

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTELLAS PHARMA INC., ASTELLAS)
IRELAND CO., LTD., and ASTELLAS)
PHARMA GLOBAL DEVELOPMENT,)
INC.,)

Plaintiffs,)

v.)

ACTAVIS ELIZABETH LLC, et al.,)

Defendants.)

Civil Action No. 16-905-SLR-CJB
CONSOLIDATED

MEMORANDUM ORDER

At Wilmington this **20th day of July, 2017**.

WHEREAS, on July 19, 2017 the Court held a teleconference regarding protective order disputes between Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, “Plaintiffs”), and Defendants Actavis Elizabeth LLC, Lupin Ltd., Lupin Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA), Inc., Cadila Healthcare Ltd. (d/b/a Zydus Cadila), Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Princeton Pharmaceutical Inc., Sawai Pharmaceutical Co., Ltd., Sawai USA, Inc., Sandoz, Inc., Apotex Inc. and Apotex Corp. (collectively, “Defendants”)¹;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. As to the parties’ first dispute, which relates to production of non-party confidential information pursuant to the Protective Order, the Court will ADOPT Plaintiffs’

¹ Plaintiffs and Defendant Windlas Healthcare Pvt. Ltd. (“Windlas”) are bound by the Stipulation and Order to Stay Claims and Be Bound By Result in Litigation, dated July 11, 2017. (D.I. 60; *see also* D.I. 61 at 1 n.1) Windlas did not participate in the teleconference.

proposed language. (*See* D.I. 61, ex. 1 at ¶ 3)² This dispute is really about the process by which confidential third-party information that is in Defendants’ possession will be disclosed or withheld, and the burdens associated with the process for producing or withholding such information. The Court finds that Plaintiffs’ proposal best accomplishes the goals of facilitating the efficient flow of discovery, while also providing a full and fair mechanism for non-parties to intervene and object to the disclosure of their confidential information.

2. The parties’ second dispute relates to the disclosure of Plaintiffs’ confidential information between Defendants. As to this dispute, the Court will again ADOPT Plaintiffs’ proposed language. (*See id.* at ¶ 10) That language specifies that the proposed restrictions shall apply only to confidential information “that relates *solely* to the validity, enforceability or infringement of [United States] Patent No. 6,346,532 (the '532 patent)[.]” (*Id.* (emphasis added)) It is not disputed that if Plaintiffs possess records that do in fact relate *solely* to the validity, enforceability or infringement of the '532 patent, then the Defendant Groups that are not asserting that the '532 patent is invalid, unenforceable, and/or not infringed would have no right to such documents under Federal Rule of Civil Procedure 26, since the records would not be “relevant to any [of those Defendant Group’s] claim[s] or defense[s.]” Fed. R. Civ. P. 26(b). And the Court finds that Plaintiffs’ proposal provides the best way for the parties to identify and tee up with the Court any disputes about whether a record falls into this category, and whether it may be shared with certain other Defendants.

3. With regard to the parties’ third dispute, which relates to the disclosure by

² The parties shall change the phrase “the Court shall order production of” in Plaintiffs’ proposal to “the Producing Party shall produce[.]”

Plaintiffs of Defendants' confidential information between other Defendants, the Court will ADOPT Defendants' proposed language. (*See* D.I. 61, ex. 1 at ¶ 10) In balancing here between the competing interests of (1) litigation-related efficiency and (2) protecting the parties' confidential information, the Court errs on the side of the latter. The Court notes that Defendants' proposed language is consistent with other Protective Orders in ANDA cases within this District. *See, e.g., AstraZeneca LP v. Sigmapharm Labs., LLC*, Civil Action No. 15-1000-RGA (D. Del. Apr. 26, 2016) (D.I. 71 at ¶ 16); *Forest Labs., LLC v. Apotex Corp.*, Civil Action No. 15-18-GMS (D. Del. Sept. 18, 2015) (D.I. 48 at ¶ 19).

4. As to the parties' final dispute, which concerns participation in post-grant proceedings by those with access to confidential information, the Court will ADOPT Plaintiffs' proposed language, and DENY Defendants' request to preclude Plaintiffs' trial counsel from "providing recommendations regarding drafting, crafting, or amending of patent claims" in any post-grant proceedings with respect to patents involving mirabegron. (D.I. 61, ex. 1 at ¶ 10(A)) In adjudicating disputes over what kind of prosecution bar should be entered, the Court must balance (1) any unacceptable risk of inadvertent disclosure or competitive use of confidential information against (2) the potential harm the party affected by the portion of the bar at issue would face were that portion adopted, and were it denied its counsel of choice. *See Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, Civil Action No. 15-691-LPS-CJB, 2016 WL 447794, at *1 (D. Del. Feb. 4, 2016) (hereinafter, "TSST-K") (citing *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1379-80 (Fed. Cir. 2010)). It is Defendants' burden to show good cause for its proposed provision effecting a prosecution bar. *See, e.g., id.* at 1 n.1; *Xerox Corp. v. Google, Inc.*, 270 F.R.D. 182, 183-84 (D. Del. 2010). And here, there is very little

concrete evidence in the record regarding either (1) the risk of inadvertent disclosure or competitive use of confidential information, or (2) the potential harm that Plaintiffs would suffer were they to be denied the counsel of their choice. The Court is also cognizant that “it is hard to dispute that the magnitude of [the risk of inadvertent disclosure of or competitive use of confidential information] is far less pronounced with respect to an IPR proceeding (in which [the patentee’s] claims may be only narrowed, not enlarged) as compared to the prosecution of a new patent[.]” *TSST-K*, 2016 WL 447794, at *2 (citations omitted). In light of this, and the lack of record evidence on the issue, the Court finds that Defendants have not met their burden here. However, the Court will consider a request to modify the Protective Order in the future as to this issue, if the evidence warrants it. *Cf. Boston Scientific Corp. v. Cook Group Inc.*, Civil Action No. 15-980-LPS-CJB (D. Del. Apr. 18, 2016) (D.I. 36 at ¶ 9).

5. The parties are ORDERED to submit a final proposed Protective Order, incorporating the above decisions, by no later than **July 27, 2017**.



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE