UNITED STATES DISTRICT COURT

Northern District of California

Oakland Division

DEPOMED, INC.,

Plaintiff,

v.

LUPIN PHARMACEUTICALS, INC., et al.,

Defendants.
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No. C 09-05587 LB

ORDER REGARDING THE PARTIES' JOINT DISCOVERY LETTER DATED JANUARY 17, 2012

I. INTRODUCTION

This is an action under the Hatch-Waxman Act[1] that arises out of Defendants Lupin Pharmaceuticals, Inc. and Lupin Limited's (collectively, "Lupin") desire to market a generic version of Plaintiff Depomed, Inc.'s ("Depomed") Glumetza® product. A dispute has arisen over whether, and/or to what extent, Lupin must respond to certain of Depomed's document requests and its noticed Rule 30(b)(6) deposition topics. Upon review of the parties' joint discovery letter dated January 17, 2012 and relevant legal authority, the court ORDERS Lupin to respond to Depomed's document requests and deposition notice in the manner described below for the products that are the subject of ANDA No. 91-664.

[1] *See* "Drug Price Competition and Patent Term Restoration Act of 1984," Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282) ("Hatch-Waxman Act").

II. BACKGROUND[2]

Depomed is a specialty pharmaceutical company that designs, develops, and markets pharmaceutical products utilizing optimized drug delivery technologies. Its three patents-in-suit focus on the development of a gastric-retentive drug delivery system designed as a conventionally-sized pill, which swells over time in the stomach, thus providing continuous and controlled drug delivery to the patient's upper gastrointestinal ("GI") tract.

U.S. Patent Nos. 6,340,475 ("the '475 patent") and 6,635,280 ("the '280 patent"), both entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode," were issued to Depomed as assignee of the inventors on January 22, 2002, and October 21, 2003, respectively. The invention of the '475 and '280 patents relates to an oral drug dosage form (a dosage form that is swallowed or ingested – typically, one or more tablets), which benefits from a prolonged period of controlled release in the upper GI tract, and from an enhanced opportunity of absorption in the upper GI tract rather than in the lower portions of the GI tract. The controlled release oral dosage form (described in Claim 1 of the '475 and '280 patents) comprises a drug dispersed within a polymeric matrix. This polymeric matrix has a special property of being able to absorb or imbibe water, thereby causing the dosage form to increase in size and, in turn, retard the rate of release of drug from the swollen dosage form.

U.S. Patent No. 6,448,962 ("the '962 patent"), entitled "Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms," was issued to Depomed as assignee of the inventors on December 3, 2002, and arises out of an application filed in June 2000. The invention of the '962 patent discloses an improvement over the '475 and '280 patents by extending gastric retention of a dosage form by using particular shapes, sizes, and swelling properties. The particular shape of these dosage forms and the minimum dimensions of the dosage form increase gastric retention over the dosage forms of the '475 and '280 patents.

With these patents, Depomed commercialized Glumetza® – a product used to treat adults diagnosed with type-2 diabetes. Glumetza® contains the drug metformin HCL, formulated in

[2] In drafting this section, the court relied heavily on Judge Hamilton's factual description in her Order Construing Claims dated May 17, 2011. *See* 5/17/2011 Order, ECF No. 107.

extended controlled-release 500 mg. and 1000 mg. tablets.

In 2009, Lupin, which is in the business of making and selling generic pharmaceutical products, submitted Abbreviated New Drug Application ("ANDA") No. 91-664 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market generic metformin HCL extended-release tablets in the 500mg and 1000mg dosage strengths. In November of that year, Lupin sent Depomed written notification that Lupin had filed the ANDA. It also asserted that the '475, '280, and '962 patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin products covered by the ANDA. Following this notification, Depomed filed the present lawsuit. Original Complaint, ECF No. 1.[3]

Discovery has been open since March 2010. *See* 3/18/2010 Minute Order, ECF No. 52. On May 17, 2010, Depomed served contention interrogatories on Lupin. James Declaration, Ex. 2, ECF No. 131-3. Lupin responded to these interrogatories on July 2, 2010. *Id*., Ex. 3, ECF No. 131-4. Over a year later, on August 26, 2011, Lupin supplemented its original interrogatory responses. *Id*., Ex. 4, ECF No. 131-5. In these supplemental responses, Lupin contended that Lupin's accused products do not infringe Depomed's patents-in-suit in part because Lupin's products use a "reservoir system," rather than a polymeric "matrix system" as claimed in the patents-in-suit, to extend the release of the drug. *See id*., Ex. 4, ECF No. 131-5 at 12-17.

