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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.

Petitioner

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner

U.S. Patent No. 8,497,393
Issue Date: Jul. 30, 2013
Title: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®

Case IPR2016-00006

JOINT MOTION TO SEAL

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to the Board's Order in Paper No. 14, United Therapeutics Corporation ("Patent Owner") and SteadyMed Ltd. ("Petitioner") hereby submit this Joint Motion to Seal, accompanied by a Joint Written Statement and a redacted copy of the Decision to Institute, identifying the specific parts of the Decision to Institute that should remain under seal as follows (the exact words being redacted are shown in the attached redacted version of the Decision to Institute):

On page 17, lines 21-23;

On page 18, line 24;

On page 19, lines 1-4, 16-18, and 20-22;

On page 20, lines 1-17 and footnote 7; and

On page 21, lines 1-3 and 6-9.

As directed by the Board's Order (Paper No. 14), Patent Owner has discussed the proposed redactions with Petitioner, who has indicated that it has no objection. Pursuant to 37 C.F.R. § 42.12, Patent Owner seeks to seal these limited portions of the Decision to Institute because they discuss information that is confidential for the same reasons stated in Patent Owner's prior outstanding Motion to Seal (Paper No. 7), which relates to sealing portions of Patent Owner's Preliminary Response and also Exhibits 2003-2006 in their entireties. The

proposed portions of the Decision to Institute to be placed under seal are limited strictly to those which discuss the same information requested to be placed under seal in the Patent Owner's prior outstanding Motion to Seal (Paper No. 7).

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).

On page 17, lines 21-23, the Decision to Institute discusses proprietary purity information from Exhibit 2006 submitted to and held in confidence by the FDA (the reasons why this information should be sealed are presented below).

On page 18, line 24, the Decision to Institute discusses proprietary purity information from multiple sources, including Exhibits 2003-2006 submitted to and held in confidence by the FDA, and its relationship to the Walsh Declaration (the reasons why this information should be sealed are presented below).

On page 19, lines 1-4, 16-18, and 20-22, the Decision to Institute discusses

proprietary purity information from multiple sources, including Exhibits 2003-2006 submitted to and held in confidence by the FDA (the reasons why this information should be sealed are presented below).

On page 20, lines 1-17 and footnote 7, the Decision to Institute discusses specific data from Exhibits 2003-2006 submitted to and held in confidence by the FDA (the reasons why this information should be sealed are presented below).

Finally, on page 21, lines 1-3 and 6-9, the Decision to Institute discusses specific data from Exhibit 2006 submitted to and held in confidence by the FDA (the reasons why this information should be sealed are presented below) and compares it to certain data in Exhibit 1002.

Exhibit 2003 is a confidential communication from the FDA to Patent Owner approving a process change in the manufacture of Patent Owner's proprietary Remodulin® product. Exhibit 2004 is a process validation report (Protocol No. "VAL-00131") that provides confidential information about the manufacture of Remodulin®. Exhibit 2005 is a Process Optimization Report that provides confidential information about the manufacture of Remodulin®. Exhibit 2006 is a confidential communication from the Patent Owner to the FDA regarding the manufacturing of Remodulin®.

Exhibits 2003-2006 contain information about the manufacturing process for Remodulin®. 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 entireties of Exhibits 2003-2006 relate to highly confidential manufacturing process details for Remodulin®, as discussed with FDA and presently held in confidence by the FDA.

Exhibits 2003-2006 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. The information contained in Exhibits 2003-2006 is also held in confidence by the FDA.

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.

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 Joint Motion to Seal has not been published or otherwise made public. Efforts to maintain the confidentiality of this information have also been undertaken by Patent Owner in the related district court proceeding and with the FDA, and such information

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