

Filed On Behalf Of:

Novartis AG and LTS Lohmann Therapie-Systeme AG

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**NOVEN PHARMACEUTICALS, INC.,
Petitioner**

v.

**NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners**

***Inter Partes* Review No.: 2014-00550
U.S. Patent No. 6,335,031**

**PATENT OWNERS' UNOPPOSED MOTION FOR ENTRY OF
STIPULATED PROTECTIVE ORDER AND TO SEAL EXHIBITS 1033-
1036 AND PORTIONS OF PETITIONER'S REPLY PETITION AND
EXHIBIT 1031**

Pursuant to the Office Patent Trial Practice Guide (Federal Register, Vol. 77, No. 157, Aug. 14, 2012) and 37 C.F.R. § 42.54, Patent Owners, Novartis AG and LTS Lohmann Therapie-Systeme AG, respectfully submit this motion for entry of a stipulated protective order and to seal Exhibits 1033, 1034, 1035, and 1036, which contain Patent Owners' confidential information. In addition, Patent Owners move to seal the portions of Petitioner's Reply Petition and accompanying declaration of Agis Kydonieus, Ph.D. (Exhibit 1031) containing substantive reference to the above exhibits.

On February 18, 2015, Petitioner provided Patent Owners with a detailed description of four confidential documents that are subject to the protections of the Stipulated Protective Order entered in the concurrent district court litigation, *Novartis Pharm. Corp. et al. v. Noven Pharmaceuticals, Inc.*, D. Del. No. 13-CV-527 (RGA), which Petitioner stated that it intended to use in its Reply Petition. On February 20, 2015, Patent Owners notified Petitioner that they consented to Petitioner's use of the cited materials in the manner described provided that the parties agree to the entry of a protective order in this proceeding. Thereafter, the parties conferred on scope of a protective order. By email dated March 13, 2015, Petitioner confirmed that it would not object to Patent Owners' motion for entry of the stipulated Protective Order or to Patent Owners' motion to seal.

I. Motion For Entry Of A Stipulated Protective Order

Patent Owners move for entry of a Stipulated Protective Order, which is a slightly 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 2055. Patent Owners certify pursuant to 37 C.F.R. § 42.54 that they have conferred with Petitioner and have reached agreement regarding the scope of the proposed Stipulated Protective Order. Attached as Exhibit 2056 is a signed Stipulated Protective Order to which the parties agree to be bound in this matter.

In particular, provision 2(A) of the Default Protective Order has been removed, as no individual natural person is either a Patent Owner or Petitioner in this proceeding. Also, to avoid the possibility of disclosure of designated protective order material to employees of the non-designating party, the parties have agreed to remove provision 2(A). Further, the parties have agreed to identify by name specific in-house counsel in provision 2(C). This last modification is consistent with paragraph 6 of the Stipulated Protective Order entered by the district court in the concurrent litigation. For the Board's reference, attached as Exhibit 2057 is the Stipulated Protective Order entered in the district court proceeding.

II. Motion to Seal

The Patent Trial Practice Guide provides that “[t]he rules aim to 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.” 77 FED. REG. 48756, 48760 (Aug. 14, 2012). “The rules identify confidential information in a manner 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.*

Patent Owners identify Exhibits 1033, 1034, 1035, and 1036 as containing sensitive confidential research and development information, including Patent Owners’ proprietary, internal test methods and test data for rivastigmine transdermal formulations. Although the documents at issue contain some subject matter that is similar to that contained in Exhibits 2015, 2032 and 2053, the substance is in fact different and unlike those documents, the exhibits at issue here were not entered as trial exhibits in the trial of *Novartis Pharm. Corp. et al. v. Watson Labs., Inc. et al.*, D. Del. No. 11-CV-1077 (consolidated) (RGA). Accordingly, Exhibits 1033, 1034, 1035, and 1036 have not previously been published or made public. Efforts to maintain the confidentiality of this information have been undertaken by the parties in the concurrent district court proceeding. As summarized below, Exhibits 1033, 1034, 1035, and 1036 contain

Patent Owners' sensitive confidential information that Patent Owners maintain an interest in protecting:

Exhibit	Summary of Contents	Good Cause for Filing Under Seal
1033	Internal Novartis memorandum written by Dr. Tiemessen.	Contains sensitive business and technical research and development information, including test methods and data, and has been marked "Confidential" in the concurrent district court litigation.
1034	Internal Novartis e-mail communication from Dr. Tiemessen to O. Garinot.	Contains sensitive research and development information and has been marked "Confidential" in the concurrent district court litigation.
1035	Meeting minutes of the LTS-Sandoz (Novartis)	Contains sensitive business and technical

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