

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS :
CORPORATION, NOVARTIS AG, :
NOVARTIS PHARMA AG, and :
NOAVRTIS INTERNATIONAL :
PHARMACEUTICAL LTD., :
 :
 :
Plaintiff, :
 :
 :
v. : Civil Action No. 00-800-JJF
 :
 :
EON LABS MANUFACTURING, INC., :
 :
 :
Defendant. :

Stuart B. Young, Josy W. Ingersoll, and John W. Shaw, Esquires of
YOUNG, CONAWAY, STARGATT & TAYLOR, LLP, Wilmington, Delaware.
Of Counsel: Robert L. Baechtold, Nicholas N. Kallas, Brian V.
Slater, Esquires of FITZPATRICK, CELLA, HARPER & SCINTO, New
York, New York.
Attorneys for Plaintiffs.

George H. Seitz, III and Patricia P. McGonigle, Esquires of
SEITZ, VAN OGTROP & GREEN, P.A., Wilmington, Delaware.
Of Counsel: Martin Pavane and Mindy H. Chettih, Esquires of
COHEN, PONTANI, LIEBERMAN & PAVANE, New York, New York.
Attorneys for Defendant.

MEMORANDUM OPINION

March 28, 2002
Wilmington, Delaware

FARNAN, District Judge

Presently before the Court is Plaintiffs' Motion To Compel Discovery Materials Improperly Withheld by Eon (D.I. 139), and Defendant's Motion For A Protective Order To Vacate, In Part, A Rule 30(B)(6) Deposition Notice (D.I. 121). By its Motion, Plaintiffs seek to compel various categories of documents. (D.I. 139). In a recent Memorandum Opinion, the Court granted the portion of Plaintiffs' Motion (D.I. 139) which seeks to compel the production of all documents underlying Defendant's advice of counsel defense to Plaintiffs' claim of willful infringement. For the same reasons set forth by the Court in its recent Memorandum Opinion, Defendant's Motion For A Protective Order (D.I. 121), to the extent it seeks to vacate the portions of Plaintiff's 30(B)(6) Deposition Notice which request testimony from Defendant on materials underlying Defendant's advice of counsel defense, will be denied.¹ With regard to the unresolved portions of Plaintiffs' Motion To Compel (D.I. 139) and Defendant's Motion For A Protective Order (D.I. 121), for the reasons set forth below, Plaintiffs' Motion To Compel (D.I. 139) will be denied and Defendant's Motion For A Protective Order (D.I. 121) will be granted.

¹ Because the majority of Defendant's Motion For A Protective Order (D.I. 121) seeks to vacate portions of Plaintiffs' 30(B)(6) Deposition Notice on these grounds, there is only one remaining issue with respect to Defendant's Motion For A Protective Order that needs to be addressed.

I. BACKGROUND

In June 1998, Defendant Eon Labs Manufacturing, Inc. (hereinafter "Eon") prepared and submitted an application for Federal Drug Administration (hereinafter "FDA") approval of a cyclosporin-based product intended for sale to transplant patients. (D.I. 145 at 4). On January 13, 2000, the FDA approved Eon's application. (D.I. 145 at 4).

In an Amended Complaint filed on February 8, 2001, Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd. (collectively "Novartis") brought this action against Eon, alleging, among other things, that Eon infringed Novartis' United States Patent No. 5,389,382 (hereinafter "'382 Patent").² (D.I. 145 at 1). During the course of discovery, the parties filed the instant Motions (D.I. 139; D.I. 121).

II. DISCUSSION

A. Whether Documents Responsive To Novartis' Request Numbers 41 and 47 Should Be Produced, And Whether Testimony on Novartis' Deposition Topics 8, 9, And 10 Should Proceed

Novartis moves to compel the production of documents in response to its Request Numbers 41 and 47, which seek the following:

² The Original Complaint was filed only by Novartis Pharmaceuticals Corporation on August 30, 2000.

Request No. 41: All documents and things relating to or concerning any consideration given to filing and/or the decision to file for FDA approval of any drug product containing cyclosporin, including, without limitation, Eon's product

Request No. 47: All documents and things relating to or concerning the decision to market, or any consideration given to marketing, a cyclosporin-based composition, a generic version of Neoral®, a generic version of Sandimmune®, and/or Eon's product.

