United States District Court,
D. Massachusetts.

In re '639 PATENT LITIGATION

No. CIV.A.97-12416-RCL

Aug. 16, 2000.

MEMORANDUM ORDER ON MOTIONS REFERRED TO SPECIAL MASTER

LINDSAY**, District J.**

This case involves United States Patent No. 4,420,639 (" '639 Patent") issued for the compound known as nabumetone to Anthony W. Lake and Carl J. Rose on December 13, 1983 and assigned to the Beecham Group, p.l.c., one of the plaintiffs herein. The '639 patent contains four claims: claims 1-3 recite the compound in solid form or at different melting points, and claim 4 recites the compound *per se*. The plaintiffs manufacture and sell the anti-inflammatory pharmaceutical product Relafen, whose active ingredient is nabumetone. The defendants, Copley Pharmaceutical Inc., Teva Pharmaceuticals U.S.A., Inc., and Eon Labs Manufacturing, Inc. seek to market a generic version of the Relafen product. The plaintiffs initiated this suit to enjoin these defendants and one other from infringing the '639 patent. The three defendants named above (the "defendants") have filed two motions for summary judgment-one attacking the validity of the '639 patent and the other attacking the enforceability of the patent. In addition, the defendants have filed a third motion to vitiate the attorney-client privilege as to communications between the plaintiffs and their attorneys (the "motion to vitiate") occurring during the prosecution of the applications that led to the issuance of the '639 patent. The defendants claim that the privilege should be vitiated because of misrepresentations made to the Patent and Trademark Office in the course of the prosecution of the applications.

On November 5, 1999, and over the objection of the plaintiffs, I referred the two motions for summary judgment and the motion to vitiate to a special master, Thomas Creel, Esquire, of the law firm of Kaye, Scholer, Fierman, Hays and Handler, LLP for a report and recommendation. (The order referring the motions to the special master will be referred to herein as the "order of reference.") I had previously appointed Mr. Creel, with the consent of the parties, to oversee discovery in this case. I referred the motions for summary judgment and the motion to vitiate to the special master pursuant to Fed.R.Civ.P. 53. The order of reference provided, however, that proceedings before the special master and any subsequent proceedings on the motions in this court would be governed by the provisions of 28 U.S.C. s. 636(b)(1), relating to the referral of, among other things, dispositive motions to United States magistrate judges for a recommended disposition. In other words, the order incorporated, for the consideration of these motions, the procedures and protections of s. 636(b)(1), insofar as that statute relates to the referral of dispositive matters to a magistrate judge for a report and recommended disposition. Under s. 636(b)(1), and thus under the order of reference here, any disposition of the motions recommended by the special master is subject to *de novo*

review by this court.

On January 28, 2000, the special master submitted reports on each of the three motions, with a recommended disposition of each, together with reasons. In one report, the special master recommended that the '639 patent be ruled invalid because its claims were anticipated by a publication by scientists Chatterjea and Prasad entitled "Condensation of Mannich Base Salts with Phenols: Orientation of Adducts" published in the Indian Journal of Chemistry, volume 11 at 213-18 (March 1973) ("Chatterjea & Prasad publication"). In a second report, the special master recommended that summary judgment be denied as to the defendants' claim that the '639 is unenforceable by reason of inequitable conduct of the plaintiffs in the prosecution of the applications that resulted in the issuance of the patent. In a third report, the special master recommended that the motion to vitiate be denied.

The parties filed objections to the special master's recommendations in accordance with the procedures set out in 28 U.S.C. s. 636(b)(1)(C), as incorporated into the order of reference. The court has conducted a *de novo* review of the issues raised by the motions. On the basis of that review, I make the following rulings.

I. ***Summary Judgment as to Invalidity by Anticipation***

Defendants allege that the '639 patent is invalid under 35 U.S.C. s. 102(b) because all of its claims were anticipated by the Chatterjea & Prasad publication. An invention is not novel, and therefore unpatentable, if a prior art reference discloses every element of the asserted invention. *See* Friction Div. Prods., Inc. v. E.I. de Nemours & Co., Inc., 693 F.Supp. 114, 122 (D.Del.1988), *aff'd,* 883 F.2d 1027 (Fed.Cir.1989). Under 35 U.S.C. s. 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 is therefore not entitled to a patent. The parties do not dispute that the Chatterjea & Prasad publication meets the requirement that the prior art reference be a publication printed more than one year prior to the date of the relevant application. The dispute focuses on whether that publication adequately "describes" the '639 patent.

