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

CHEMI SPA	:	CIVIL ACTION
	:	
v.	:	
	:	
GLAXOSMITHKLINE	:	NO. 04-4545

MEMORANDUM

Bartle, J. February 8, 2005

This is an antitrust action for unlawful monopolization pursuant to § 2 of the Sherman Act and § 4 of the Clayton Act. 15 U.S.C. §§ 2, 15. Before the court is the motion of defendant GlaxoSmithKline ("GSK") for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure on the grounds that this action is barred by the applicable statute of limitations and that plaintiff does not have standing to bring this lawsuit.

I.

In ruling on a motion for judgment on the pleadings, the well-pleaded facts of the complaint will be taken as true. In addition, we may consider matters of public record, and authentic documents upon which the complaint is based if attached to the complaint or as an exhibit to the motion. Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1391 (3d Cir. 1994); Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196-97 (3d Cir. 1993) (citations omitted), cert. denied, 510 U.S. 1042 (1994). A motion for judgment on the

pleadings under Rule 12(c) is judged under the same standards as a motion to dismiss pursuant to Rule 12(b)(6). See Jubilee v. Horn, 975 F. Supp. 761, 763 (E.D. Pa. 1997), aff'd 151 F.3d 1025 (3d Cir. 1998).

II.

On September 27, 2004, plaintiff Chemi SpA ("Chemi") sued GSK for unlawful monopolization of the market for nabumetone, an anti-inflammatory drug. According to the complaint, Chemi, an Italian corporation with its headquarters in Italy, is the largest manufacturer of nabumetone in the world. GSK is a pharmaceutical manufacturer with headquarters here in Philadelphia.

On December 13, 1983, the Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,420,639 for nabumetone, which was ultimately assigned to GSK. In December, 1991, defendant[1] received final marketing approval from the Food and Drug Administration ("FDA"). It began marketing the drug in 1992 and in that year listed the nabumetone patent in the Orange Book of the FDA. Under the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), a patent holder which identifies its patent in this way receives certain benefits. See

1. The PTO issued patent No. 4,420,639 to Anthony W. Lake and Carl J. Rose, who assigned the patent to Beecham Group, P.L.C., then the parent company of SmithKline Beecham P.L.C. ("SKB") Compl. at ¶ 11. Defendant GSK was formed in December, 2000 as the result of a merger between Glaxo Wellcome and SKB. For present purposes, we will use "GSK" and "the defendant" to include GSK's predecessors in interest.

21 U.S.C. § 355. When an entity other than a patent holder of the drug listed in the Orange book seeks FDA approval of a new drug that is for the same use or has a reference to the listed drug, that entity must file with the FDA "an abbreviated application for the approval of a new drug." 21 U.S.C. § 355(j)(1). The abbreviated new drug application ("ANDA") must contain a "certification, ... with respect to each patent [listed in the Orange Book] ... that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Thereafter, the patent holder may file suit to enforce its patent against the entity which filed an ANDA. Upon the filing of such a suit, the patent holder obtains an automatic injunction lasting thirty months barring the FDA from granting final approval of the alleged infringer's ANDA. Id.

Chemi avers that in 1996 it decided that it could manufacture nabumetone on a commercial scale. It approached Teva Pharmaceuticals USA ("Teva") and Eon Labs Manufacturing, Inc. ("Eon") to determine its potential demand and then to market it. Compl. at ¶ 15. It provided Teva with batches of test nabumetone. Id. On December 23, 1996, Chemi filed a Drug Master File ("DMF") with the FDA, in which it specified its production data and set forth other required information for FDA approval of its nabumetone product. It listed Teva and Eon as companies authorized to reference its application in any subsequent filings

those companies might make with the FDA. Thereafter, Teva and Eon filed with the FDA their own ANDA's for nabumetone. These companies, and other manufacturers who also intended to market nabumetone, certified in their applications with the FDA that defendant's nabumetone patent was invalid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

In October and December, 1997, defendant filed patent infringement actions against Teva and Eon in the United States District Court for the District of Massachusetts. Compl. at ¶ 19. The filing of these actions resulted in an automatic thirty-month stay of the FDA's authority to grant final approval to the pending applications for nabumetone. As a result of the stay, Teva and Eon could not purchase and sell Chemi's nabumetone. On August 14, 2001, Judge Reginald C. Lindsay, following a trial in the District of Massachusetts, held that defendant had procured the nabumetone patent through fraudulent misrepresentations to the PTO and that the patent was thus unenforceable.[2] See In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001), aff'd, 45 Fed. Appx. 915 (Fed. Cir. 2002). The district court found that defendant had procured the nabumetone patent by knowingly misrepresenting the prior art and the research conducted by its scientists.

