismissed.

Aventis' Motion to Dismiss the Complaints

Aventis also moves separately (Doc. No. 35) to dismiss the Complaints, arguing that Plaintiffs have not adequately alleged any knowing participation by Aventis in the alleged fraud on the PTO and other activities. Rule 9 of the FRCP requires that: "[i]n 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." *FRCP Rule 9(b).* On a motion to dismiss for failure to plead fraud with sufficient particularity, Plaintiffs are bound by the standards of Rule 9(b), but are entitled to reasonable inferences from the facts alleged.

As earlier mentioned, Aventis is the exclusive licensee of the patent for the sale of DDAVP tablets in the United States. Plaintiffs alleged that for over thirty years, Aventis has had a "close working relationship with Ferring," and note Ferring's description of its "key commercial partnership" with Aventis. *Direct Purchaser Complaint at ¶42.* They argue that in the process of applying for a New Drug Application from the FDA (held by Aventis, and not Ferring), between 1989 and 1991, Aventis had to make a certification of whether there was a patent that claims the product, or a patent on which a reasonable patent infringement suit could be brought. Plaintiffs contend that between 1989 and 1991, while Ferring was submitting declarations with omissions, that Aventis had to be aware of those declarations and that Aventis had to have knowledge of the status of the patent because the NDA would had to have been amended once the patent was granted. No such *res ipsa* is apparent to this Court. Plaintiffs also contend that Aventis had performed its own study, and therefore "must have known" that the Citizen's Petition filed by Ferring requesting the FDA to require further bioequivalence testing was baseless. This does not, in logic follow, nor is there reason to believe that having made internal studies of its own, a citizen is blocked from petitioning for studies by the FDA.

To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman

> Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. *See Twombly*, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim showing that the pleader is entitled to relief' that Rule 8(a) requires."). However, bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6).

In re Tamoxifen Citrate Antitrust Litig., supra at *38-39 (some citations and quotations omitted).

Plaintiffs have failed to allege and plead sufficient facts indicating that Aventis participated in the prosecution of the '398 Patent, or that Aventis knew or subsequently learned of Ferring's inequitable conduct to obtain the '398 Patent. That Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason. That Aventis agreed with Ferring to participate in a scheme to exploit an unenforceable patent or that Aventis shared Ferring's allegedly anti-competitive intent also makes no sense. The pleadings against Aventis are threadbare, and as understandably argued by Aventis, implicate the traditional concerns that pleadings must provide a defendant with notice of a plaintiff's claim sufficient to answer and defend and of avoiding harassment and harm to a defendant's good will. Plaintiffs have failed to meet their burden of alleging sufficiently that Aventis had knowledge of an alleged fraud upon the PTO by Ferring.

Conclusions

The motions are granted. All claims pleaded under federal law are dismissed. The claims arising under state law are dismissed without prejudice. The Clerk shall file a final judgment.

SO ORDERED.

Dated: White Plains, New York
November 2, 2006

Charles L. Brieant, U.S.D.J.