

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner

v.

UNITED THERAPEUTICS CORP.

Patent Owner

Patent No. 9,339,507

Issue Date: May 17, 2016

Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01622

PATENT OWNER'S MOTION TO FILE UNDER SEAL

37 C.F.R. § 42.54

Pursuant to 37 C.F.R. § 42.54, United Therapeutics Corporation (“Patent Owner”) hereby submits this Motion to Seal Exhibits 2049-2051, 2055, 2058, 2065-2068, 2071, 2074, 2075, 2083, 2088, 2089 and certain portions of Exhibit 2053.

I. Good Cause Exists for Sealing Certain Confidential Information

The Office Patent Trial Practice Guide provides that “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.” 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012). These 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.* (citing 37 C.F.R. § 42.54).

Good cause exists to support the sealing of the Exhibits 2049-2051, 2055, 2058, 2065-2068, 2071, 2074, 2075, 2083, 2088, 2089 and the requested portions of Exhibit 2053. The requested portions of Ex. 2053 to be sealed are narrowly limited to certain information at pp. 26, 32, and 62. These portions contain confidential material describing details about the development and sales of Patent Owner’s commercial product, Tyvaso[®], and proprietary information submitted and held in confidence by the FDA.

Exhibits 2049-2051, 2055, 2058, 2065-2068, 2071, 2074, 2075, 2083, 2088, 2089 were produced in a litigation (*United Therapeutics Corp. v. Sandoz, Inc.*, Civ. No. 14-cv-05499) as confidential documents and remain under seal in the litigation. Exhibits 2055, 2058, 2065-2068, 2071, 2074, 2075, 2088, 2089 report marketing, sales, and pricing information for Tyvaso[®] and other United Therapeutic products. Exhibits 2049-2051 and 2083 describe information on protocols, procedures, and data submitted to and held in confidence by the FDA in relation to the approval of Tyvaso[®]. Such information could be improperly used by competitors to gain unfair business and competitive advantage with customers in the marketplace, including using details of Patent Owner's process for competitive commercial products.

The Board has granted a Motion to Seal certain exhibits in their entireties for similar reasons in *Purdue Pharma L.P. v. Depomed, Inc.*, IPR2014-00377, paper no. 62 at 4-6, (PTAB March 17, 2015), where "Patent Owner avers that the 'highly confidential nature of' the information contained in those documents makes it 'impossible to reasonably redact [them] for public disclosure.'" *Id.* at 4.

The requested portions of Exhibit 2053 report information from one or more of Exhibits 2055, 2058, 2065-2068, 2071, 2074, 2075, 2088, and 2089. The proposed scope of confidential information in Exhibit 2053 is, thus, narrowly limited in this motion to the details taken from the exhibits produced

and under seal in the litigation.

The confidential information designated by this motion could be improperly used by competitors to gain unfair business and competitive advantage with customers in the marketplace, including using details of Patent Owner's development process for competitive commercial products.

II. Certification of Non-Publication

On behalf of Patent Owner, undersigned counsel certifies that, to the best of their knowledge, the information sought to be sealed by this Motion to Seal has not been published or otherwise made public. Efforts to maintain the confidentiality of this information have been undertaken by Patent Owner in the related district court proceeding noted above, and such information currently is under seal in that litigation.

III. Certification of Conference with Opposing Party Pursuant to 37 C.F.R. § 42.54

Patent Owner has conferred with Petitioner about both this motion to seal, and Petitioner has consented to the motion.

IV. Protective Order

The confidential information will be subject to the protective order entered by the Board's Order dated April 27, 2018 (Paper 36).

V. Conclusion

For the reasons stated above, Patent Owner respectfully requests that Exhibits 2049-2051, 2055, 2058, 2065-2068, 2071, 2074, 2075, 2083, 2088, 2089 and the requested portions of Exhibit 2053 remain under seal.

Date: April 27, 2018

Respectfully submitted,

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