

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

PATENT OWNER'S MOTION TO FILE UNDER SEAL

37 C.F.R. § 42.14

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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 37 C.F.R. § 42.12, United Therapeutics Corporation (“Patent Owner”) hereby submits this Motion to Seal Exhibits 2003-2006 in their entireties and a portion of Patent Owner’s Preliminary Response (limited to section IX where it discusses Exhibits 2003-2006) filed concurrently herewith.

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).

Patent Owner requests that four documents (*i.e.*, Exhibits 2003-2006) be placed under seal in their entireties.

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 it would not be reasonably possible to separate non-confidential information because the documents are thoroughly interspersed with confidential details about the manufacturing process.

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.

Exhibits 2003-2006 are cited and discussed in Patent Owner's Preliminary Response at section IX. A non-redacted version of Patent Owner's Preliminary Response has been filed under seal and a redacted version of Patent Owner's Preliminary Response (in which only limited portions of section IX are redacted) has been publicly filed. To preserve confidentiality of this information, Patent Owner moves to maintain the entireties of Exhibits 2003-2006 and the non-redacted version of Patent Owner's Preliminary Response under seal.

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 and with the FDA, and such information currently is under seal in that litigation and at the FDA.

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 the acceptance of the appended default protective order, and Petitioner has consented to the default protective order attached as Appendix A.

IV. Proposed Protective Order

Patent Owner submits a copy of the stipulated protective order attached as Appendix A, to which both parties have agreed. It is the Default Protective Order in the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48771 (Aug. 14, 2012).

V. Conclusion

For the reasons stated above, Patent Owner respectfully requests that Exhibits 2003-2006, as well as the non-redacted version of Patent Owner's Preliminary Response, remain under seal.

Date: January 14, 2016

Respectfully submitted,

/Stephen B. Maebius/

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Reg. No. 35,264

Counsel for Patent Owner

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