UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

IN RE APPLICATION OF ELI LILLY AND COMPANY AND ELI LILLY, CANADA INC. FOR ORDER TO OBTAIN DISCOVERY FOR USE IN ACTION PENDING BEFORE THE FEDERAL COURT OF CANADA	:	NO. 3:09MC296(AWT)

RULING ON MOTION TO COMPEL

Pending before the court is a motion filed by Eli Lilly and Company and Eli Lilly Canada ("Lilly") to compel production of documents and deposition testimony from Chemwerth Inc. (Doc. #7.) After careful consideration of the arguments made in the papers and in oral argument, the court grants the motion.

I. Background

This motion arises from patent infringement litigation in Canada. In the underlying Canadian litigation, the plaintiff Lilly alleges that the defendant Hospira Healthcare Corp. ("Hospira") infringed Lilly's patented process for manufacturing the chemical compound gemcitabine hydrochloride, the active pharmaceutical ingredient in a chemotherapy agent. See Eli Lilly Canada Inc. and Eli Lilly and Company v. Hospira Healthcare Corp., No. T-1773-07. Lilly alleges that its patent covers the only processes that can produce commercial quantities of gemcitabine in an efficient and cost effective manner. (Doc. #7b, Ex. F, Sec. Amended St. of Claims ¶20.) The patented process is known as the S_N2 process. The defendant Hospira purchases the gemcitabine it uses in Canada from a Connecticut company called Chemwerth. Chemwerth in turn

obtains the gemcitabine from a manufacturer in China, Jiangsu Hansen Pharmaceutical ("Hansen"). Neither Chemwerth nor Hansen are parties to the Canadian litigation. In this motion, Lilly seeks discovery from Chemwerth.

According to the Canadian court, the central issue in Lilly's patent case against Hospira is "whether the process used by Hospira's supplier, [Hansen], to manufacture in China the bulk gemcitabine subsequently imported and sold by Hospira in Canada infringes the claims of the patent at issue." (Doc. #7b, Ex. H, Order at 2.) The defendant Hospira contends that Hansen, its manufacturer, does not use the patented S_N2 process but uses a different process, known as the S_N1 reaction. It is undisputed that the S_N1 reaction is non-infringing.

Lilly sought discovery from Hospira regarding the process its manufacturer Hansen used to make the gemcitabine Hospira sold in Canada. (Doc. #7b, Ex. H at 3.) Specifically, Lilly requested "batch production records[1] and related certificates of analysis for the gemcitabine product actually imported and offered for sale in Canada by Hospira." (Id.) The Canadian court noted that Hospira did not dispute that the batch records "would constitute direct evidence of the process Hansen actually used in manufacturing the

[1]According to Hospira, a drug manufacturer creates batch records for the gemcitabine hydrochloride that it manufactures. Batch records identify the manufacturer and "may indicate the manufacturing process." (Doc. #13, Hospira Opp'n at 3 n2.)

bulk gemcitabine." (Doc. #7b, Ex. H at 3.) On June 19, 2009, the Canadian court ordered Hospira to produce, inter alia, "batch records and certificates of analysis for the bulk gemcitabine imported and sold in Canada by Hospira."[2] (Doc. #7b, Ex. H at 11.)

In response, Hospira produced certificates of analysis and one batch record. (Doc. #13, Def's Opp'n at 4, Chan Decl. ¶¶7-8.) Dissatisfied with Hospira's production on the grounds the documents did not "indicate which batches have been imported into Canada or show the process used to make any of those batches," (doc. #18 at 3) Lilly seeks discovery from Chemwerth, who sold the gemcitabine to Hospira. Chemwerth, in addition to being Hansen's exclusive sales agent for North America, is Hansen's regulatory agent and assisted Hansen in an 2008 inspection by the FDA of Hansen's gemcitabine manufacturing site in China. To obtain discovery from Chemwerth, Lilly filed in this court an "Ex Parte Application for Order Pursuant to 28 U.S.C. § 1782(a) to Obtain Discovery for Use in Action Pending Before the Federal Court of Canada." (Doc. #1.) Section 1782(a) provides in pertinent part:

> The district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal, including criminal investigations conducted before formal accusation.

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[2]Hospira appealed and on December 31, 2009, the Federal Court of Canada dismissed the appeal. Hospira indicates that it is appealing the decision to the Canadian Federal Court of Appeal. (Doc. #23.)

In its application, Lilly requested that the court authorize the issuance of a subpoena to Chemwerth to obtain evidence for use in its patent infringement litigation against Hospira in Canada. The subpoena, which Lilly attached to its motion, contains four production requests and five deposition topics. (Doc. #1, Ex. B.)

The court (Thompson, C.J.) granted Lilly's application. (Doc. #3.) To address potential concerns by Chemwerth regarding confidentiality, Lilly sent Chemwerth a proposed protective order. Chemwerth served objections to the subpoena and did not produce any documents. The plaintiff in turn filed the instant motion to compel. In response, Hospira filed a memorandum in opposition,[3] which Chemwerth joined. (Doc. #13, 14.)

II. Discussion

Production Request 1:

In production request 1, Lilly seeks batch records and certificates of analysis for gemcitabine made by Hansen that Chemwerth sold to Hospira for the Canadian market.[4] Hospira does not dispute that the information requested is relevant. It argues, however, that the court should deny Lilly's motion to compel

[3]Lilly does not contest that Hospira has standing to oppose Lilly's motion to compel directed at Chemwerth.

[4]In its brief and during oral argument, Lilly clarified that its request is limited to batch records and certificates of analysis for commercial quantities of gemcitabine that Chemwerth sold or assisted in selling to Hospira in Canada. (Doc. #18 at 2 fn. 2; tr. at 36, 41.)

because the information is available to the Canadian court through Hospira. (Doc. #13, Hospira Opp'n at 6.)

Section 1782 "authorizes, but does not require, a federal district court to provide judicial assistance to foreign or international tribunals or to 'interested person[s]' in proceedings abroad." Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 247 (2004). In Intel Corp., 542 U.S. 241 (2004), the Supreme Court identified various factors to assist district courts in determining whether to exercise that discretion in favor of granting a § 1782 application[5]:

> (1) Whether the documents or testimony sought are within the foreign tribunal's jurisdictional reach, and thus inaccessible absent § 1782 aid;
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> (2) The nature of the foreign tribunal, the character of the proceeding underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance;
>
> (3) Whether the § 1782 request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States; and
>
> (4) Whether the subpoena contains unduly intrusive or burdensome requests.

In re Microsoft Corp., 428 F. Supp.2d 188, 192-93 (S.D.N.Y. 2006)

[5]Hospira does not dispute that the statutory requirements of § 1782 are satisfied: (1) that the entity from whom discovery is sought reside (or be found) in the district of the district court to which the application is made, (2) that the discovery be for use in a proceeding before a foreign tribunal, and (3) that the application be made by a foreign or international tribunal or "any interested person." Application of Esses, 101 F.3d 873, 875 (2d Cir. 1996).

(citing Intel Corp., 542 U.S. 241 (2004)).

The first discretionary factor asks the court to evaluate whether the documents or testimony sought by the application are within the foreign tribunal's jurisdictional reach, and thus accessible absent resort to § 1782. Microsoft, 428 F. Supp.2d at 192-93. Hospira argues that this factor weighs against granting discovery because the batch records and certificates of analysis for the gemcitabine it sold in Canada are available to the Canadian court. (Doc. #13 at 6.) In support of its argument, Hospira proffers the declaration of its Executive Vice President Song Lin, who states that Chemwerth "does not regularly maintain batch records for each batch distributed by Hansen to its customers." (Lin Decl. ¶3.) According to Lin, Chemwerth requested that Hansen produce batch records for gemcitabine manufactured for Hospira and intended for the Canadian market and in response to its request, received one batch record. (Id. at ¶4.) Hospira maintains that Lilly's request to Chemwerth is futile and cumulative.

Lilly responds that Lin's declaration is ambiguous as to whether Chemwerth has batch records for some batches it sold to Hospira. (Doc. #26, Tr. at 17.) Lilly points to Lin's statement that "[t]here are no other batch records for gemcitabine to be sold in Canada that are in Chemwerth's possession, custody or control." (Lin Decl. ¶4.) Lilly argues that this statement "leaves the possibility that Chemwerth has batch records for gemcitabine that

had been sold to Hospira." (Doc. #18 at 2.)

Based on the record before it, the court is not persuaded that Lilly's request for indisputably relevant records should be denied on the grounds that it is futile and/or cumulative.

Hospira next argues that the request should be denied because any records held by Hansen in China are beyond the reach of § 1782. (Doc. #13 at 14.) Lilly makes clear in response, however, that at this juncture, it is not seeking an order that Chemwerth obtain documents from Hansen located in China. (Doc. #18 at 9; tr. at 13.) Rather, it is seeking records that Chemwerth has. Request 1 is granted.

