# IN THE UNITED STATES DISTRICT COURT

#### FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND:
PHARMACEUTICALS, WARNER-:
LAMBERT COMPANY, WARNER-:
LAMBERT COMPANY, LLC, and:
WARNER-LAMBERT EXPORT, LTD.,:

Plaintiffs,

:

v. : Civil Action No. 03-209-JJF

: (Consolidated)

RANBAXY LABORATORIES LIMITED : and RANBAXY PHARMACEUTICALS, : INC., :

:

Defendants.

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Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire and Mary W. Bourke, Esquire of CONNOLLY BOVE LODGE & HUTZ LLP, Wilmington, Delaware.

Attorneys for Plaintiffs.

Steven J. Balick, Esquire and John G. Day, Esquire of ASHBY & GEDDES, Wilmington, Delaware.

Of Counsel: Darrell L. Olson, Esquire, John P. Giezentanner, Esquire and William R. Zimmerman, Esquire of KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, California.

Jay R. Deshmukh, Esquire and George E. Heibel, Esquire of RANBAXY INC., Princeton, New Jersey.

Attorneys for Defendants.

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# MEMORANDUM OPINION

June 18, 2004

Wilmington, Delaware

# Farnan, District Judge.

Pending before me is a Motion To Compel Production Of Documents Withheld On Grounds Of Privilege (D.I. 122) filed by Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer") against Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals, Inc. (collectively, "Ranbaxy"). By its Motion, Pfizer contends that Ranbaxy has improperly refused to produce certain documents forming the basis of the statements and conclusions made in Ranbaxy's Paragraph IV notification letters. The documents at issue are three e-mail letters reflecting the review, analysis and written opinions of Ranbaxy's in-house and outside counsel. Pfizer contends that Ranbaxy waived any claim of attorney-client privilege with respect to these documents by including information from the documents in its non-privileged paragraph IV notification letters.

In response, Ranbaxy contends that it has not waived any claim of attorney-client privilege or work product immunity with respect to the documents at issue. Ranbaxy contends that the mere fact that the ANDA notification was based on or consistent with the opinions of its counsel does not amount to a waiver of the attorney-client privilege or work product immunity. Ranbaxy further contends that Pfizer's motion to compel is an attempt to

circumvent my order bifurcating the issue of willful infringement from the other issues in the case. Ranbaxy contends that it has not yet made the decision of whether it will rely on the opinions of its counsel in the willfulness phase of the trial, and it should not have to make that decision during this phase of the case.

Based on the parties' respective arguments, it appears that Pfizer does not contest Ranbaxy's assertion that the documents at issue are protected by work product immunity and/or the attorneyclient privilege. Thus, the only question remaining for me is the narrow inquiry of whether Ranbaxy waived its privilege and/or immunity by filing its Paragraph IV notification letters based on the advice and opinions of its counsel as relayed in the subject documents. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an abbreviated new drug application ("ANDA") must contain a certification that, in the opinion of the applicant and to the best of his or her knowledge, the patent on the subject drug is "invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted." addition, the ANDA applicant is required to provide the patent owner with a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

I conclude that the fact that an ANDA applicant bases its

Paragraph IV notification letter on the opinions and advice of its attorneys is insufficient to constitute a waiver of the attorney-client privilege and/or work product immunity with respect to the underlying documents expressing that advice or opinion. Pfizer points to several cases suggesting that a party's partial disclosure of attorney-client communications is sufficient to waive the privilege; however, none of these cases involve an ANDA applicant. In this regard, I agree with Ranbaxy that the circumstances of this case are analogous to the numerous litigation circumstances in which a client and attorney discuss general information and some of that information makes its way into public filings, such as complaints and answers to interrogatories. Courts considering such circumstances have concluded that the privileges are not waived with respect to the underlying communication between the attorney and the client. See Beery v. Thomson Consumer Electronics, Inc., 218 F.R.D. 599 (S.D. Ohio 2003) (plaintiff in patent infringement suit did not waive attorney-client privilege by relying on attorney's claim construction or infringement opinions at deposition); Frieman v. USAir Group, Inc., 1994 WL 675221, \*7 (E.D. Pa. 1994) (holding that privilege was not waived with respect to attorney-client communications about cause of accident where certain information was divulged in interviews, depositions and pleadings); Bristol-Myers Co. v. Sigma Chemical Co., 7 U.S.P.Q.2d 1574 (D. Del. 1988) (holding that Rule 11 affidavit submitted for purposes of demonstrating a good faith basis for instituting infringement actions did not waive privilege with respect to documents protected by privileges); Knogo Corp. v. United States, 213 U.S.P.Q. 936, 941 (Ct. Cl. 1980) (holding that assertion of privilege is not precluded over communications in which attorney and client discussed technical information concerning the patent, and some of the technical information was later disclosed in patent application and recognizing that client does not waive privilege by testing validity of patent).

Further, I am persuaded, based on the line of questioning pursued by Pfizer at the deposition of Ranbaxy's Jay R. Deshmukh, Esquire, that the subject documents relate primarily to Pfizer's allegations of willful infringement. I have bifurcated the issue of willful infringement from the issues of infringement and validity, and therefore, the issue of whether Ranbaxy will rely on its opinions of counsel to defend against Pfizer's claims of willful infringement is not currently an active issue.

Accordingly, Pfizer is not yet entitled to the discovery of these otherwise privileged documents.

An appropriate Order will be entered.

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RANBAXY LABORATORIES LIMITED : and RANBAXY PHARMACEUTICALS, : INC., :

:

Defendants.

# ORDER

At Wilmington, this 18th day of June 2004, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that Plaintiff Pfizer's Motion To

Compel Production Of Documents Withheld On Grounds Of Privilege

(D.I. 122) is DENIED.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE