

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD., LUPIN PHARMACEUTICALS INC., INNOPHARMA  
LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA  
INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., and  
MYLAN INC.

Petitioners

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and  
BAUSCH & LOMB PHARMA HOLDINGS CORP.

Patent Owner

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IPR2015-01105 (US Patent No. 8,871,813)<sup>1</sup>

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**PETITIONERS' MOTION TO SEAL UNDER 37 C.F.R. § 42.54**

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<sup>1</sup> IPR2016-00090 has been joined with IPR2015-01105.

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## I. INTRODUCTION

In its June 21, 2016, Decision relating to IPR2015-01097, IPR2015-01100, and IPR2015-01105, the Patent Trial and Appeal Board (the “Board”) found deficiencies in both the Patent Owner’s Motion to Seal and Stipulated Protective Order. Paper 58. Thus, the Board denied both without prejudice. *Id.* at 10. In its Decision, the Board ordered that the Patent Owner may file the default protective order or an amended protective order and revised motion to seal addressing the identified deficiencies on or before July 31, 2016. *Id.* In a related Decision of the same day, the Board denied without prejudice Petitioners’ Motion to Seal. Paper 60. In that Decision, the Board ordered that a party may file a revised or new motion to seal on or before July 31, 2016. *Id.* at 4.

Accordingly, pursuant to 37 C.F.R. §§ 42.14 and 42.54 Lupin Ltd., Lupin Pharmaceuticals Inc., (collectively, “Lupin” and “Petitioners”) respectfully move to seal Exhibit 2109 in its entirety, and portions of Exhibit 2082 and Patent Owner’s Response (Paper No. 25), which were submitted by Senju Pharmaceutical Co., Ltd., Bausch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp. (collectively, “Patent Owner”). Exhibit 2109 contains Lupin’s Abbreviated New Drug Application (“ANDA”). Exhibit 2082, which contains Patent Owner’s expert Declaration of Robert O. Williams, III, Ph.D. (the “Williams Declaration”), and Patent Owner’s Response, cite to or substantially describe the confidential

information in Exhibit 2109 that Petitioners seek to seal. Petitioners certify that the information identified as confidential in this motion has not been published or otherwise made public.

## **II. GOOD CAUSE EXISTS FOR SEALING CONFIDENTIAL INFORMATION IN EXHIBITS 2109 AND 2082, AND PATENT OWNER'S RESPONSE**

Under 35 U.S.C. § 316(a)(1), the default rule is that all papers filed in an *inter partes* review are open and available for access by the public, and a party may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion.

37 C.F.R. § 42.14 provides:

The record of a proceeding, including documents and things, shall be made available to the public, except as otherwise ordered. A party intending a document or thing to be sealed shall file a motion to seal concurrent with the filing of the document or thing to be sealed. The document or thing shall be provisionally sealed on receipt of the motion and remain so pending the outcome of the decision on the motion.

The rules promulgated by the USPTO “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.” Office Trial Practice

Guide, 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012). It is, however, only “confidential information” that is protected from disclosure. 35 U.S.C. § 316(a)(7). The moving party has the burden of establishing “good cause” for sealing documents containing confidential information. *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 37 at 4 (PTAB, Apr. 5, 2013); *see also* 37 C.F.R. §§ 42.20(c), 42.54.

The Board’s 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. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012). Accordingly, the Board has recognized that an ANDA contains confidential commercial information that should be protected from public disclosure. *See Sandoz, Inc. v. EKR Therapeutics, LLC*, IPR2015-00005, paper 21 (PTAB, Apr. 24, 2014).

The Exhibits that Petitioners move to seal contain confidential and highly sensitive proprietary information. The information the parties seek to seal has not been made public by any party or by the Food and Drug Administration (“FDA”), and is not otherwise available to the public. At issue is Lupin’s ANDA, which was filed confidentially with the FDA in order to obtain FDA approval to market Lupin’s generic pharmaceutical product. The information the parties seek to seal

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