To "describe" an invention, a publication must place the invention in the possession of the public by enabling others to practice the invention. *See* In re Donohue, 766 F.2d 531, 533 (Fed.Cir.1985). "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *Id*. As the parties and special master agree, to be entitled to succeed on the issue of anticipation, the defendants must demonstrate both identity of invention and enablement by the prior art reference. *See* Akzo v. U.S. Int'l Trade Commission, 808 F.2d 1471, 1479 (Fed.Cir.1986). The special master concluded, as to the anticipation issue, that there were no material facts in genuine dispute, and that I should rule, as a matter of law, that the Chatterjea & Prasad publication describes, enables, and therefore anticipates nabumetone. Accordingly, the special master recommended that I grant the defendants' motion as to invalidity of the patent.

Respectfully, however, I do not accept the special master's conclusions as to invalidity. Upon *de novo* review, I determine that there is a material issue of fact in genuine dispute, at least as to the first prong of the anticipation issue, identity of invention. Having so determined, it is not necessary that I address in depth the second prong, enablement. I have concluded, however, for reasons similar to those stated below as to identity of invention, that there is a genuine issue of material fact as to enablement as well.

Identity of invention requires that a prior reference disclose to one of ordinary skill in the art all elements

and limitations of the patent claim. *See* Scripps Clinic & Research Foundation v. Genetech, Inc., 927 F.2d 1565, 1576 (Fed.Cir.1991). There is no dispute that the Chatterjea & Prasad publication literally states the chemical name for what is now called nabumetone "(beta)-(2-Methoxy-6-naphthyl) ethyl methyl ketone" ("methoxy ketone" or nabumetone") and describes a process by which this compound may be synthesized from other compounds. Taken alone, the words that identify the chemical name for nabumetone and that describe a method for deriving it would be sufficient to establish identity of the compound named in the Chatterjea & Prasad publication with the compound named in the several claims of the patent.

The Chatterjea & Prasad publication describes a series of chemical reactions which result in what the Chatterjea & Prasad publication calls methoxy ketone. (I use throughout the remainder of this Order the shorthand "methoxy ketone" in place of the formal, chemical name for nabumetone.) As described by the Chatterjea & Prasad publication, the starting point for these reactions is a compound called methoxy acetate, which the authors say they derived using a method described by R.C. Jones and others in a 1948 publication ("Jones publication"). The Jones publication, however, contains an error: it names as "methoxy acetate," a compound which is in reality another called "bydroxy acetate." The parties and the special master refer to this error as the "Jones error."

A 1955 paper published by Ormancey and Horeau (the "Ormancey paper") recognized and explained the Jones error as an unintended "demethylation" that went unnoticed by Jones. FN1 If one follows the chemical reactions underlying the present dispute from the Jones publication and the Ormancey paper through the Chatterjea & Prasad publication, the compound one actually derives, by the process set out in the Chatterjea & Prasad publication, is hydroxy ketone, not methoxy ketone. Hydroxy ketone is an analogue of methoxy ketone.

FN1. Demethylation is reaction by which a methyl group on a compound becomes substituted with a hydrogen atom. Thus, as the Ormancey paper described the Jones error, demethylation of the precursor to methoxy acetate (methoxy acid) occurred, converting the methoxy acid to hydroxy acid and resulting in the misnaming of the resulting hydroxy acetate as methoxy acetate. Ormancy also described, however, a method of remethylation, that is, a method of reconverting the hydroxy acid to a methoxy acid and deriving methyl acetate.

The parties agree, for the purposes of the present motion that, in 1973, the hypothetical person of ordinary skill in the art would know of the Jones error in the Chatterjea & Prasad publication, at least by virtue of his knowledge of the Jones publication and Ormancey paper. FN2 The parties also agree that the person of ordinary skill would know how to derive methoxy acetate by methods other than that described in the Jones publication. From this, the defendants argue, and the Special master concluded, that with methoxy ketone named in the Chatterjea & Prasad publication and knowledge of the Jones error, the person of ordinary skill would recognize the Chatterjea & Prasad publication to disclose methoxy ketone and the series of chemical reactions by which that compound may be derived.

FN2. For the purposes of this motion, the parties agree that the person of ordinary skill in the art is a medicinal chemist with a doctoral degree and one to two years of industry experience and familiarity with non-steroidal anti-inflammatory drugs, or such a chemist with a masters degree and at least five years of industry experience. *See* Helifix Limited v. Blok-Lok, Ltd., 208 F.3d 1339, 1347 (Fed.Cir.2000) (holding that "court should have considered the educational level of the inventor" in determining relevant skill in the art). This hypothetical person of ordinary skill in the art would be presumed to know all publications on the

relevant subject. *See* Custom Accessories, Inc., 807 F.2d 955, 962 (Fed.Cir.1986).

