

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC,
ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN
PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL
INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,

Petitioners,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2017-00854¹
U.S. Patent No. 9,187,405

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

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

¹ Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined
with this proceeding.

Pursuant to 37 C.F.R. § 42.54, Patent Owner Novartis AG respectfully submits this motion for entry of a stipulated protective order and to seal Exhibits 2057 and 2063-66, which contain Novartis's confidential information. In addition, Novartis moves to seal the portions of its Patent Owner's Response and accompanying declarations (Exs. 2022, 2024-26) containing substantive reference to the above exhibits. Novartis has filed public, redacted versions of those documents and is serving Petitioners with both versions of each document.

I. Motion for Entry of a Stipulated Protective Order

Novartis moves for entry of a Stipulated Protective Order (Ex. 2074), which is an amended version of the Default Protective Order provided in Appendix B of the Trial Practice Guide, 77 Fed. Reg. 48756, 48771 (Aug. 14, 2012). A redlined version of the Default Protective Order showing where modifications have been made is attached hereto as Exhibit 2075. After conferring with Novartis, counsel for the Apotex Petitioners agreed to entry of the Stipulated Protective Order via email on November 10, 2017.

The Stipulated Protective Order differs from the Default Protective Order by addition of a category of confidential material to be marked "OUTSIDE ATTORNEY'S EYES ONLY – PROTECTIVE ORDER MATERIAL." Access to such material is restricted to outside counsel, experts, one in-house counsel of a party, and support personnel. (Ex. 2074 at 5.) An identical protective order was

entered by a similarly constituted panel of the Board in *Torrent Pharms. Ltd. et al v. Novartis AG et al*, IPR2014-00784, Paper 41 (May 7, 2015).

Novartis is submitting one Exhibit with redactions required by Swiss law. Novartis has corresponded with Petitioners and if Petitioners wish to see the redacted information, Novartis reserves the right to seek confidentiality protections beyond those in the attached protective order before revealing that information to Petitioners.

II. Motion to Seal

Novartis seeks to file the documents under seal because they contain or make reference to non-public, sensitive business information. In the case of Exhibit 2057, the document describes the methods and results of confidential Novartis research that has not been publicly disclosed. Exhibits 2063-66 represent confidential communications with the FDA and/or disclose proprietary information regarding the design and execution of Novartis clinical trials. Novartis holds the information contained in these exhibits as confidential and takes precaution to prevent their distribution. Additionally, at least Exhibit 2057 contains redactions of specific personal information that is subject to Swiss Privacy Law and may not be distributed outside of Novartis. As a result, public disclosure of these documents could cause competitive business harm and good cause exists to seal them.

As summarized below Exhibits 2057 and 2063-66 contain Novartis's sensitive confidential information that Novartis maintains an interest in protecting:

Document	Summary of Contents	Good Cause for Filing Under Seal
Ex. 2057	Internal Novartis report summarizing highly confidential research	Constitutes sensitive technical research and development information, including test methods and data, and has been marked “Confidential” internally at Novartis.
Ex. 2063	Email between Novartis and clinical investigators discussing clinical trial strategy.	Constitutes confidential communications with potential investigators about confidential aspects of Novartis clinical trials.
Ex. 2064	Letter from Novartis to FDA communicating confidential clinical trial strategy.	Constitutes information regarding clinical trial design and strategy as reflected in confidential regulatory communication.
Ex. 2065	Email between Novartis and clinical investigators discussing clinical trial strategy.	Constitutes confidential communications with potential investigators about confidential aspects of Novartis clinical trials.
Ex. 2066	Letter from Novartis regulatory personnel to clinical investigators conveying confidential minutes from meetings with FDA.	Constitutes confidential clinical trial design and strategy as reflected in confidential regulatory communication.

In addition, Patent Owner moves to seal the portions of the Patent Owner’s Response and accompanying declarations of Lawrence Steinman (Ex. 2022), William Jusko (Ex. 2024), Fred Lublin (Ex. 2025), and Christian Schnell (Ex. 2026) containing substantive reference to the above exhibits.

CONCLUSION

For the foregoing reasons, the Novartis respectfully requests that the Board seal the aforementioned exhibits, and the unredacted versions of documents in which they are described, to protect the confidential information of the parties.

Respectfully submitted,

Dated: November 13, 2017

/Jane M. Love, Ph.D./

Jane M. Love, Ph.D.

Reg. No. 42,812

Lead Counsel for Patent Owner

Gibson, Dunn & Crutcher LLP

200 Park Avenue

New York, New York 10166-0193

jlove@gibsondunn.com

Tel: 212-351-3922

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