(D.I. 146, Ex. B at 12, 14). Novartis has also served Eon with a 30(B)(6) Deposition Notice, which seeks testimony along the same lines. Specifically, paragraphs 8, 9, and 10 of Novartis'

30(B)(6) Deposition Notice request testimony concerning:

8. Any consideration given by Eon to developing or licensing a generic cyclosporin product, including without limitation the decision to license the Eon Product from Hexal.
9. Any consideration given by Eon to filing an AADA or ANDA on a generic cyclosporin product, including without limitation the decision to file an AADA or ANDA on the Eon Product.
10. Any consideration given by Eon to marketing a generic cyclosporin product, including without limitation any consideration given to marketing the Eon Product.

(D.I. 122, Ex. A). Novartis contends that the testimony and documents sought by these requests is relevant to the issue of willful infringement. (D.I. 145 at 22). Specifically, Novartis contends that these requests are designed to uncover evidence of Eon's motivation and timing in deciding to infringe Novartis' patent. (D.I. 145 at 5). Novartis contends that evidence of the decision-making process employed by Eon is particularly relevant

to the issue of willful infringement in this case because Eon decided to file its application with the FDA and market its cyclosporin product before it received the opinion of counsel. (D.I. 145 at 5).

Eon has refused to produce documents in response to Novartis' Request Numbers 41 and 47, and has filed a Motion For A Protective Order (D.I. 121) to vacate paragraphs 8, 9, and 10 of Novartis' 30(B)(6) Deposition Notice. Eon contends that these requests seek discovery on matters not relevant to this litigation. (D.I. 152 at 2). Specifically, Eon contends that its consideration to market or file for FDA approval products which are not the subject of this litigation are neither relevant to nor probative of its decision to market the allegedly infringing product. (D.I. 152 at 2).

Under Federal Rule of Civil Procedure 26(b)(1), the Court may order discovery for good cause "on any matter relevant to the subject matter involved in the action." Fed.R.Civ.P. 26(b)(1).

The Court agrees with Eon and finds that the discovery sought by Novartis' Request Numbers 41 and 47 and paragraphs 8, 9, and 10 of Novartis' 30(B)(6) Deposition Notice does not pertain to the subject matter of this litigation. The only allegedly infringing product in this litigation is Eon's cyclosporin capsules. Thus, Eon's consideration of possible alternatives in a business context to its cyclosporin capsules is

not "subject matter" within the scope of discovery. Accordingly, the Court will deny Novartis' Motion To Compel (D.I. 139) to the extent it seeks documents responsive to request numbers 41 and 47, and will grant Eon's Motion For A Protective Order (D.I. 121) to the extent it seeks to vacate paragraphs 8, 9, and 10 of Novartis' 30(B)(6) Deposition Notice.

B. Whether Eon Is Required To Produce Materials Received From Michael R. Violante

Novartis moves to compel all documents Eon has received from Michael R. Violante, a third-party witness whom Eon contends performed activities in the late 1980s relevant to the validity of the '382 Patent. (D.I. 145 at 10). During discovery, Eon served a Rule 45 subpoena for documents and a deposition on Mr. Violante. (D.I. 145 at 11). Three days before Mr. Violante's scheduled deposition, Eon withdrew its subpoena. (D.I. 145 at 11). Prior to Eon's withdraw of its subpoena, Mr. Violante produced documents to Eon. (D.I. 145 at 11). Novartis contends that Eon has failed to produce all of these documents, and has now filed this Motion To Compel. (D.I. 145 at 11, 28)

In opposition, Eon contends that it has already produced all of the documents it has received from Mr. Violante. (D.I. 152 at 8). Eon further contends that any additional documents it may receive from Mr. Violante will be produced, to the extent that Eon intends to rely on such documents at trial. (D.I. 152 at 8).

The Federal Rules of Civil Procedure allow for a broad scope of discovery. Specifically, under Rule 26(b)(1), the parties "may obtain discovery regarding any matter ... that is relevant to the claim or defense of any party.... Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed.R.Civ.P. 26(b)(1).

The Court finds that all documents Eon has received or will receive from Mr. Violante are discoverable pursuant to Federal Rule of Civil Procedure 26(b)(1), regardless of whether Eon intends to rely upon such documents at trial. Eon invoked the Court's subpoena power to obtain documents from Mr. Violante because Eon initially contended that Mr. Violante performed activities relevant to the validity of the '382 Patent. Because the validity of the '382 Patent is highly relevant to this litigation, the Court finds that any documents Eon has received or will receive from Mr. Violante must be produced. However, because the Court is convinced that all documents Eon has received from Mr. Violante have already been produced, the Court will deny Novartis' Motion To Compel and, in the event Eon receives additional documents from Mr. Violante, Eon is required to produce the same.

C. Whether Eon Is Required To Produce The "Hexal File"

Novartis moves to compel Eon to produce all documents in the

"Hexal File." The "Hexal File" is a shorthand term used in a technology license between Eon and Hexal AG (hereinafter "Hexal"), a non-party German Corporation, to describe various kinds of technical information. The Product Royalty Agreement between Eon and Hexal defines the term "Hexal File" as follows:

(b) The term 'Hexal File' shall mean any and all technology, formulations, regulatory dossiers, technical information, manufacturing processes and other know-how and intellectual property rights, including the patents listed on Schedule A hereto, in any way relating to cyclosporin and with respect to which Hexal now has, or hereafter obtains, any right, title or interest.

(D.I. 146, Ex. A). The Agreement grants Eon the right to use Hexal's technical information which comprises of the "Hexal File" in developing products for sale in the United States. (D.I. 152 at 9).

Novartis contends that Eon's license to access Hexal File documents makes every Hexal File document discoverable. (D.I. 156 at 13). Specifically, Novartis contends that all documents covered by the Hexal File are relevant to this litigation and are within the "custody" of Eon because Eon has a legal right to obtain these documents pursuant to the Product Royalty Agreement. (D.I. 156 at 13).

In opposition, Eon contends that it has produced all Hexal File documents in its possession which were used in filing its application for FDA approval and in formulating and developing its accused products. Additionally, Eon contends that Novartis'

Motion finds no support in the Federal Rules of Civil Procedure, as it demands that Eon request information, which has not been used in connection with the accused products, from a non-party who is a potential competitor of Novartis in Europe.

Federal Rule of Civil Procedure 34(a) permits a party to serve a request for production of documents which are within the scope of discovery and "which are in the possession, custody or control of the party upon whom the request is served." Fed. R. Civ. P. 34(a). If a corporate entity is deemed to be in "control" of documents sought, a district court can compel the production of those documents, regardless of whether they are also in the possession and control of a non-party. See Pennwalt Corp. v. Plough, Inc., 85 F.R.D. 257, 263 (D. Del. 1979) (holding that "this occurs most often when a parent corporation is requested to produce documents of a wholly-owned subsidiary"). However, in cases in which the corporate entities are not parent and subsidiary, production is rarely ordered, unless the respective business operations of each entity "are so intertwined as to render meaningless their separate corporate identities." Id.

The Court finds that Novartis' Motion To Compel Eon to produce all Hexal File documents is beyond the scope of the Federal Rules of Civil Procedure. Eon contends and Novartis does not dispute that all Hexal File documents in Eon's possession

have been produced. Additionally, the parties do not dispute that the remainder of the Hexal File documents are in the possession and control of non-party Hexal. Because Novartis has presented no evidence that the respective business operations of Eon and Hexal "are so intertwined as to render meaningless their separate corporate identities," the Court concludes that Eon is not in "control" of the remaining Hexal File documents. Accordingly, Novartis' Motion To Compel all Hexal File documents will be denied.

III. CONCLUSION

For the reasons discussed, the Court will deny the remaining portions of Novartis' Motion To Compel Discovery Materials Improperly Withheld by Eon (D.I. 139), and will partially grant Eon's Motion For A Protective Order To Vacate, In Part, A Rule 30(B)(6) Deposition Notice (D.I. 121).

An appropriate Order will be entered.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS :
CORPORATION, NOVARTIS AG, :
NOVARTIS PHARMA AG, and :
NOAVRTIS INTERNATIONAL :
PHARMACEUTICAL LTD., :
 :
 :
Plaintiff, :
 :
 :
v. : Civil Action No. 00-800-JJF
 :
 :
EON LABS MANUFACTURING, INC., :
 :
 :
Defendant. :

ORDER

At Wilmington this 28th day of March, 2002, for the reasons set forth in the Memorandum Opinion issued this date, IT IS HEREBY ORDERED that:

- 1) Novartis' Motion To Compel (D.I. 139) documents responsive to Request Numbers 41 and 47 is **DENIED**;
- 2) Novartis' Motion To Compel (D.I. 139) all documents Eon has received from Michael R. Violante is **DENIED**, provided that any additional documents that Eon may receive from Mr. Violante shall be produced within ten (10) days from the date of receipt;
- 3) Novartis' Motion To Compel (D.I. 139) all Hexal File documents is **DENIED**;
- 4) Eon's Motion For A Protective Order (D.I. 121) is **DENIED** to the extent it seeks to vacate the portions of

Novartis' 30(B)(6) Deposition Notice which request testimony from Eon on materials underlying Eon's advice of counsel defense;

- 5) Eon's Motion For A Protective Order (D.I. 121) is **GRANTED** to the extent it seeks to vacate paragraphs 8, 9, and 10 of Novartis' 30(B)(6) Deposition Notice.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE