HEYMAN ENERIO GATTUSO & HIRZEL LLP
PRACTICING THE ART OF LAW

300 DELAWARE AVENUE • SUITE 200 • WILMINGTON, DELAWARE 19801
TEL: (302) 472.7300 • FAX: (302) 472.7320 • WWW.HEGH.LAW

Direct Dial: (302) 472-7311
Email: dgattuso@hegh.law

July 13, 2017

VIA CM-ECF & HAND DELIVERY

The Honorable Christopher J. Burke
J. Caleb Boggs Federal Building
844 N. King Street
Unit 28
Room 2325
Wilmington, DE 19801-3555

Re: *Astellas Pharma Inc., et al. v. Actavis Elizabeth LLC, et al.*, C.A. No. 16-905-SLR-CJB

Dear Judge Burke:

I write as counsel along with Rakoczy Molino Mazzochi Siwik LLP on behalf of defendant Sandoz Inc. in the above-referenced action. We submit this opening letter on behalf of all defendants in this consolidated action pursuant to the Court's July 7, 2016 Oral Order, regarding the parties' disputes concerning the proposed Protective Order.

1. Disclosure by Plaintiffs of a Defendant's Confidential Information to Other Defendants.

Plaintiffs have refused to keep each Defendant's Confidential Information confidential from other Defendants. Documents so designated contain each Defendant's highly confidential competitive business information, and Defendants' request that this information not be shared amongst Defendants—who remain potential competitors—accords with the spirit of the Protective Order without overly burdening Plaintiffs.

Plaintiffs' opposition appears centered on a purely speculative contention—the suggestion that one or more Defendants' Confidential Information *may be* relevant to issues related to purported secondary considerations of the Patents-in-Suit. To the extent that this highly improbable event does occur later in the litigation, it can be addressed at that time on a case-by-case basis. At this stage of the litigation, however, the very real harm of sharing a Defendant's Confidential Information with direct competitors decidedly outweighs the speculative nature of Plaintiffs' proposed language. *See Prism Techs., LLC v. AT&T Mobility, LLC*, No. 12-122, 2013 U.S. Dist. LEXIS 2726, at *11-14 (D. Neb. Jan. 8, 2013) (recognizing that it would not be appropriate to allow a party to disclose information between the parties). Provisions such as those proposed by Defendants are routinely granted in this jurisdiction. *See, e.g.*, Stipulated Protective Order at 14-15, *AstraZeneca LP v. Sigmapharm Labs., LLC*, No. 15-cv-01000-RGA (D. Del. Apr.

26, 2016), D.I.; Stipulated Protective Order at 9, *Forest Labs., LLC v. Apotex Corp.*, No. 15-018-GMS (D. Del. Sept. 18, 2015), D.I. 48.

2. Disclosure of Plaintiffs' Confidential Information Between Defendants.

In Paragraph 10, Plaintiffs essentially seek to bifurcate and preclude discovery from all Defendants on one Orange Book patent (the '532 patent), which Defendants agree has only been asserted against two Defendants. The '532 patent, however, is prior art to the remaining Orange Book Patents-in-Suit. Given the highly relevant nature of this patent, Plaintiffs' proposed insertion of this language into the Protective Order amounts to an unusual and inappropriate request for the Court to cordon off the majority of Defendants from discovery that would otherwise be appropriate. All discovery relating to the '532 patent, regardless of who it is asserted against, pertains to the invalidity of the compounds and methods claimed. Plaintiffs should not be permitted to use a protective order to preclude sharing of relevant discovery regarding the '532 patent.

Indeed, Plaintiffs have not demonstrated how they are harmed by allowing all Defendants to participate in discovery related to the '532 patent to the extent Defendants choose to do so. Nor can Plaintiffs point to any applicable precedent supporting the inclusion of such a restriction.

Plaintiffs have already advised that they do not intend to share information and documents related to the '532 patent with all Defendants. After failing in their request that the Court adopt a Scheduling Order that bifurcated discovery between the '532 patent and the other Patents-in-Suit, Plaintiffs are now trying to re-litigate that issue by restricting discovery through the Protective Order. The Scheduling Order as entered consolidates the litigation between all Defendants for all patents. Plaintiffs' renewal of their previously unsuccessful relevancy argument regarding discovery related to the '532 patent should not be heard to convert the Protective Order into a substantive order on the merits of Defendants' discovery requests.

