

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

SHIRE DEVELOPMENT LLC,
SHIRE PHARMACEUTICAL
DEVELOPMENT INC., COSMO
TECHNOLOGIES LIMITED and
NOGRA PHARMA LIMITED,

Plaintiffs,

v.

Case No: 8:12-cv-1190-T-30AEP

MYLAN PHARMACEUTICALS INC.
and MYLAN INC.,

Defendants.

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ORDER

This matter comes before the Court on Plaintiffs' Motion to Compel Discovery (Dkt. No. 43), Defendants' response in opposition thereto (Dkt. No. 54), Defendants' Motion to Compel (Dkt. No. 48), and Plaintiffs' response in opposition thereto (Dkt. No. 56). Plaintiffs initiated this action for patent infringement under the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act based on Defendants' submission of an Abbreviated New Drug Application ("ANDA") seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic drug. (Dkt. No. 1.) Plaintiffs allege that the proposed generic drug Defendants seek to produce infringes upon Plaintiffs' patent, specifically United States Patent No. 6,773,720 (the "Patent"). (Dkt. No. 1.)

Currently, Plaintiffs seek an order compelling Defendants to provide supplemental responses to several interrogatories¹ and to provide a date to schedule a Rule 30(b)(6)

¹Specifically, Plaintiffs seek supplemental responses to interrogatories 3, 5, 7, and 9. (Dkt. No. 43 at 3.) Plaintiffs originally sought supplementation of interrogatories 1 and 8 as

deposition regarding the formulation of Defendants' proposed generic drug. (Dkt. No. 43.) On the other hand, Defendants seek an order compelling Plaintiffs to produce unredacted deposition transcripts and expert materials, including the corresponding exhibits, from three related cases² involving the Patent and to present for deposition three of the four inventors listed on the Patent. (Dkt. No. 48.)

As a result of Defendants' request to compel production of materials from related cases, nonparties Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively the "Zydus Parties") filed an objection, arguing that Defendants should proceed in the United States District Court for the District of Delaware, the court currently presiding over the Zydus Case, if they seek to obtain materials produced by the Zydus Parties in the Zydus Case. (Dkt. No. 58 at 4.) Furthermore, the Zydus Parties argue that Defendants should not be permitted to obtain the materials from the Zydus Case because the materials are highly confidential and the potential benefits gained by Defendants from obtaining these materials is minuscule compared to the harm that could occur to the Zydus Parties if the materials were released to Defendants. (Dkt. No. 58 at 5.) The Court construes the Zydus Parties' objections as a motion to intervene and motion for protective order. Similarly, nonparties Osmotica Kereskedelmi és Szolgáltató Kft, Osmotica Pharmaceutical Corp., and Osmotica Pharmaceutical Argentina S.A. (collectively the "Osmotica Parties") have filed a motion to intervene and seek a protective order to prevent Defendants from obtaining materials produced by the Osmotica Parties in the Osmotica Case, arguing, as did the Zydus Parties,

well; however, since filing the motion, Plaintiffs and Defendants have resolved the issues with respect to Defendants' responses to interrogatories 1 and 8. (Dkt. No. 57.)

²*Shire Dev. LLC et al. v. Cadila Healthcare Ltd. et al.*, No. 1:10-cv-581-KAJ (D. Del.) [hereinafter the Zydus Case]; *Shire Dev. LLC et al. v. Watson Pharm., Inc. et al.*, No. 0:12-cv-60862-DMM (S.D. Fla.) [hereinafter the Watson Case]; *Shire Dev. LLC et al. v. Osmotica Pharm. Corp. et al.*, No. 1:12-cv-904-AT (N.D. Ga.) [hereinafter the Osmotica Case].

that the potential harm resulting to the Osmotica Parties from disclosure of its confidential, proprietary information outweighs Defendants' need to obtain that information. (Dkt. No. 59.)

As an initial matter, the Court addresses the Osmotica Parties' motion to intervene (Dkt. No. 59) and the Zydus Parties' construed motion to intervene (Dkt. No. 58).³ Under Federal Rule of Civil Procedure 24(b), a party may intervene in a matter when the "disposit[ion] of the action may as a practical matter impair or impede the movant's ability to protect its interest." Here, Defendants' discovery requests, at which their motion to compel is directed, specifically seeks materials designated by the Osmotica Parties and the Zydus Parties as confidential and which allegedly contain proprietary business information. These nonparties clearly have an interest in protecting the disclosure of their confidential, proprietary business information. Accordingly, such an interest is sufficient to justify intervention under Rule 24(a). *See, e.g., Northrop Grumman Info. Tech., Inc. v. United States*, 74 Fed. Cl. 407, 414 (Fed. Cl. 2006) (stating that "trade secrets and proprietary information are the very type of interest the protection of which justifies intervention under Rule 24(a)"); *United States v. Am. Tel. & Tel. Co.*, 642 F.2d 1285, 1291 (D.C. Cir. 1980) (allowing intervention where the intervenor had an interest in protecting documents it claimed were protected by work product privilege).

Next, the Court addresses Defendants' request to compel Plaintiffs to produce materials from the Zydus Case, the Watson Case, and the Osmotica Case. In these three cases, as in this case, Plaintiffs alleged that the defendants' generic drug products infringed one or more claims of the Patent. Obviously, Plaintiffs have employed various discovery

³Defendants do not oppose the Osmotica Parties' motion to intervene, accordingly, the Court assumes that Defendants would be unopposed to the intervention of the Zydus Parties as well. (Dkt. No. 59 at 4.)

mechanisms in these cases to explore and develop their claims. In each of these cases, the respective courts entered protective orders, stipulated and agreed upon by the parties in each case, which established the conditions upon which information designated as confidential by the producing party could be disclosed. (Dkt. No. 48, Exs. H, J, K.) Both the Osmotica Parties and the Zydus Parties (collectively “the Intervenor”) argue that materials produced to Plaintiffs in the other cases contain their technical and business information, which they marked as either “Confidential” or “Highly Confidential.” Accordingly, the Intervenor contend that this Court should enter a protective order preventing Plaintiffs from disclosing those materials to Defendants.

First, however, the Zydus Parties argue that this Court is the improper venue in which Defendants should seek to compel Plaintiffs to produce materials pertaining to the Zydus Case. (Dkt. No. 58 at 3-5.) Instead, the Zydus Parties argue that Defendants should seek production of these materials from the court that issued the protective order in the Zydus Case, i.e. the United States District Court for the District of Delaware. The Court disagrees with the Zydus Parties’ assertion. In making a determination of whether material designated as confidential pursuant to another court’s confidentiality order should be produced in another matter, the first inquiry should be whether the prior confidentiality order intends to prohibit the discovery of the protected materials in other suits. In this case, the confidentiality orders specifically state, “By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case.” (Dkt. No. 48, Exs. H, J, K.) Thus, it is clear that in entering the protective orders in the other cases, the courts did not intend to limit another court’s ability to evaluate whether the information protected by the orders in those

cases should be subject to disclosure in another case, such as the one at hand. Furthermore, this Court finds useful the four “rules of reason” identified by the District Court for the District of Maryland that a court should consider when determining whether it should issue a discovery order that has the potential effect of modifying a protective order issued by another court. *Tucker v. Ohtsu Tire and Rubber Co., Ltd.*, 191 F.R.D. 495, 500-02 (D. Md. 2000). Specifically, a court should consider (1) “the nature of the protective order issued by the first court,” (2) “the identity of the party from whom the discovery is sought,” (3) “whether the case in which the original protective order was issued is still pending, and if not, whether the burden and expense to the plaintiffs if they are required to file a new action in the [first] court simply to seek modification of the [protective o]rder issued there,” and (4) “whether it is possible to incorporate terms in its own order which will further the protections originally ordered by the [first] court.” *Id.* at 501.

As in the *Tucker* case, the protective order issued in the Zydu Case was issued upon stipulation and agreement of the parties and was merely ratified by the Delaware Court. (Dkt. No. 58 at 2; Dkt. No. 48, Ex. K.) The same is true of the protective orders entered in the Watson Case and the Osmotica Case. (Dkt. No. 48, Exs. H, J.) “There is less need for deference and comity when the order involved is really an agreement by counsel approved, almost as a ministerial act, by the court, than an action directed by the court after a full consideration of the merits of a fully briefed dispute.” *Id.* Thus, the first factor weighs in favor of this Court’s consideration of the motions for protective order. Additionally, the information sought by Defendants does not belong to Plaintiffs but rather to nonparties, which slightly tips the scales against this Court’s consideration of the motion for protective order. However, because the Court has allowed the nonparties to intervene, the nonparties’ ability to

protect their interests have been appropriately preserved. Furthermore, the Court finds that Plaintiff acted in accordance with the prior protective orders by providing the Zydus Parties, Watson Parties, and Osmotica Parties with notice of Defendants' discovery requests and motion to compel. As to the third factor, each case is at a different stage of litigation. Defendants have indicated that the Osmotica Case is currently pending, the Zydus Case may have settled, and the Watson Case is on appeal following a trial and judgment in Plaintiffs' favor. (Dkt. No. 48 at 4.) It would be an undue burden on Plaintiffs to be required to file a motion for protective order in each of the three courts in which the related cases are pending. Moreover, such a method of resolving the dispute could potentially produce piecemeal results. Therefore, in the interest of comity and cohesion, this factor also weighs in favor of this Court's consideration of the motions for protective order. Finally, in the event the Court concludes that Plaintiffs should be required to provide some or all of the materials requested by Defendants, the Court can incorporate terms into its own order that will uphold the protections afforded to the nonparties under the terms of the prior protective orders. Thus, considering all four "rules of reason," the Court concludes that, despite the protective orders entered in the prior cases, the current motions for protective order are properly before this Court.

Moving to the substance of the motions for protective order, generally, parties are entitled to discovery "regarding any non-privileged matter that is relevant to any parties' claim or defense." Fed. R. Civ. P. 26(b)(1). Relevant information need not be admissible at trial if it appears reasonably calculated to lead to the discovery of admissible evidence. *Id.* Nevertheless, a court has broad discretion in setting limits on discovery, and Rule 26(c) provides a mechanism by which parties can seek an order to protect privileged or confidential

information. *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985). Specifically, Rule 26(c)(1) provides, “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” In determining whether a protective order is warranted for “good cause,” a court must balance the requesting party’s interest in obtaining the information or material sought and the other party’s interest in keeping the information confidential. *Farnsworth*, 758 F.2d at 1547.

Defendants argue that the requested materials are relevant because “at the very least, documents from the other lawsuits could expose statements and admissions useful in this case, particularly to the extent they may reveal inconsistencies in Plaintiffs’ arguments.” (Dkt. No. 48 at 2.) Defendants assert that this information is essential to their ability to prepare their defense. (Dkt. No. 48 at 12.) On the other hand, the Intervenors contend that the requested materials include proprietary commercial information, market and demographic research, product and advertising development information, and highly sensitive technical information, including product formulations. The Intervenors further argue that they directly compete with Defendants in the market, and, therefore, exposure of their confidential information to Defendants would result in detrimental harm to their proprietary interests.

Rule 26(c) permits a court to issue a protective order requiring “that a trade secret or other confidential research, development, or commercial information not be revealed or only be revealed in a designated way.” Fed. R. Civ. P. 26(c)(7).

In order to resist discovery of . . . confidential information [such as trade secrets], a party must first establish that the information sought is indeed confidential and then demonstrate that its disclosure might be harmful. Once these requirements are met, the burden shifts to the other party to establish that discovery of the trade secrets or confidential information is relevant *and necessary* to the action. The district court must then balance the need for

protection of the trade secrets against the claim of injury resulting from the disclosure. Discovery may be denied if proof of relevancy *or need* is not established, but if relevancy and need are shown, the trade secret should be disclosed.

