

**MARION MERRELL DOW, INC., et al., Plaintiffs, v. HOECHST-ROUSSEL
PHARMACEUTICALS, INC., Defendant.**

Civil No. 93-5074 (AET)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

1994 U.S. Dist. LEXIS 10024; 32 U.S.P.Q.2D (BNA) 1156

May 4, 1994, Decided
May 5, 1994, Filed

NOTICE: [*1] NOT FOR PUBLICATION

DISPOSITION: Denied.

LexisNexis(R) Headnotes

JUDGES: THOMPSON

OPINIONBY: ANNE E. THOMPSON

OPINION:

OPINION

THOMPSON, District Judge

This matter is before the Court on Defendant's motion to dismiss the complaint pursuant *Fed.R.Civ.P. 12(b)(1)* for lack of subject-matter jurisdiction. For the reasons set forth below the Court will deny Defendant's motion.

Background

Plaintiffs Elan Corporation ("Elan"), Marion Merrell Dow, Inc. ("MMD") and Cardem Capital L.P. ("Cardem") filed the present action in this Court on November 12, 1993 alleging infringement of United States Patent Nos. 5,002,776 ("the '776 patent") and 4,894,240 ("the '240 patent") pursuant to 35 U.S.C. Section 271(e). Elan owns both patents and has issued an exclusive license to Cardem. Cardem, in turn, has issued a license to MMD and has authorized MMD to file this suit on its behalf. An amended complaint omitting Elan as a Plaintiff has since been filed.

The gravamen of Plaintiffs' complaint is that Defendant Hoechst-Roussel Pharmaceuticals, Inc. ("H-R") infringed the '776 and '240 patents by submitting a New Drug Application ("NDA") to the United States Food and

Drug Administration ("FDA"). H-R's original NDA, dated August [*2] 30, 1993, referenced Patents '776 and '240. Pursuant to 21 U.S.C. Section 355(b)(3)(B), H-R notified Plaintiffs and Elan with respect to those patent certifications. Plaintiffs then filed the instant action. H-R now claims that those references were unnecessary and were corrected by the filing of a new, corrected patent certification on January 21, 1994. Plaintiffs contend that despite the corrected certification their complaint presents a case or controversy over which this Court has jurisdiction.

H-R's patent application involved a sustained or extended time release version of diltiazem, a drug which is used to treat chronic heart conditions. Diltiazem is already on the market in both an immediate release and an extended release form. The patent for the immediate release form of the drug has already expired, however Patents '240 and '776, which cover the extended or sustained release form of the drug are still in effect.

H-R conducted its own safety investigations as required by 21 U.S.C. Section 355(b) with one exception. H-R relied upon the investigations already in existence for the drug diltiazem itself. [*3]

Critical to this motion to dismiss are 21 U.S.C. Section 355(b)(2) and 35 U.S.C. Section 271(e). They read as follows:

Section 271(e)(1) It shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section [355(j)] or as described in section [355(b)(2)] 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.

Section 355(b)(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the [*4] applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which the investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section--

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) 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; and . . .

Under section 271(e)(1), H-R could have avoided any infringement action against it by completing all of its own safety investigations. Instead, H-R chose to rely on the toxicology study performed [*5] and filed in connection with immediate release diltiazem. Even though H-R's NDA is for sustained release diltiazem, it was able to rely on the immediate release diltiazem studies because the same drug is involved; the only real difference between the two is the way in which the diltiazem is released inside the body.

By relying on the immediate release diltiazem studies, H-R became subject to an infringement action pursuant to 35 U.S.C. Section 271(e)(2) which permits a patent owner to file an infringement action against an NDA applicant if the NDA is of the type described in 21 U.S.C. Section 355(b)(2). The parties to this action agree that H-R's NDA was filed under Section 355(b)(2). (See Pls.' Br. at 2 and Def.'s Br. at 3.)

The first issue which must be dealt with is whether a patent owner may file an infringement action even though that patent is not listed by the applicant in the certification required by Section 355(b)(2)(A). In other words, may a patent owner (whose patent is on file with the FDA), who believes that his patent should have been included in the applicant's certification, commence an [*6] action in this Court even though the actual certification does not list that patent? Defendant argues that only when the certification lists a patent pursuant to Section 355(b)(2)(A)(iv), is that patent's owner permitted to file an action. The Court is not persuaded by H-R's argument. Section 271(e)(2) clearly provides a cause of action against any Section 355(b)(2) applicant whose new drug is claimed in a patent or the use of which is claimed in a patent. The statute does not require that the applicant have included the drug in its certification, nor does it limit the cause of action to patents listed pursuant to Section 355(b)(2)(A)(iv). n1 Although the legislative history indicates that NDA applicants were expected to file all necessary certifications, the use of the statute by individual patent owners would be almost impossible if they were dependent upon the applicant to first include the existing patent in its certification. See H.R. Rep. No. 857, 98th Cong., 2nd Sess., at 2647-48 and 2665 (1984). Therefore, this Court concludes that the proper inquiry is, should the certification have included the patent and if so, is there an infringement of that patent? In light of this [*7] conclusion, H-R's motion to dismiss for lack of jurisdiction must be denied because this Court has jurisdiction to determine whether the patent should have been included in the certification.