About two months later, on October 17, 2011, Depomed served a Rule 30(b)(6) deposition notice on Lupin seeking testimony about, among other topics, Lupin's products that employ its so-called "reservoir system." *Id*., Ex. 6, ECD No. 131-7.[4] Roughly a month after that, on November 22,

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[3] Citations are to the Electronic Case File ("ECF") with pin cites to the electronic page number at the top of the document, not the pages at the bottom.

[4] Topic No. 17 is "[t]he identity, structure and formulation of each and every extended-release product, product candidate, and/or formulation that LUPIN employs or has employed for the delivery of highly soluble drugs that contains hydroxypropylmethyl cellulose as a polymer matrix with a coating that comprises Eudragit"; Topic No. 19 is "[t]he identity, structure and formulation of any LUPIN product that employs reservoir system technology, including such systems that comprise Eudragit as a coating on the tablet"; and Topic No. 20 is "[t]he identity, structure and formulation of each LUPIN product that employs or has employed for the delivery of a highly soluble drug a hydroxypropylmethyl cellulose polymer matrix." James Declaration, Ex. 2, ECF No. 131-7.

2011, Depomed served additional requests for production of documents ("RFPs") seeking similar information. *Id.*, Ex. 5, ECF No. 131-6.[5]

In December 2011, Lupin objected to both Depomed's RFPs and Rule 30(b)(6) deposition topics as being, among other things, overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence, because the RFPs and deposition topics are not limited to the Lupin product covered by its ANDA. *Id.*, Exs. 7-8, ECF Nos. 131-8, 131-9. Subject to those objections, Lupin nevertheless offered to produce responsive, non-privileged documents that relate to the products covered by the ANDA and to produce a Rule 30(b)(6) deponent to testify about the same. *Id.*, Exs. 7-8, ECF Nos. 131-8, 131-9.

On January 6, 2012, Depomed filed a motion for an order compelling Lupin to respond to the four RFPs (Nos. 72-75) and to produce a deponent for the three deposition topics (Nos. 17, 19-20) at issue. Motion to Compel, ECF No. 130. On January 9, 2012, Judge Hamilton referred the motion to this court for resolution. Order of Referral, ECF No. 136. The court dismissed Depomed's motion without prejudice and instructed the parties to comply with the discovery dispute-related procedures set forth in the undersigned's standing order. Notice of Referral, ECF No. 138. In accordance with those procedures, the parties met and conferred about the dispute, during which Lupin reiterated its previous offer and also agreed to search its files for documents directly related to a statement found in one of its produced documents. Joint Letter, ECF No. 141 at 5. Depomed rejected the offer, and the parties filed the instant joint discovery letter on January 17, 2012. *Id.*

III. LEGAL STANDARD

Subject to the limitations imposed by subsection (b)(2)(C), under Rule 26, "[p]arties may obtain

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[5] RFP No. 72 seeks "ALL DOCUMENTS RELATING TO ANY LUPIN product that employs a reservoir system as part of an extended-release or delayed-release drug dosage form"; RFP No. 73 seeks "DOCUMENTS sufficient to identify ANY LUPIN product that employs a reservoir system, or that can be characterized as employing a reservoir system, as part of an extended release or delayed-release drug dosage form"; RFP No. 74 seeks "ALL DOCUMENTS RELATING TO definitions, characteristics, formulations, methods for producing, and/or methods for using a reservoir system as part of an extended-release or delayed-release drug dosage form"; and RFP No. 75 seeks "ALL DOCUMENTS RELATING TO the use of Eudragit and/or other coatings as part of an extended-release or delayed-release drug dosage form." James Declaration, Ex. 2, ECF No. 131-6.

discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." Fed. R. Civ. P. 26(b)(1). "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id*. However, "[o]n motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues." Fed. R. Civ. P. 26(b)(2)(C).