Empire of Carolina, Inc. v. Mackle, 108 F.R.D. 323, 326 (S.D. Fla. 1985) (emphasis added).

Here, Defendants merely argue that the evidence is relevant, yet they have failed to show that the information is also *necessary* to their defense. More importantly, the Intervenors have shown that the materials requested by Defendants contain their confidential, proprietary business information, such as specific formulations of their generic-drug product, and that they would be harmed if this information was provided to Defendants, their direct competitors.⁴ Defendants have presented no compelling reason for which their interest in obtaining the information sought to be protected by the Intervenors outweighs the Intervenors' interest in maintaining the confidentiality of their proprietary business information. Accordingly, the Court finds that the Zydus Parties and the Osmotica Parties are entitled to a protective order preventing the disclosure of the materials requested by Defendants from the Zydus Case and the Osmotica Case.

However, as to the materials Defendants seek related to the Watson Parties, because the Watson Parties have not filed any opposition with the Court objecting to Defendants' request, the Court will allow the Watson parties ten days to file objections following notice by Plaintiffs of this Order.

As to Plaintiffs' and Defendants' remaining requests to compel—Plaintiffs' requests to compel Defendants to provide supplemental answers to interrogatories 3, 5, 7, and 9 and to schedule a 30(b)(6) deposition and Defendants' request to compel Plaintiffs to present for deposition three of the four inventors listed on the Patent (Dkt. Nos. 43, 48)—a hearing is

⁴As highlighted by the Zydus and the Osmotica Parties, Defendants sought to protect as confidential this very same information from disclosure in this case. (*See* Dkt. No. 31.)

scheduled for January 10, 2014, at 2:00 p.m. in Tampa Courtroom 10A before Magistrate Judge Anthony E. Porcelli.

Accordingly, after due consideration, it is hereby

ORDERED:

1. The Osmotica Parties' Motion to Intervene and Motion for a Protective Order (Dkt. No. 59) is GRANTED.

2. The Zydus Parties' construed motion to intervene and motion for protective order (Dkt. No. 58) is GRANTED.

3. Defendants' Motion to Compel (Dkt. No. 48) is DENIED IN PART as to their request to obtain unredacted deposition transcripts with exhibits and expert materials with exhibits from the Zydus Case and the Osmotica Case. Defendants' request to obtain these materials as to the Watson Parties shall be considered following expiration of the Watson Parties' period to respond.

4. Plaintiffs are directed to serve a copy of this Order on the Watson Parties within three (3) days from the date of this Order. The Watson parties shall have ten (10) days from service of the Order to file any objections to Defendants' request. If no objections are filed, Plaintiffs may be directed to disclose the materials from the Watson Case requested by Defendants.

5. A hearing is scheduled for January 10, 2014, at 2:00 p.m. in Tampa Courtroom 10A before Magistrate Judge Anthony E. Porcelli. At the hearing the Court will consider the parties remaining requests, i.e. Plaintiffs' requests to compel Defendants to provide supplemental answers to interrogatories 3, 5, 7, and 9 and to schedule a 30(b)(6) deposition and Defendants' request to compel Plaintiffs to present for deposition three of the four

inventors listed on the Patent. Any party who seeks to appear telephonically for the hearing shall notify the chambers of Magistrate Judge Anthony E. Porcelli at 813-301-5540 at least twenty-four hours prior to the hearing. Once notice has been given, the party may appear telephonically at the hearing by calling toll-free number 1-888-684-8852 on the day of the hearing and entering access code 8895301 followed by security code 0110 upon request.

DONE AND ORDERED in Tampa, Florida, this 30th day of December, 2013.



ANTHONY E. PORCELLI
United States Magistrate Judge

cc: Counsel of record