

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00685
U.S. Patent No. 9,211,253

PATENT OWNERS' MOTION TO SEAL

Pursuant to 35 U.S.C. § 316(a)(1) and 37 C.F.R. §§ 42.14 and 42.54, Patent Owners Adapt Pharma Operations Limited (“Adapt”) and Opiant Pharmaceuticals, Inc. (“Opiant”) hereby move to seal Exhibits 2098–2109, 2188, 2205, and 2207, which are being filed concurrently with this Motion and Patent Owners’ Response.

I. DOCUMENTS TO BE SEALED AND REASONS FOR SEALING

The standard governing the Board’s determination of whether to grant a motion to seal is “good cause.” *Garmin Int’l, Inc. v. Cuozzo Speed Techs LLC*, Case IPR2012-00001, Paper 36 at 4 (April 5, 2013) (quoting 37 C.F.R. § 42.54). The Board aims 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.” *Id.*

The exhibits and portions of exhibits that Patent Owners seek to file under seal fall into three categories, each of which meets the “good cause” standard to be maintained in the docket under seal and available only to the parties and Board. In each instance, the material is either the confidential information of a third party who has permitted its use in this proceeding subject to a protective order, or else consists of confidential business information that would cause competitive harm to Patent Owner Adapt were it to be disclosed publicly.

A. Confidential Third-Party Documents

Exhibit 2188 (“Indivior NDA Module 3.2.P.2”) was produced by third-party Indivior, Inc. (“Indivior”) in response to a document subpoena in district court litigation between Patent Owners and a pharmaceutical manufacturer that is not a party to this IPR but seeks to make a generic naloxone product. *Adapt Pharma Operations Ltd. v. Teva Pharmaceuticals, USA, Inc.*, No. 2:16-cv-07221-BRM-JAD; see Ex. 2194 subpoena). The document is part of the confidential New Drug Application (“NDA”) submitted by Indivior to the U.S. Food and Drug Administration (“FDA”), and it contains Indivior’s confidential business information relating to its own proposed naloxone product. Although the document was subject to a protective order in the litigation in which Indivior originally produced it, Indivior has consented to its use in this proceeding provided that it is filed under seal subject to the Board’s default protective order. See Ex. 2178 (email from Indivior counsel to Adapt counsel). Accordingly, there is good cause for Exhibit 2188 to be maintained under seal.

B. Financial Documents of Patent Owner Adapt

Exhibit 2205 (“Vigil Decl.”) and **Exhibit 2207** (“Brides Decl.”) contain the confidential financial information of Patent Owner Adapt and its corporate affiliates. These exhibits contain certain financial information drawn from the internal business records of Adapt, including the sales, by various metrics, of

Narcan® Nasal Spray on a quarterly and annual basis, and various costs associated with Adapt's activities in connection with Narcan® Nasal Spray. The information is confidential business information that is not publicly available; it is competitively sensitive and its inclusion in the public docket would cause commercial harm to Adapt.

Exhibit 2205 is a declaration of Dr. Robert Vigil, an expert witness retained by Patent Owners who addresses, *inter alia*, the commercial success of Narcan® Nasal Spray. Dr. Vigil relies on the confidential financial information in connection with his commercial success analysis, and Patent Owners move to seal the specific portions of Dr. Vigil's declaration that reveal the confidential financial information. In accordance with Paragraph 5(A)(ii) of the Board's Default Protective Order, a redacted copy of Dr. Vigil's declaration is being filed publicly as Exhibit 2206.

Exhibit 2207 is a declaration of Mr. Declan Brides, Adapt's Vice President, Finance. Mr. Brides's declaration and its appended Exhibit A contain the Adapt confidential financial information described above; in addition, Mr. Brides's declaration describes the sources and methods Mr. Brides used to obtain that financial information, including information about Adapt's business operations that is not publicly known. Because the recital and authentication of the Adapt financial information—which is then analyzed and applied to the issues in the

proceeding by Dr. Vigil—constitutes the bulk of the substantive portions of Mr. Brides’s declaration, and appended Exhibit A is a spreadsheet consisting of confidential information, Patent Owners move to seal Exhibit 2205 in its entirety.

In light of the confidential nature of the information in these documents and the considerations discussed above, there is good cause to maintain this information under seal.

C. Confidential Regulatory Documents Containing Confidential Formulation and Manufacturing Information

Exhibit 2098, Exhibit 2099, Exhibit 2100, Exhibit 2101, Exhibit 2102, Exhibit 2103, Exhibit 2104, Exhibit 2105, Exhibit 2106, Exhibit 2107, Exhibit 2108, and Exhibit 2109 are portions of Adapt’s NDA for Narcan® Nasal Spray. NDA materials are filed on a confidential basis with the U.S. Food and Drug Administration. The portions of the NDA submitted here contain confidential details of the formulation and manufacture of Patent Owners’ Narcan® Nasal Spray product, and the public release of these documents could benefit Patent Owners’ competitors (including competitors who may be seeking to copy Patent Owners’ product) and thereby cause competitive harm to Patent Owners.

Exhibit 2201 (“Jones Decl.”) is a declaration of Dr. Stuart Jones, an expert witness retained by Patent Owners who addresses, *inter alia*, whether Narcan® Nasal Spray embodies the challenged claims. Dr. Jones relies on confidential formulation and manufacturing information drawn from Adapt’s NDA in

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