IV. DISCUSSION

In order to resolve this dispute, the court must determine whether, and to what extent, the information sought by Depomed is relevant to any party's claim or defense. In their joint letter, Depomed contends that the information is relevant because Lupin's non-infringement position, which Lupin "grounded . . . in three pages of supplemental interrogatory response that broadly distinguished between reservoir technology and matrix-based technology," "is not limited to just the two accused products, but represents broad statements on technological approaches for developing extended-release tablets upon which its experts will surely rely." Joint Letter, ECF No. 141 at 5, 6. In other words, "Lupin has placed into issue a theory that its two accused products fall within the generic family of reservoir system, extended-release tablets as compared to the matrix family." *Id*. at 6. Thus, because "Lupin came to the development of the accused products with knowledge of the use of coatings in extended-release drugs," "Depomed seeks discovery that would specifically show Lupin's knowledge and experience regarding the reservoir system approach to extended-release tablets in comparison to matrix-based systems, and how Lupin has employed that technology for extended-release drug products." *Id*.

While Lupin has already offered to produce responsive, non-privileged documents that relate to the products covered by the ANDA and to produce a Rule 30(b)(6) deponent to testify about the

same, it disagrees that its non-infringement defense based on its use of a "reservoir system" allows Depomed "sweeping discovery on unidentified Lupin products that are not at issue in this case." *Id.* Indeed, as Lupin points out, Depomed has not identified any products (aside from the two products covered by the ANDA) that might be relevant, but instead wants to (in Depomed's words) "explore the scope and content of Lupin's institutional knowledge." *Id*. at 6, 7.

Upon consideration of the parties' arguments, the court believes that the requested information is relevant but only with respect to the two Lupin products covered by the ANDA. Depomed argues that Lupin's interrogatory responses "are not specifically tied to the two accused extended-release pharmaceutical tablets," but it is wrong. Depomed's interrogatories sought the bases for Lupin's claim that its two ANDA-covered products do not infringe Depomed's patents, and Lupin responded that its two ANDA-covered products do not infringe Depomed's patents because the two products use a "reservoir system" rather than a "matrix system." After such a response, Depomed surely is entitled to its requested information with respect to Lupin's two ANDA-covered products – the two products at issue in this case. But Lupin's insertion of a description and comparison of a "reservoir system" and a "matrix system," whether three paragraphs or three pages, does not transform its interrogatory response into a defense of all of its products, nor does it allow Depomed to mine, without restriction, Lupin's "institutional knowledge" on the subject.

V. CONCLUSION

Based on the foregoing, the court ORDERS the following:

1. With respect to RFP Nos. 72-75, Lupin shall produce responsive, non-privileged documents within its possession, custody, or control that relate to Lupin's products that are the subject of ANDA No. 91-664, to the extent that such documents exist and have not already been produced. In so producing, Lupin, per its offer in the parties' joint letter, shall search its files for documents "directly related to the following statement on LUP(GLUM)000257 that from previous formulation experience, when Hypromellose was used as [a] control release polymer for preparing a matrix, it was unable to control the burst release."
2. With respect to Topic Nos. 17, 19, and 20 of Depomed's Rule 30(b)(6) deposition notice, Lupin shall designate a witness to testify regarding relevant, non-privileged information concerning the

identity, structure, and formulation of Lupin's products that are the subject of ANDA No. 91-664. The deposition shall take place during the week of January 22, 2012, with the specific date, time and location to be determined by the parties.

This disposes of ECF No. 141.

IT IS SO ORDERED.

Dated: January 20, 2012

LAUREL BEELER
United States Magistrate Judge