Production Requests 2 and 3 and Deposition Topics 1 and 2

As indicated, in 2008 Chemwerth assisted Hansen in an FDA inspection of Hansen's gemcitabine manufacturing site in China. In requests 2 and 3, Lilly seeks batch records and certificates of analysis shown to or prepared to be shown to the FDA in connection with this inspection and the process information submitted to the FDA as part of Hansen's Drug Master File ("DMF") regulatory submission for gemcitabine. In deposition topics 1 and 2, Lilly seeks testimony regarding Hansen's commercial manufacturing process and the FDA's 2008 inspection of Hansen.

Hospira argues that the requests are not limited to the gemcitabine that Hansen manufactured for Hospira for sale in Canada. The requests "relate not to the Canadian market but to the

United States." (Doc. #13 at 11.) Hospira contends that information about the process that Hansen uses to produce gemcitabine for other companies and/or other countries is not relevant to the process Hansen uses to manufacture gemcitabine for Hospira for the Canadian market.

Lilly counters that Hansen's manufacturing process is relevant because the court "can reasonably infer that a commercial manufacturer of bulk chemical product would use materially the same commercial process for the countries of North America." (Doc. #18 at 7.) In support, Lilly offers the declaration of its expert, Dr. Luke, who opines that a commercial manufacturer of an active pharmaceutical ingredient such as gemcitabine for sale to customers for use in pharmaceutical products in the United States and other countries likely would use the same commercial process to manufacture the ingredient for sale to customers for those uses." (Doc. #18, Luke Decl. ¶18.)

"The proper scope of the discovery sought under section 1782, like all federal discovery, is governed by Federal Rule 26(b)." In re Application Pursuant to 28 U.S.C. Section 1782, 249 F.R.D. 96, 106 (S.D.N.Y. 2008). The court is persuaded that information as to the commercial manufacturing process Hansen uses to make gemcitabine for the United States is relevant.

Chemwerth argues that the motion should nevertheless be denied because the information regarding Hansen's method for making

gemcitabine for customers other than Hospira is confidential. (Doc. #14 at 2.) It argues that if ordered to produce the information, it will "lose control" of the information and that a protective order "would not mitigate its concern" as the action is pending in Canada. (Id.; doc. #26, Tr. at 44.) Lilly notes that it has offered to enter into a protective order, but that Chemwerth has failed to respond to its proposal. Chemwerth has not pointed the court to any authority in which a court in an § 1782 proceeding has sustained such an objection to the production of relevant material and it has not sustained its burden, as the party resisting discovery, of showing why the requests should be denied. See Minatec Finance S.A.R.L. v. SI Group Inc., 1:08-CV-269 (LEK/RFT), 2008 WL 3884374, at *9 (N.D.N.Y. Aug. 18, 2008)("the beauty of § 1782 is that it permits this Court to impose a protective order that would extinguish any concern that privileged, confidential, or proprietary information would be indecorously revealed"). Requests 2 and 3 and deposition topics 1 and 2 are granted.

Request 4 and deposition topic 5:

In production request 4, Lilly seeks agreements between Chemwerth and Hansen for Chemwerth to serve as Hansen's North America gemcitabine sales agent and to assist Hansen with regard to the FDA in Hansen's manufacture of gemcitabine. In deposition topic 5, Lilly seeks testimony regarding "Chemwerth's relationships

and agreement with Hansen concerning gemcitabine, including Chemwerth's ability to obtain documents from Hansen concerning Hansen's processes for commercially manufacturing gemcitabine." Hospira argues that these requests should be denied because even assuming arguendo Chemwerth has control over Hansen's documents, the court cannot compel their production because § 1782 may not be used to seek discovery of documents held outside the United States and cites as support In re Godfrey, 526 F. Supp.2d 417, 423 (S.D.N.Y. 2007) ("for purposes of § 1782(a), a witness cannot be compelled to produce documents located outside of the United States").

The court is persuaded that documents regarding Chemwerth's control and ability to obtain relevant documents from Hansen are relevant. See In re Application of Gemeinshcaftspraxis Dr. Med. Schottdorf, No. Civ. M19-88 (BSJ), 2006 WL 3844464, at *5 (S.D.N.Y. Dec. 26, 2006) (concluding that § 1782(a) does not require that the documents sought to be discovered be found in the district). Production request 4 and deposition topic 5 are granted.

Deposition topics 3 and 4

Deposition topics 3 and 4, which seek testimony as to Chemwerth's search for and production of responsive documents as well as their authenticity and contents, are granted.

III. Conclusion

For these reasons, Lilly's "Motion to Compel Production of

Documents and Deposition Testimony from Third Party Chemwerth, Inc." (doc. #7) is granted.

SO ORDERED at Hartford, Connecticut this 15th day of June, 2010.

_____/s/_____
Donna F. Martinez
United States Magistrate Judge