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

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

MEMORANDUM

Bartle, J. July 18, 2005

This is an antitrust action against defendant GlaxoSmithKline ("GSK") for unlawful monopolization pursuant to § 2 of the Sherman Act and § 4 of the Clayton Act. 15 U.S.C. §§ 2 and 15. Before the court is the motion of plaintiff Chemi SpA ("Chemi") for issue preclusion and for partial summary judgment.

I.

On September 27, 2004, 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. Chemi alleges that GSK obtained a patent unlawfully for the purpose of maintaining its monopoly on the sale of nabumetone. It also contends that GSK filed patent infringement actions against third parties in order to trigger regulatory delays by the FDA and to frustrate Chemi's

sales of nabumetone in the United States in violation of federal antitrust laws.

On December 13, 1983, the Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,420,639 ("the '639 Patent") for a chemical compound known as nabumetone. It 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 as Relafen 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 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

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. 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.

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, GSK filed patent infringement actions against Teva and Eon in the United States

District Court for the District of Massachusetts.[2] 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 sixteen day consolidated bench trial, held that claims 2 and 4 of the '639 Patent were invalid as anticipated by prior art. In re '639 Patent Litig., 154 F. Supp. 2d 157, 186-87 (D. Mass. 2001). Judge Lindsay also determined that the patent was unenforceable because of GSK's inequitable conduct. Id. at 194. The Court of Appeals for the Federal Circuit affirmed Judge Lindsay's decision as to the invalidity but did not reach the issue of inequitable conduct. SmithKline Beecham Corp. v. Copley Pharm., 45 Fed. Appx. 915, 917 (Fed. Cir. 2002).

II.

Chemi contends that the doctrine of issue preclusion, that is, collateral estoppel, prevents defendant GSK from relitigating the issues decided by Judge Lindsay in In re '639 Patent Litig. It seeks an order giving preclusive effect to 53 of his findings. While Chemi was not a party to the patent

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2. These two actions, together with GSK's patent infringement action against Copley Pharmaceuticals, Inc., which also sought to market a generic version of Relafen, were consolidated for all purposes in the infringement action. See In re: '639 Patent Litig., 154 F. Supp. 2d 157, 160 (D. Mass. 2001).

litigation, mutuality is no longer required. See Parklane Hosiery Co. v. Shore, 439 U.S. 322, 331 (1979); Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971).

A party seeking to invoke issue preclusion must establish that: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." Raytech Corp. v. White, 54 F.3d 187, 190 (3d Cir. 1995) (citations omitted). GSK disputes elements (1) and (3) -- the identity of the issues to be precluded and the necessity of the findings in question.

Issue preclusion applies only when "the issue sought to be precluded is the same as that involved in the prior action." Nat'l R.R. Passenger Corp. v. Pa. P.U.C., 288 F.3d 519, 525 (3d Cir. 2002) (citations omitted). Issues are not identical "if the second action involves application of a different legal standard, even though the factual setting of both suits be the same." 18 Charles Alan Wright, Arthur R. Miller, Edward H. Cooper, Fed'l Prac. & Proc., Jurisdiction 2d § 4417 (2002).

Chemi's complaint makes two claims: (1) GSK fraudulently procured its patent or enforced a patent knowingly obtained by fraud on the PTO; and (2) GSK filed and prosecuted sham litigation to cover an attempt to interfere directly with the business relationships of its competitors. With respect to the first claim, Chemi must demonstrate by clear and convincing

evidence that GSK procured the '639 Patent by knowing and willful fraud and that it enforced the patent with knowledge of that fraud. Walker Process Equip. v. Food Mach. & Chem. Corp. ("Walker Process"), 382 U.S. 172, 178 (1965). To prevail on its second claim, an antitrust claim of "sham litigation," Chemi must show that GSK's patent infringement lawsuits were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." See Professional Real Estate Investors v. Columbia Pictures Indus., Inc. ("PRE"), 508 U.S. 49, 60 (1993). In addition, there is a subjective component. Plaintiff must demonstrate that GSK brought the patent lawsuits in bad faith "through the use of governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon." Id. (citations omitted).

In the prior patent litigation, Judge Lindsay determined GSK's patent for nabumetone was invalid as anticipated by prior art. In re '639 Patent Litig., 154 F. Supp. 2d at 186. Under 35 U.S.C. § 102(b), if an invention "was ... described in a printed publication in this or another country ... more than one year prior to the date of application for patent in the United States," it has been anticipated and therefore cannot be patented. To be anticipating, a prior art reference must disclose each and every limitation of the claimed invention in a way that enables a person of "ordinary skill in the field of the invention" to make the claimed invention. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1347 (Fed. Cir. 2000). Judge Lindsay

found by clear and convincing evidence that a 1973 article by scientists J.N. Chatterjea and R. Prasad entitled "Condensation of Mannich Base Salts with Phenols: Orientation of Adducts," published in the Indian Journal of Chemistry, Volume 11 at 214-18 (March 1973) (the "Chatterjea & Prasad publication") described nabumetone in 1973 to the ordinary chemist skilled in the art and anticipated claim 2 and claim 4 of the '639 Patent. In re '639 Patent Litig., 154 F. Supp. 2d at 186-87. Alternatively, he determined that the '639 Patent was unenforceable because of GSK's inequitable conduct. Id. at 194.