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2. The Court of Appeals for the Federal Circuit affirmed the district court's determination that claims 2 and 4 of GSK's patent were invalid for anticipation. SmithKline Beecham Corp. v. Copley Pharm., Inc., 45 Fed. Appx. 915, 917 (Fed. Cir. 2002).

After GSK's nabumetone patent was found invalid, Copley Pharmaceuticals ("Copley"), another company that manufactured generic nabumetone products, and Teva filed antitrust suits against GSK in the District of Massachusetts. In addition, various direct purchasers and end-payors filed individual class actions in both the District of Massachusetts and the Eastern District of Pennsylvania. These actions were eventually consolidated before Judge William G. Young in the District of Massachusetts.[3] In re Relafen Antitrust Litig., CIV.A. No. 01-12239 (D. Mass.). The parties have entered into settlement agreements, which we are told are currently awaiting judicial approval.[4]

Similar to other drug companies' allegations in the actions before Judge Young, Chemi's complaint in the instant action alleges that defendant undertook to obtain the patent unlawfully for the purpose of maintaining its monopoly on the sale of nabumetone. Chemi contends that GSK filed patent infringement actions that were motivated by a desire to trigger

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3. On November 24, 2004, we denied the motion of GSK to transfer this action to the United States District Court for the District of Massachusetts.

4. Judge Young issued four published opinions in these actions. One decision determined the preclusive effect of the findings of Judge Lindsay on the subsequent antitrust actions. See In re Relafen Antitrust Litig., 286 F. Supp. 2d 56 (D. Mass. 2003). The remaining three decisions involved issues related to class certification, class representation, and the prospective application of state statutes. See In re Relafen Antitrust Litig., 2004 WL 2441256 (D. Mass. Sept. 2, 2004); 221 F.R.D. 260 (D. Mass. 2004); 218 F.R.D. 337 (D. Mass. 2003).

regulatory delays by the FDA and to frustrate Chemi's sales of nabumetone in the United States.

III.

We turn first to GSK's contention that Chemi's claims are barred by the four-year statute of limitations for an antitrust claim. 15 U.S.C. § 15(b).

Section 15(b) of the Clayton Act requires that suits to recover damages for violations of the federal antitrust laws be "commenced within four years after the cause of action accrued." A cause of action under the antitrust laws "accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business." Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 338 (1971). The Supreme Court has held that the limitations period does not begin to run until the damages are inflicted and ascertainable. Id. at 338-40. In addition, the Court has "rejected the argument that, in the context of a defendant's continuing violation of the Sherman Act, the statute of limitations runs from the violation's earliest impact on a plaintiff." In re Lower Lake Erie Antitrust Litig., 998 F.2d 1144, 1171 (3d Cir. 1993) (citing Hanover Shoe, Inc. v. United Shoe Mach. Corp., 392 U.S. 481, 502 n.15 (1968)). Instead, "[u]nder the continuing violations theory, ... each time a plaintiff is injured by an act of the Defendants, a cause of action accrues and the statute of limitations runs from the commission of the act, allowing Plaintiff to recover for the damages from that act." In re K-Dur Antitrust Litig., 338 F.

Supp. 2d 517, 551 (D. N.J. 2004) (citing Zenith Radio Corp., 401 U.S. at 328).

As our Court of Appeals has recognized, statute of limitations issues "present mixed questions of law and fact." In re Lower Lake Erie, 998 F.2d at 1171. In order to be entitled to a judgment as a matter of law on the ground that the action is time barred, GSK must "point to undisputed facts in the record which demonstrate conclusively that [Chemi] had notice of [its] claims, and, that, had it exercised reasonable diligence, it would have discovered adequate grounds for filing this antitrust lawsuit during the limitations period." Morton's Market, Inc. v. Gustafson's Dairy, Inc. 198 F.3d 823, 832 (11th Cir. 2000) (citations omitted). "It is not enough ... to point to facts which **might** have caused a plaintiff to inquire, or **could** have led to evidence supporting his claim." Id. at 833 (emphasis in original) (citations omitted). Moreover, our Court of Appeals has cautioned that generally the statute of limitations defense cannot be decided in the context of a Rule 12 motion, except in situations where "the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading." See Oshiver, 38 F.3d at 1385 n.1 (citations omitted)

GSK contends that Chemi's claims accrued when GSK filed its sham patent infringement actions against Copley and Teva in

October and November, 1997,[5] more than four years before the filing of this lawsuit on September 27, 2004. It also argues in the alternative that the statute began to run no later than August 17, 2000, the date on which the thirty-month stay on the FDA final approval of the ANDA's for nabumetone expired. According to GSK, Chemi should have assumed that GSK's patent was invalid and that GSK was conducting the infringement action in bad faith prior to the court's judgment of invalidity.

Chemi counters that its cause of action did not accrue until August, 2001 when GSK's nabumetone patent was held invalid and unenforceable by the District Court in Massachusetts. See In re '639 Patent Litig., 154 F. Supp. 2d 157, 185-86 (D. Mass. 2001). According to Chemi, it was not until that time that it knew or through the exercise of reasonable diligence could have known of GSK's fraudulent conduct to frustrate Chemi's efforts to market nabumetone. See Compl. at ¶ 31.

In Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49 (1993), the Supreme Court explained that an antitrust action based on a prior sham litigation is

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5. Chemi, in its compliant, alleges that GSK filed its infringement actions against Teva and Eon in October and December, 1997. Compl. at ¶ 19. However, GSK states that it filed the first infringement suit against Copley in October, 1997. It then filed a second suit against Teva in November, 1997. In the course of the litigation, Teva acquired Copley, and their applications for generic nabumetone were merged. GSK filed its third infringement suit against Eon in February, 1998. See Def.'s Mot. for J. on the Pleadings at 5 n.4. For the reasons set forth in this memorandum, the discrepancies over when GSK filed suits against Teva and Eon are irrelevant.

analogous to the common law tort of malicious prosecution. Id. at 63. Such claims do not accrue for statute of limitations purposes until the underlying litigation has terminated. See RESTATEMENT (SECOND) TORTS, § 653 (malicious prosecution). Similarly, an antitrust claim based on baseless litigation requires proof that the litigation was unsuccessful, which can only be determined upon the termination of the initial action. See Mark D. Janis and Mark A. Lemly, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, § 11.1 (2005 supp.). Thus, Chemi's antitrust claim based on GSK's bogus lawsuit could not have accrued at least until Judge Lindsay issued his ruling on August 14, 2001. We cannot accept GSK's argument that Chemi should have been clairvoyant at an earlier point in time about the invalidity of GSK's patent and its fraudulent misrepresentations.

Because GSK's nabumetone patent was held invalid less than four years before this lawsuit was instituted, it is timely under § 4 of the Clayton Act. 15 U.S.C. § 15.

IV.

GSK also moves for judgment on the pleadings on the ground that Chemi lacks standing to bring this antitrust action. Section 2 of the Sherman Act prohibits monopolization, attempts to monopolize and conspiracies to monopolize any part of interstate trade or commerce. 15 U.S.C. § 2. Section 4 of the Clayton Act provides a treble-damages remedy to "any person who

shall be injured in his business or property by reason of anything forbidden in the antitrust laws." 15 U.S.C. § 15(a).

The Supreme Court has noted that the "lack of restrictive language in § 4 reflects Congress' 'expansive remedial purpose' in enacting ... a private enforcement mechanism that would deter [antitrust] violators ... and would provide ample compensation to victims of antitrust violations." Blue Shield of Va. v. McCready, 457 U.S. 465, 472 (1982) (citations omitted). The Court recognized that standing under this statute is not confined "to consumers, or to purchasers, or to competitors, or to sellers. ... The Act is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated." Id. (citations and internal quotations omitted). Nevertheless, "it is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property." Id. at 477. The antitrust standing analysis invoked by the Supreme Court has similarities to the common law test for determining proximate cause. It requires that a plaintiff asserting an antitrust claim prove: (1) "injury of the type the antitrust laws were intended to prevent," and (2) injury that "flows from that which makes the defendants' acts unlawful." Int'l Raw Materials, Ltd. v. Stauffer, 978 F.2d 1318, 1327-28 (3d Cir. 1992) (citing Brunswick Corp. v. Pueblo

Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)); see also Blue Shield of Va., 457 U.S. at 478.

Our Court of Appeals has set forth the following five-factor test to determine antitrust standing:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie, 998 F.2d at 1165-66; see also Assoc. Gen. Contractors of Cal., Inc., 459 U.S. 519, 538 (1983). This "standing analysis is essentially a balancing test comprised of many constant and variable factors and that there is no talismanic test capable of resolving all § 4 standing problems." Bravman v. Basset Furniture Indus., Inc., 552 F.2d 90, 99 (3d Cir. 1977).

Chemi alleges in its complaint that GSK's antitrust violation is directly connected to Chemi's injury. Specifically, it contends that GSK's anticompetitive action in filing a baseless patent infringement suit was intended to prohibit others such as Chemi from selling nabumetone in the United States.

Next, we must determine whether Chemi's alleged injury, as set forth in the complaint, "is of the type for which the

antitrust laws were intended to provide redress." In re Lower Lake Erie, 998 F.2d at 1165. The complaint states that plaintiff was "injured in its business and property" because of GSK's exclusionary conduct. Compl. at ¶¶ 38, 39. GSK's monopoly, extended through its sham nabumetone patent infringement suit, allegedly prevented competition and thereby thwarted the Act's "central interest in protecting the economic freedom of participants in the relevant market." In re Lower Lake Erie, 998 F.2d at 1168 (citing Blue Shield of Va., 457 U.S. at 483). In our view the antitrust laws are intended to provide a remedy to the manufacturers and sellers of a product where the monopoly was specifically designed to prevent the sale of that very product in the marketplace.

With respect to the third and fourth standing criteria enumerated In re Lower Lake Erie, GSK argues that Chemi, as a supplier of nabumetone to GSK's competitors, Teva and Eon, is not a direct market participant and therefore "cannot seek recovery under the antitrust laws because [its] injuries are too secondary and indirect to be considered 'antitrust injuries.'" Sefcz v. Jewel Food Stores, 67 F.3d 591, 597 (7th Cir. 1995).

GSK relies on SAS of Puerto Rico, Inc. v. Puerto Rico Tel. Co., 48 F.3d 39, 44 (1st Cir. 1995). In that antitrust action, plaintiff, a seller of pay telephones, alleged a conspiracy to monopolize the long distance telephone service market. Plaintiff contended that its sales of telephones were adversely affected when a potential customer joined a conspiracy

to exclude long distance carriers from the market. The court reasoned, in affirming the district court's grant of defendant's motion to dismiss, that plaintiff was only "coincidentally involved," and not the plaintiff best situated to challenge defendant's alleged antitrust violation. Id. at 44. The plaintiff sold telephones, an ancillary product in this market, and not long distance services, the primary product excluded from this market.

GSK also cites International Raw Materials v. Stauffer Chemical Co., 978 F.2d 1318, in which our Court of Appeals affirmed the grant of summary judgment in an antitrust action in favor of defendants, an association of soda ash producers and its members. Plaintiff, an operator of a terminal that was used to load products including soda ash into vessels, alleged that there was a price-fixing cartel among the producers of soda ash to fix rates of domestic terminalling services for the export of soda ash. It also claimed that the association's relationship with another terminal operator restrained trade and reduced competition in the business of terminal services. The case involved the Webb-Pomerene Act, § 2, 15 U.S.C. §62, which is of no concern here. In any event, the court reasoned that because plaintiff was neither a producer nor a consumer of soda ash, it [was] not the plaintiff best situated to challenge [defendant's] allegedly unlawful conduct in the soda ash market." Int'l Raw Materials, 978 F.2d at 1329 (emphasis added).