In accordance with the Scheduling Order, Defendants are working together to streamline the litigation, including coordinating on written discovery and invalidity contentions. Defendants intend to continue to work together to streamline the litigation, but Plaintiffs' proposed provision regarding the '532 patent will only hamper the progress of this litigation, including invalidity positions, fact depositions, expert discovery, pretrial proceedings and trial. Cooperation can only continue if Defendants are not segregated by an artificial restriction on discovery relevant to all their claims and defenses.

3. Production of Non-Party Confidential Information Pursuant to the Protective Order.

In Paragraph 3 of the Protective Order, Plaintiffs propose "automatic production" of third-party Confidential Information that may be in the possession of a Defendant but belongs solely to a third party, such that the Defendant has an obligation of confidentiality with respect to the third-party Confidential Information. Defendants oppose such language and instead propose that should such third-party Confidential Information exist and the third party objects to its production, then

the Receiving Party seeking production of the same should be required to move the Court to compel production or seek such information through formal third-party discovery. Stated otherwise, if the Receiving Party seeks to obtain such third-party Confidential Information, it must do so by traditional means, either seeking judicial relief against the Producing Party or seek such information pursuant to Federal Rule of Civil Procedure 45. Plaintiffs have not articulated what burden apart from the requirements already set forth in the Federal and Local Rules of Civil Procedure this procedure places on the Receiving Party.

Problematically, Plaintiffs' proposal does not provide any mechanism for the Court to evaluate any claim for such discovery and simply states that the Court "shall order" production of any such information if the Producing Party or third-party does not "object" to such disclosure. Plaintiffs propose no mechanism for the Producing Party or third party to object. Instead, Plaintiffs propose circumventing third party discovery mechanisms if the Producing Party does not seek judicial relief, *i.e.*, moving for a different type of protective order. But to defeat such a motion for protective order or move to compel production of third-party Confidential Information, Plaintiffs must make a showing that such third-party Confidential Information would be relevant to the claims and defenses in this litigation. *See, e.g.*, *Avago Techs. U.S., Inc. v. IPtronics, Inc.*, 309 F.R.D. 294, 299-300 (E.D. Penn. Sep. 15, 2015). The proposed language would bypass this required showing, placing a Producing Party and third parties in positions of potentially great prejudice.

4. Post-Grant Proceeding Participation by Those with Access to Confidential Information.

The parties agree that those persons with access to Confidential Information may participate in any post grant proceedings involving the Patents-in-Suit; however, the parties differ in the level of participation such persons may have. Defendants maintain that persons with access to Confidential Information should not be allowed to participate in drafting, crafting or amending of patent claims and providing recommendations regarding the same. *See, e.g.*, *EPL Holdings, LLC v Apple, Inc.*, No. 12-04306, 2013 WL 2181584, *4 (N.D. Cal. May 20, 2013) ("The Court concludes that EPL's litigation counsel, as with the litigation counsel in *Grobler*, may participate in third-party initiated review proceedings so long as counsel is prohibited from assisting in any crafting or amendment of patent claims."); *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, No. 11-cv-04494, 2013 WL 5935005, *6 (N.D. Cal. Nov. 4, 2013) ("The defendants are suitably protected by an order that bars the specified individuals from using the defendants' confidential information in any proceedings in the PTO and bars them from any involvement in drafting any new claims or claim amendments.").

Thus, Defendants propose that no party with access to Confidential Information be allowed to use such Confidential Information in any post-grant proceedings or have any mechanism to do so. Defendants' provision is consistent with similar provisions in this jurisdiction. *See, e.g.*, Stipulated Protective Order at 11, *Forest Labs.*, No. 15-018-GMS. Plaintiffs, on the other hand, appear to be attempting to reserve the ability to use Defendants' Confidential Information in post-grant proceedings if Plaintiffs obtain consent or seek an Order from the Court. Plaintiffs have demonstrated no legitimate reason for such a reservation, and Defendants do not agree that any

party should be able to seek leave to use Confidential Information for any purpose besides this litigation.

Counsel are available at the convenience of the Court should Your Honor have further questions.

Respectfully,

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)

cc: All Counsel of Record (via CM/ECF)