The Federal Circuit affirmed the district court as to the issue of invalidity based on the finding that the Chatterjea & Prasad publication anticipated claims 2 and 4 of the '639 Patent. Smithkline Beecham, 45 Fed. Appx. at 916-17. The Court of Appeals did not reach the issue of inequitable conduct. Id. at 917. Where a district court judgment is based on alternative grounds and only one of those grounds is affirmed on appeal, only the findings essential to the ground which was affirmed can be subject to issue preclusion in the later case. See Wright, Miller & Cooper, Fed'l Prac. Proc. § 4421, at 570 (2002); In re Real Estate Title and Settlement Servs., 869 F.2d 760, 764 n.1 (3d Cir. 1989) (citing Restatement (Second) of Judgments § 27 (1982)).

In the instant action, one of the elements Chemi must establish in order to prevail is that GSK knowingly sought to enforce an invalid patent. Accordingly, whether GSK's patent is

invalid under federal patent law is an issue to be resolved in this case. See e.g., In re Relafen Antitrust Litig., 286 F. Supp. 2d 56, 66 (D. Mass. 2003). The issue of invalidity in the prior action and in this action is identical. See Raytech Corp., 54 F.3d at 190.

Proof of misrepresentations, fraud, and bad faith are also essential to Chemi's claims under PRE and Walker Process. Chemi argues that a number of Judge Lindsay's findings which were relevant to inequitable conduct and are also relevant to Chemi's PRE and Walker Process claims were "necessary to the decision" of patent invalidity. See Raytech, 54 F.3d at 190. We are not persuaded. Judge Lindsay's determination of inequitable conduct was based upon GSK's knowledge, beliefs, conduct, and state of mind in applying for and enforcing the nabumetone patent. These are subjective matters. Because Judge Lindsay's decision was appealed, we must focus on what the Court of Appeals for the Federal Circuit decided. In contrast to Judge Lindsay, the Court of Appeals simply held that GSK's patent for nabumetone was invalid and did not pass upon the question of inequitable conduct. It ruled the patent invalid under an objective standard, that is, that the Chatterjea and Prasad article described the invention to a person of ordinary skill in the art. See Helifix, 208 F.3d at 1346 (emphasis added). While the Court of Appeals noted that one of the inventors as well as the GSK patent department knew about the article, these references are extraneous to its holding. In other words, the court's holding

of invalidity based on anticipation would have been the same regardless of Rose's or the patent department's awareness of the Chatterjea and Prasad article. The knowledge of Rose and the GSK patent department is essential only to the issue of inequitable conduct which the Court of Appeals did not reach.

The only findings which were necessary to the Court of Appeals decision on invalidity of the '639 Patent were:

> (1a) "[T]he Chatterjea & Prasad publication described nabumetone to the ordinary chemist in 1973 and anticipated claim 4 of the '639 patent." In re '639 Patent Litig., 154 F. Supp. 2d at 186, aff'd, Smithkline Beecham, 45 Fed. Appx. at 916.
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> (1b) "[T]he fact that a compound, like nabumetone, is solid at room temperature is an inherent property of that compound. In re '639 Patent Litig., 154 F. Supp. 2d at 187, aff'd,Smithkline Beecham, 45 Fed. Appx. at 917.
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> (1c) "[T]he Chatterjea & Prasad publication anticipates claim 2 as well as claim 4 of the '639 patent." In re '639 Patent Litig., 154 F. Supp. 2d at 187, aff'd, Smithkline Beecham, 45 Fed. Appx. at 917.

Accordingly, these findings and only these findings will be given preclusive effect in the current action. GSK, at this point, may contest Chemi's allegations of misrepresentations, fraud, and bad faith. See PRE, 508 U.S. at 60; Walker Process, 382 U.S. at 178.

Except as noted above, we will deny the motion of plaintiff for issue preclusion and partial summary judgment on defendant's liability. See Fed. R. Civ. P. 56.

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ORDER

AND NOW, this 18th day of July, 2005, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of plaintiff Chemi SpA for issue preclusion and partial summary judgment on defendant's liability is GRANTED in part;

(2) defendant GlaxoSmithKline is precluded from relitigating the following issues in this lawsuit:

> (a) the Chatterjea & Prasad publication described nabumetone to the ordinary chemist in 1973 and anticipated claim 4 of the '639 patent.
>
> (b) the fact that a compound, like nabumetone, is solid at room temperature is an inherent property of that compound.
>
> (c) the Chatterjea & Prasad publication anticipates claim 2 as well as claim 4 of the '639 patent.

and

(3) the motion of plaintiff is otherwise DENIED. See Fed. R. Civ. P. 56.

BY THE COURT:

/s/ Harvey Bartle III
J.