21 U.S.C. § 355(b)(2) and 35 U.S.C. § 271(e).

Discussion

n1 The Court notes that the Sections 355(b)(2)(A)(i)-(iii) would not provide a cause of

action for infringement because those sections refer solely to patents which have expired, will expire or have not been filed with FDA. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677, 110 L. Ed. 2d 605, 110 S. Ct. 2683 (1990).

H-R's original certification filed with the FDA included the '240 and '776 patents. Since that time, and after the filing of this law suit, H-R filed a corrected certification which does not list either patent. The question is, then, should H-R's certification have included the '240 and '776 patents? In order to answer this question, the Court must examine Section 355(b)(2)(A).

In cases of statutory construction, a court's first job is to determine [*8] congressional intent "using traditional tools of statutory construction". *Id.* at 175 (citations omitted). "An agency's construction of a statute is entitled to deference if it is reasonable and not in conflict with congressional intent." *Id.* Section 355(b)(2)(A) requires "each patent which claims the drug for which such investigations were conducted . . ." 21 U.S.C. § 355(b)(2)(A). n2 H-R states that it intended to rely on the toxicology data for diltiazem which was collected and is now on file with the FDA in connection with immediate release diltiazem. (See Def.'s Br. at 2.) Since patents '240 and '776 relate to sustained release diltiazem, H-R argues that it was unnecessary for it to include those patents in its certification. Hence, H-R is attempting to create a distinction between immediate release diltiazem and sustained release diltiazem by defining the term "drug" to mean the finished drug product covered by the patent, i.e. immediate release diltiazem, as opposed to the active ingredient, i.e. diltiazem.

n2 The Court notes that the investigations need not have been conducted for a particular patent in order for that patent to be included in the certification. A certification must include any patent which covers a drug for which the investigations were conducted.

[*9]

In *Pfizer, Inc. v. Food and Drug Administration*, 753 F. Supp. 171 (D. Md. 1990) the court sought to determine the meaning of the term "drug" as used in Sections 355(1) and (c)(2). The Pfizer Court reached its conclusion after an examination of FDA reports and the case law which has touched upon this issue. Most importantly, the Pfizer Court noted that the term drug was read to include both drug products as well as the active and inactive ingredients which comprise those products. *Id.* at 176 (citing *United States v. Generix Drug Corp.*, 460

U.S. 453, 459, 75 L. Ed. 2d 198, 103 S. Ct. 1298 (1983)). Nevertheless, the Pfizer Court held that the term "drug", as used in Sections 355(1) and (c)(2), had a more limited meaning because:

The relevant statutory section in this case, however, modifies the word "drug" by attaching the phrase "for which the applicant submitted the application."

Id. at 176. Since the application in that case was submitted for a drug product, "drug" as referred to in the relevant sections also meant drug product.

The section [*10] under scrutiny here modifies the word "drug" by "for which the investigations were conducted". 21 U.S.C. § 355(b)(2)(A). In H-R's own words it intended to rely upon the investigations for "diltiazem itself, which was already on file with the FDA in connection with the original NDA filed for immediate release diltiazem." (See Def.'s Br. at 2.) (emphasis added). Hence the drug for which the investigations were conducted was diltiazem and not immediate release diltiazem. Therefore, any patent which covers diltiazem itself should have been listed by H-R in its certification. Any other construction of this statute would be contrary to its plain meaning and inconsistent with Congress' intent not only to provide the public with easier and faster access to new drugs, but also to protect those individuals who pioneered patented new drugs which are on file with the FDA. See H.R. Rep. No. 857, 98th Cong., 2nd Sess., at 2647-48 and 2655 (1984). Since the '240 and '776 patents cover the drug diltiazem for which the studies relied upon by H-R were conducted, these patents were properly included in H-R's original certification. The Court will deny [*11] Defendant's motion.

Conclusion

In light of the foregoing, the Court will deny Defendant's motion to dismiss. An appropriate Order is filed herewith.

May 4, 1994

ORDER

For the reasons set forth in the Memorandum Opinion filed herewith, it is on this 4th day of May 1994

ORDERED that Defendant's motion to dismiss the complaint be and hereby is denied.

ANNE E. THOMPSON, U.S.D.J.