

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,
Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,
Patent Owner

Case IPR2020-01053
Patent No. 9,815,827

PATENT OWNER'S MOTION TO SEAL UNDER 37 CFR § 42.54

I. Introduction

Pursuant to 37 CFR § 42.54, Patent Owner, Sumitomo Dainippon Pharma Co., Ltd, respectfully submits this Motion to Seal Exhibits 2058-2060, 2069, 2074-2076, 2078, 2080, 2082-2083, 2089-2090, 2092-2095, 2131, 2132, and 2138, as well as its Patent Owner Response. In the case of Ex. 2131 and its Patent Owner Response, Patent Owner submits herewith non-confidential (redacted versions). Below, Patent Owner explains that Good Cause exists for placing these exhibits and the Patent Owner Response under seal.

II. Applicable Legal Principles for Sealing Confidential Information

There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in a patent and therefore affects the rights of the public. *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, IPR2013-00258, Decision to Revised Motion to Seal 37 C.F.R. §§ 42.14 and 42.54, Paper 28 at 2. 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. *Id.*

It is, however, only “confidential information” that is protected from disclosure. 35 U.S.C. § 316(a)(7) (“The Director shall prescribe regulations -- ...

providing for protective orders governing the exchange and submission of confidential information”). *Id.* In that regard, the *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012), provides:

The 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.

* * *

Confidential Information: 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. § 42.54.

The standard for granting a motion to seal is “for good cause.” 37 C.F.R. § 42.54. Patent Owner, as the moving party, has the burden of proof in showing entitlement to the requested relief. *Id.*

III. Good Cause Exists for Sealing Exhibits 2058-2060, 2069, 2074-2076, 2078, 2080, 2082-2083, 2089-2090, 2092-2095, 2131, 2132, and 2138, and the Patent Owner Response.

Exhibit 2132: Exhibit 2132 is the declaration of Dr. Brian Reisetter. Dr. Reisetter opines that the invention claimed in the challenged patent (U.S. 9,815,827) has been commercially successful. In reaching his opinion, Dr. Reisetter relies upon and discusses sensitive financial and competitive commercial

information from Patent Owner—in particular Exhibits 2069, 2074-2076, 2078, 2080, 2082-2083, and 2089-2090.

Exhibit 2069: Exhibit 2069 (Lurasidone, Strategic Business Plan, October 1, 2009) contains sensitive financial and competitive commercial information relating to the anticipated commercial launch of LATUDA®.

Exhibit 2074: Exhibit 2074 (Latuda Financial Information FY11-FY20 YTD) contains sensitive financial information, including sales and pricing information, related to LATUDA®.

Exhibit 2075: Exhibit 2075 (LATUDA Monthly Commercial Analytics Meeting, June 2016) contains sensitive financial and competitive commercial information related to LATUDA®.

Exhibit 2076: Exhibit 2076 (LATUDA Situational Assessment – FY 2020, Aug 2, 2020) contains sensitive financial and competitive commercial information, as well as confidential business analyses related to LATUDA®.

Exhibit 2078: Exhibit 2078 (Latuda® (lurasidone HCl) 2013 Brand Plan) contains sensitive financial and competitive commercial information relating to the 2013 marketing plan for LATUDA®.

Exhibit 2080: Exhibit 2080 (Latuda Physician ATU Tracker Findings, Q3'11 Insights Report) contains proprietary data and analysis related to the use of LATUDA® by physicians.

Exhibit 2082: Exhibit 2083 (LATUDA – Bipolar Depression HCP ATU, FY16-Q4, March 20, 2017) contains proprietary data and analysis related to the use of LATUDA® for treating bipolar depression by physicians.

Exhibit 2083: Exhibit 2083 (The Bipolar Disorder Patient Journey, Sunovion Commercial Insights & Analytics, INSYNC, June 22, 2020) includes proprietary competitive commercial analysis relating to LATUDA® and its use to treat bipolar disorder.

Exhibit 2089: Exhibit 2089 (Sunovion Senior Leadership Budget Presentation, Latuda Brand Strategy and Budget, December 10, 2010) contains sensitive financial and competitive commercial information relating to the budget and marketing strategy for LATUDA®.

Exhibit 2090: Exhibit 2090 (Latuda® 2012 Budget Presentation Meeting, November 7, 2011) contains sensitive financial and competitive commercial information relating to the proposed LATUDA® budget for 2012.

Exhibit 2131: Exhibit 2131 is the declaration of Dr. Stephen Stahl. In the declaration, Dr. Stahl expresses his opinion that claims 1-75 of the challenged patent (U.S. 9,815,827) would not have been obvious. In forming his opinion, Dr. Stahl relied upon and discusses confidential documents containing proprietary data and confidential communications with FDA and third parties.

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