

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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®

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Case IPR2016-00006

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**PATENT OWNER'S AMENDED MOTION TO FILE UNDER SEAL  
(AMENDMENT TO PAPER NO. 18)**

***Mail Stop "PATENT BOARD"***

Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.14 and the E-mail communication of the Patent Trial and Appeal Board (“Board”) dated November 23, 2016, United Therapeutics Corporation (“Patent Owner”) hereby submits this Amended Motion to File Under Seal in order to exclude certain materials that Patent Owner intends to include in its demonstratives for the Final Hearing scheduled to be held on November 29, 2016.

In Joint Motion to File Under Seal previously filed on April 21, 2016, Patent Owner and Steadymed Ltd. (“Petitioner”) had jointly moved to seal certain portions of the Decision to Institute. In the present amended motion, Patent Owner moves to retain sealed status of all information in the prior motion except for the information in page 20, line 13, which was previously held confidential.

Accordingly, a redacted version of the Decision to Institute is submitted herewith, identifying the specific parts of the Decision to Institute that should remain under seal, which are found at:

On page 20, lines 3, 5, 8-10, and 13-17, and footnote 7, lines 1-2; and

On page 21, lines 1-3 and 6-8.

#### **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 20, lines 3, 5, 8-10, and 13-17 and footnote 7, lines 1-2, 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 6-8, 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<sup>®</sup> product. Exhibit 2004 is a process validation report (Protocol No. “VAL-00131”) that provides confidential information about the manufacture of Remodulin<sup>®</sup>. Exhibit 2005 is a Process Optimization Report that provides confidential information about the manufacture of Remodulin<sup>®</sup>. Exhibit 2006 is a confidential communication from the Patent Owner to the FDA regarding the manufacturing of Remodulin<sup>®</sup>.

Exhibits 2003-2006 contain information about the manufacturing process for Remodulin<sup>®</sup>. 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<sup>®</sup>, as discussed with FDA and presently held in confidence by 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 and Petitioner, undersigned counsels certify 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 currently is under seal in that litigation and at the FDA.

### **III. Conclusion**

For the reasons stated above, Patent Owner and Petitioner respectfully request that the portions indicated herein of the Decision to Institute remain under seal and only the accompanying redacted version of the Decision to Institute be made available to the public.

Date: Nov. 23, 2016

Respectfully submitted,

/Stephen B. Maebius/

Stephen B. Maebius

Reg. No. 35,264

Counsel for Patent Owner

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