The parties do not appear to dispute that the person of ordinary skill, following the syntheses set out in the Chatterjea & Prasad publication, would make an adjustment in his experimentation to account for the Jones error. What is in dispute, however, is what adjustment the person of ordinary skill in the art would make in the face of the Jones error. Would he adjust by substituting methoxy acetate for the actual hydroxy acetate the Chatterjea & Prasad publication uses as the starting compound for the syntheses, and thereby understand the publication to teach the derivation of methoxy ketone; or would he adjust instead by assuming that the Chatterjea & Prasad publication erroneously calls what is actually hydroxy acetate (the starting compound) by the name methoxy acetate, and conclude that the publication teaches only a series of reactions of hydroxy compounds by which hydroxy ketone, not methoxy ketone, is derived? The decision as to what the Chatterjea & Prasad publication teaches depends on which of these two courses the person of ordinary skill in the art would follow. On this question, the plaintiffs have submitted affidavits by Dr. Paul A. Bartlett to the effect that the person of ordinary skill would have made the latter choice, that is, he would disregard the erroneous use of the name methoxy acetate as the starting compound in the process taught by the Chatterjea & Prasad publication and thereby conclude that the publication teaches only hydroxy ketone and a method for deriving it. On the other hand, the record contains evidence to the contrary of the proposition asserted by Dr. Bartlett. Among such evidence is that tending to show that, at one point in the prosecution of applications that led to the issuance of the '639 patent, both the patent examiner and the plaintiffs themselves concluded that the Chatterjea & Prasad publication anticipated, and therefore precluded patentability of, nabumetone. The present record therefore leaves the matter unresolved and creates a triable issue as to identity of invention with respect to claim 4 of the '639 patent. Accordingly, summary judgment is not appropriate as to that claim.

Because a disputed issue of material fact on the question of identity of invention relates to the nabumetone compound *per se,* as identified in claim 4, it necessarily follows that there is a disputed issue of material fact as to the identity of invention with respect to claims 1-3 of the '639 patent. As noted above, these claims recite the compound nabumetone in various forms.

Accordingly, I reject the recommendation of the special master that I grant the defendants' motion for summary judgment as to invalidity of all four claims of the '639 patent. Instead, that motion is denied.

II. ***Summary Judgment as to Unenforceability by Inequitable Conduct***

As to the motion for summary judgment on unenforceability, I accept and adopt the special master's analysis and conclusions. That motion, therefore, is denied.

III. ***Vitiation of the Attorney-Client Privilege***

The defendants seek to vitiate the plaintiffs' attorney-client privilege on the basis of the crime-fraud exception. They base their motion on three representations made to the Patent and Trademark Office on behalf of the patent holder during the prosecution of the application leading to the issuance of the '639 patent: (1) a representation by Dr. Carl J. Rose that the product of the reactions set out in the Chatterjea & Prasad publication produced an oil rather that a solid, and that therefore the publication does not disclose nabumetone because nabumetone is a solid at room temperature; (2) a representation by Dr. Rose that scientists not having methoxy acid readily available to them would be "obliged" to use the Jones publication in deriving methoxy acetate as prescribed in the Chatterjea & Prasad publication; and (3) a representation by

Dr. Richard Anderson that the hydroxy analogue of nabumetone is an oil. All of these representations, the defendants say, are false. Common law fraud having been committed on behalf of the plaintiffs by the making of these false statements, the defendants contend, the plaintiffs have forfeited their attorney-client privilege with respect to communications with counsel during the prosecution of the applications that resulted in the issuance of the '639 patent.

To vitiate the attorney-client privilege on the crime-fraud exception, a party challenging the privilege must make a prima facie showing that the communication was made "in furtherance of" a crime or fraud. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 2000 WL 146096 (Fed.Cir.2000). The Federal Circuit has held that, generally, such common law fraud does not exists unless the following factors are found to be present:

(1) a representation of a material fact,

(2) the falsity of that representation,

(3) the intent to deceive, or at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent,

(4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and

(5) injury to the party deceived as a result of his reliance on the misrepresentation.

See Nobelpharma AB. v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70 (Fed.Cir.1998).

I accept the special master's recommendation that I deny the defendants' motion to vitiate, but I do so not entirely for the several reasons stated by the special master. My conclusion is that, in no instance involving the representations set out above, have the defendants made a prima facie showing of clear reliance on the representation. In this context, reliance means "that the patent would not have issued but for the misrepresentation or omission." Id. at 1071. Accordingly, the motion to vitiate is denied.

IV. *Conclusion*

For the reasons stated above, I deny the motions of the defendants for summary judgment made on the basis (1) that the patent is invalid and (2) that the patent is unenforceable. I likewise deny the motion to vitiate the attorney-client privilege of the plaintiffs.

So ordered.

D.Mass.,2000.
In re '639 Patent Litigation

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