Chemi relies on Carpet Group International v. Oriental Rug Importers Association, Inc., 227 F.3d 62, 78 (3d Cir. 2000). There, plaintiffs, a corporation and its sole shareholder, were in the business of making imported oriental rugs available to retailers directly from manufacturers. Plaintiffs bypassed importers at the wholesale level. They brought an antitrust action against an association of oriental rug importers and wholesalers in which they alleged conspiracy to restrain trade and monopolize the oriental rug market. Plaintiffs were neither sellers nor manufacturers of rugs. Nevertheless, our Court of Appeals, in reviewing the district court's grant of defendant's motion to dismiss, ruled that plaintiffs had standing under the antitrust laws because defendant's anticompetitive acts taken against plaintiffs' customers effectively thwarted plaintiffs' business. Id. at 64-65. The court recognized that there was a "cross-elasticity of demand between the plaintiffs' offering and the defendants' offering."[6] Id. at 77.

Here, as in Carpet Group International and in contrast to SAS of Puerto Rico and International Raw Materials, the alleged injury Chemi suffered "was not merely an indirect or remote consequence of [GSK's] actions." Id. at 78. Even though Chemi was not a direct competitor of GSK, its alleged injury was

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6. "Cross-elasticity of demand is defined as a relationship between two products, usually 'substitutes for each other, in which a price change for one product affects the price of the other.'" Carpet Group Int'l, 227 F.3d at 77 n.13 (citing Black's Law Dictionary, 7th ed.).

"inextricably intertwined with the injury [GSK] sought to inflict on [the nabumetone] market." Blue Shield of Va., 457 U.S. at 483-84. After Chemi determined it could manufacture nabumetone commercially, it sought to market the product to Teva and Eon. If the allegations in the complaint are true, Chemi was prevented from selling nabumetone to these vendors when GSK brought a bogus patent infringement suit against them with the very purpose of perpetuating its monopoly with respect to nabumetone. Chemi's injury is direct, and its claim is not speculative. See Carpet Group Int'l, 227 F.3d at 78; In re Lower Lake Erie, 998 F.2d at 1165.

Finally, in determining whether Chemi has standing, we must consider the "potential for duplicative recovery or complex apportionment of damages." In re Lower Lake Erie, 998 F.2d at 1165-66. Chemi maintains that it has suffered a unique injury for which Eon and Teva could not recover. It claims that any suit Eon or Teva brought against GSK to recover lost profits necessarily excluded the amount they would have paid Chemi for the nabumetone. Chemi's damages would be the profits it lost on its sale of nabumetone to Teva and Eon. In In re Lower Lake Erie, steel companies, docking companies, and trucking companies brought an antitrust action against railroads for conspiracy to monopolize dock handling, storage, and land transportation of iron ore along lower Lake Erie. The jury awarded damages to the docking companies and trucking companies. The Court of Appeals, in upholding these awards, observed that the different parties

alleged different injury: "the steel companies' claim is for the savings which would be realized if the less expensive method of transport was in place, while the vessel and dock companies' claim focuses on lost profits." 998 F.2d at 1169. We cannot say at this stage that there is likely to be duplicative recovery or complex apportionment of damages. See id.

From the record before us, Chemi has standing to bring this antitrust action.

V.

Accordingly, we will deny the motion of GSK for judgment on the pleadings. Chemi has set forth sufficient allegations supporting timeliness and standing to withstand GSK's motion.

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CHEMI SPA	:	CIVIL ACTION
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v.	:	
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GLAXOSMITHKLINE	:	NO. 04-4545

ORDER

AND NOW, this 8th day of February, 2005, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of defendant GlaxoSmithKline for judgment on the pleadings is DENIED.

BY THE COURT:

/s/ Harvey Bartle III
J.