

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner,

v.

CIPLA LTD.
Patent Owner

Case. IPR2017-00807

Patent 8,168,620

**PATENT OWNER'S MOTION FOR ENTRY OF STIPULATED
PROTECTIVE ORDER AND MOTION TO SEAL**

I. Introduction

As authorized by the Board on November 17, 2017, Patent Owner Cipla Ltd. respectfully submits this joint Motion for Entry of Stipulated Protective Order under 37 C.F.R. § 42.54 and Motion to Seal under 37 C.F.R. § 42.14, filed concurrently with Cipla's Patent Owner Response.

II. Motion For Entry Of Stipulated Protective Order

Cipla anticipates disclosing highly confidential information in this proceeding and also anticipates that deposition testimony will be taken relating to this highly confidential information. For example, Patent Owner intends to rely in its Response on non-public, highly confidential information disclosed to the United States Food and Drug Administration concerning the commercial embodiments of U.S. Patent No. 8,168,620.

The Stipulated Protective Order differs from the Default Protective Order in that it deviates from the Default Protective Order for disclosure of confidential information to (1) all persons who are owners of the patent involved, (2) all in-house counsel of a party, and (3) other employees of the parties. The parties have agreed that designated confidential information may only be disclosed to counsel of record in this proceeding, two in-house representatives who agree to the

provisions of the protective order, the designated experts who agree to the provisions of the protective order, the Office, and their support staff. These amendments are necessary because Cipla would suffer serious injury, including a potential loss of competitive advantage, if this confidential information was disclosed to its competitors. Limitations on disclosure to Petitioner's employees are the least restrictive means to ensure that both Cipla's and Petitioner's interests are served.

Cipla met and conferred with Petitioner and the parties stipulate to entry of the Stipulated Protective Order. Attached as CIP2160 is the agreed-to Stipulated Protective Order, showing in redline the modifications from the Default Protective Order. Patent Owner therefore respectfully requests entry of this Stipulated Protective Order.

III. Motion To Seal Exhibits CIP2151-CIP2155, Portions of the Second Declaration of Dr. Hugh Smyth (CIP2150), and Potential Deposition Testimony of Dr. Smyth

Cipla moves to seal CIP2150-CIP2155, portions of the Second Declaration of Dr. Hugh Smyth, and Dr. Smyth's upcoming deposition transcript ("Proposed Sealed Exhibits") to prevent public disclosure of Cipla's confidential research

information. The public's interests are served because Cipla has filed non-confidential redacted versions of the sealed documents, bearing exhibit numbers CIP2171-2175, that contain unredacted headers and other information to provide an overview of the type of information contained in the redacted material discussed within the documents. And because portions of Dr. Smyth's Second Declaration (CIP2150) cite to and disclose this sealed information, and Cipla anticipates that portions of Dr. Smyth's deposition transcript may reveal this confidential information, Cipla moves to seal portions of Dr. Smyth's Second Declaration and deposition transcript. A redacted version of Dr. Smyth's Second Declaration, bearing exhibit number CIP2176, ensures that the public's interests are served.

IV. Good Cause exists for Sealing Certain Confidential Information.

In determining whether to grant a Motion to Seal, the Board must find "good cause" and "strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." 37 C.F.R. § 42.54(a); 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012). As laid out in the *Office Trial Practice Guide*, confidential information is "consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for

protective orders for trade secret or other confidential research, development, or commercial information.” *Id.* The Federal Circuit has further held that while “it is impossible to define the exact contours of what may and may not be marked as confidential pursuant to [Federal Circuit] Rule 28(d), it is clear that the parties must confine their confidentiality markings to information covered by a protective order” and such confidentiality markings must not “fall[] outside the scope of the protective order.” *In re Violation of Rule 28(d)*, 635 F.3d 1352, 1360 (Fed. Cir. 2011).

Specifically, the Proposed Sealed Exhibits contain confidential formulation details of Cipla’s Duonase product and/or Meda/Mylan’s Dymista[®] product. These exhibits are important to establish a nexus between commercial embodiments of the challenged claims and the several persuasive objective indicia of non-obviousness presented by Cipla in its Patent Owner Response. The information contained in the Proposed Sealed Exhibits reveals proprietary formulation and manufacturing information that, were it disclosed to Petitioner’s employees or the public, could be used to Cipla’s, Meda’s, or Mylan’s competitive disadvantage, e.g., to draft blocking patent claims, provide important formulation details to

Cipla's competitors, or otherwise influence Petitioner's or the public's research strategies. These Proposed Sealed Exhibits are also covered by the Stipulated Protective Order (CIP2160) and in no way "falls outside the scope" of the Order.

The relevant portions of the Proposed Sealed Exhibits are discussed in detail in portions of Dr. Hugh Smyth's Second Declaration (and likely will be discussed in his upcoming deposition). Thus, the relevant portions of the Second Declaration of Hugh Smyth and any deposition transcript arising from that declaration should be sealed for the same reasons. A redacted version of Dr. Smyth's Second Declaration (CIP2176) provides the public a general understanding of the redacted material, and therefore serves the public's interest in disclosure.

V. Certification Of Nonpublication

Undersigned counsel, on behalf of Cipla Ltd., certifies that the information sought to be sealed has not, to their knowledge, been published or otherwise made public by Cipla Ltd.

VI. Certification of Conference with Opposing Party Pursuant to 37 C.F.R. § 42.54.

Patent Owner Cipla Ltd. has in good faith conferred with Petitioner as to the scope of a proposed Protective Order. The joint proposed Stipulated Protective

Order resulting from the parties' discussions has been filed as CIP2160.

VII. Conclusion

For the foregoing reasons, Cipla respectfully requests that the Board enter Stipulated Protective Order CIP2060 and seal Exhibits CIP2150– CIP2155, portions of the Second Declaration of Hugh Smyth, and portions of Dr. Smyth's upcoming deposition transcript as confidential information.

Respectfully submitted,
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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned “Patent Owner's Motion for Entry of Stipulated Protective Order and Motion to Seal” was served in its entirety on November 20, 2017, upon the following parties via electronic mail:

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