

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 AMENDED MOTION TO FILE UNDER SEAL
(AMENDMENT TO PAPER NO. 7)**

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 Patent Owner’s Motion to File Under Seal previously filed on January 14, 2016 (Paper No. 7), Patent Owner had moved 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). In the present amended motion, Patent Owner moves to retain sealed status of all information in the prior motion except for the following three portions of Exhibit 2006, which were previously held confidential:

- (a) “The chemical manufacturing steps have not changed during the transfer to [supplier A] and [supplier B] from the process used by UT in Chicago to prepare benzindene triol.”
- (b) “There is a release specification for benzindene triol that must be achieved for each lot of benzindene triol before it is released for use by UT to prepare treprostiniol. This is the same specification that was used by United Therapeutics in our Chicago facility.”
- (c) “In all lots [of benzindene triol from suppliers A, B, C, and D], the total unidentified impurity level (%AUC) decreased from triol [step (a)] to UT-15C intermediate [step (c)].”

Accordingly, a redacted version of Ex. 2006 is submitted herewith in which all but the above 3 statements are redacted.

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 three documents (*i.e.*, Exhibits 2003-2005) be placed under seal in their entireties, and Exhibit 2006 be placed under seal for all except the above-reproduced contents.

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, except for the unredacted text of Ex. 2006 noted above, 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.

IPR2016-00006
Patent 8,497,393

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 2003-2005, all except the above reproduced content of Exhibit 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 maintained under seal by this Amended Motion to File Under 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. Conclusion

For the reasons stated above, Patent Owner respectfully requests that Exhibits 2003-2006 (except for the 3 portions of Ex. 2006 noted above), as well as the non-redacted version of Patent Owner's Preliminary Response, remain under seal.

Date: Nov. 23, 2016

Respectfully submitted,

/Stephen B. Maebius/

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