IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 02-581 JJF
v.	:	
	:	
AVENTIS PHARMACEUTICALS, INC.,	:	
	:	
	:	
Defendant.	:	

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Attorneys for Defendant Aventis Pharmaceuticals, Incorporated.

MEMORANDUM OPINION

February 5, 2004

Wilmington, Delaware

Farnan, District Judge

Presently before the Court is Plaintiff's Motion for Summary Judgment for Non-Infringement of Claims 2 and 3 of U.S. Patent No. 5,527,814 (D.I. 114-1), asserting that Plaintiff has not and will not infringe the patent of the Defendant and will not induce such infringement.

BACKGROUND

Defendant Aventis Pharmaceuticals, Inc. ("Aventis") owns U.S. patent No. 5,527,814 ("'814 patent"). The '814 patent involves the use of the chemical compound riluzole to treat amyotrophic lateral sclerosis ("ALS"), more commonly known as Lou Gehrig's disease. Claims 1, 2, and 3 of the patent are relevant in this case:

> [Aventis] claim[s]: 1. A method for treating a mammal with amyotrophic lateral sclerosis, comprising the step of administering to said mammal in recognized need of said treatment an effective amount of [riluzole]. 2. The method according to claim 1 wherein said amyotrophic lateral sclerosis is with early bulbar involvement. 3. The method according to claim 1 wherein said amyotrophic lateral sclerosis is the bulbar form.

Plaintiff's exhibit 1.

In 2001, Plaintiff Impax Laboratories, Inc. ("Impax") filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") requesting approval to market riluzole to treat ALS. Impax planned to market riluzole generally without targeting its drug to treat specific forms or

symptoms of ALS.

Aventis filed an action in this Court seeking a preliminary injunction to stop Impax from marketing riluzole as a treatment for ALS. Aventis asserted that Impax's proposed market entry would infringe its patent. On December 12, 2002, this Court entered a preliminary injunction barring Plaintiff's market entry. Impax now requests the Court find that marketing riluzole as a general treatment for ALS will not infringe two of Aventis's patent claims.

DISCUSSION

I. Parties' Contentions

Impax asserts that neither its ANDA nor its proposed general marketing of riluzole will infringe either claim 2 or 3 of Aventis's patent but concedes that its ANDA and marketing will infringe claim 1 of the patent. Impax claims it intends to market and sell riluzole only as a general remedy for ALS and asserts that this general use of riluzole will not infringe the more specific uses of riluzole detailed in claims 2 and 3 of Aventis's patent.

Aventis contends that the Plaintiff's proposed marketing will infringe claims 2 and 3 of its patent. Aventis asserts that ALS is one disease and claims 2 and 3 describe different incidences of the disease; therefore, according to Aventis, advocating and allowing the use of riluzole to treat ALS will

lead to riluzole's use in treating the incidences described in claims 2 and 3. Aventis contends that even general marketing of riluzole will lead to infringement on the specific claims of Aventis's patent.

II. The Standard of Review

A. Summary Judgment

Rule 56(c) of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). Thus, to properly consider all of the evidence, the "court should give credence to the evidence favoring the non-movant as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that evidence comes from disinterested witnesses." Id. (quoting

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250-251 (1986))

To defeat a motion for summary judgment, Rule 56(c) requires the non-moving party to show that there is more than "some metaphysical doubt as to the material facts.... In the language of the Rule, the non-moving party must come forward with 'specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (quoting FED. R. CIV. P. 56(c)). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). Additionally, the Court should consider the evidentiary standard that applies at trial. See Eli Lily & Co. v. Barr Labs, Inc., 251 F.3d 955, 962 (Fed. Cir. 2001) (stating that "[w]hen evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at trial to the merits." (citations omitted)). In determining whether a patent has been infringed, the patent owner has the burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir.1988) (citations omitted).

B. Infringement

In relevant part, 35 U.S.C. § 271 (a), (b), and (e)(2) provide that:

> (a) [e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent[;] (b) [w]hoever actively induces infringement of a patent shall be liable as an infringer;]

and that:

> (e)(2) [i]t shall be an act of infringement to submit (a) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ...claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271 (a), (b), (e)(2).

A patent owner may prove infringement under either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir.1987); Robert L. Harmon, Patents and the Federal Circuit 195 & n. 31 (3d ed.1994). For there to be infringement under the doctrine of equivalents, the accused product or process must embody every element of a claim, either literally or by an equivalent. Warner-Jenkinson, 520 U.S. 17, 41 (1997). Thus, the mere showing that an accused device is equivalent overall to the

claimed invention is insufficient to establish infringement under the doctrine of equivalents.

Infringement is a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires the court to compare the accused products with the properly construed claims of the patent. Step one is a question of law; step two is a question of fact. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); Organon, Inc. v. Teva Pharmaceuticals, Inc. 244 F. Supp. 2d 370, 377 (D.N.J. 2002).

A party alleging inducement "has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements." Manville Sales Corp. v. Paramount Systems, Inc. 917 F.2d 544, 553 (Fed. Cir. 1990). Inducement of infringement must also involve direct infringement and is dependent upon proof of such. Epcon Gas Systems, Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1033 (Fed. Cir.2002).

III. Decision and Rationale

For purposes of the instant motion, most of the relevant issues are uncontested. The parties do not disagree on the scope of the claims or the nature of ALS. Both parties agree that claims 2 and 3 involve the application of riluzole to specific

permutations of ALS.

The parties only disagree on whether marketing the use of riluzole for the general treatment of ALS will infringe, or induce others to infringe, the Defendant's patent claims for more specific treatments that fall under the same ALS umbrella. Once construed, whether Defendant's claim is infringed is a question of fact. Organon, Inc. v. Teva Pharmaceuticals, Inc. 244 F. Supp. 2d 370, 377 (D.N.J.,2002).

In Bell Communications Research, Inc. v. Vitalink Communications Corp., the court stated that "[a]n accused product that sometimes, but not always, embodies a claimed method nonetheless infringes." 55 F.3d 615, 622 -623 (Fed. Cir. 1995). Impax seeks to use riluzole in a manner which differs from Aventis's claim 2 and 3 primarily because Impax's suggested use is more comprehensive. Impax's proposed use of riluzole does not avoid conflict with the Defendant's patent simply because Impax would instruct others to use riluzole as a general treatment. Impax's general marketing of riluzole to treat ALS would solicit use of riluzole that violates claims 2 and 3 of the '814 patent. Further, Impax knows or should know that marketing riluzole generally will lead to infringement of claims 2 and 3. Therefore, the Court concludes that Impax's proposed sale of riluzole will infringe and induce others to infringe claims 2 and 3 of the '814 patent.

For the reasons discussed, Impax's motion for summary judgment will be denied. An order consistent with this Memorandum Opinion will be entered.

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O R D E R

At Wilmington, this 5th day of February 2004, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that Plaintiff's Motion for Summary Judgement of Non-Infringement (D.I. 114-1) is **DENIED**.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE