

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

MOTION TO SEAL

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

United Therapeutics Corporation (“Patent Owner”) hereby submits this Motion to Seal certain portions of Patent Owner’s Response, Ex. 2020, Ex. 2022, 2037, and Ex. 2051 and to seal Exhibits 2052-2054 in their entireties. The exact words and numbers being redacted are shown in the attached, redacted versions of:

- (1) Patent Owner’s Response: pp. 3, 4, 9-11, 21, 25, 27, 28, 30, 34, 45, 48, and 49;
- (2) Williams Declaration (Ex. 2020): at footnote 1, paragraphs 91, 94-98, 102, and 103, and Appendix B;
- (3) Ruffolo Declaration (Ex. 2022): at paragraphs 66-73;
- (4) Ex. 2037: everything except certain data at pp. 44 and 195; and
- (5) Ex. 2051: at pp. 77, 78, 81, 82, 84, 86-88, 128, 129, 130, 131-133, and 135.

For Exhibits 2052-2054, Patent Owner requests that they be sealed in their entireties for the reasons discussed below.

Patent Owner has discussed the proposed redactions with Petitioner, who has indicated that it has no objection if the sealed information follows the Board’s earlier ruling in Paper No. 27. Pursuant to 37 C.F.R. § 42.12, Patent Owner seeks to seal these limited portions of Patent Owner’s Response, Ex. 2020, Ex. 2022, Ex. 2037, and Ex. 2051, as well as the entireties of Ex. 2052-2054, because they discuss

information that the Board has already ruled upon and determined to be confidential: “we agree with the parties that the disclosed numerical amounts and ranges, identity of the impurities detected, and particulars of the FDA treprostinil purity standard is confidential information concerning the manufacturing process for Remodulin®, submitted and held in confidence to the FDA, and susceptible to misuse by competitors seeking commercial advantage” (Paper No. 27 at p. 5). With respect to Exhibits 2052-2054, the references to confidential material are so extensive that Patent Owner requests sealing them in their entireties, as was requested for Exhibits 2003-2006 in the earlier Motion to Seal (Paper No. 7).

I. Good Cause Exists for Sealing Certain Confidential Information

Each of the proposed redactions and proposed exhibits to be sealed in their entireties contain information that the Board has already ruled upon and determined to be confidential in Paper No. 27, so good cause has already been found by the Board for sealing this information.

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.

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

Patent Owner and Petitioner have conferred about this Motion to Seal and

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Petitioner has no objection.

IV. Protective Order

The Board has entered a protective order in Paper No. 16, which the parties have agreed will govern handling of information designated confidential in this proceeding.

V. Conclusion

For the reasons stated above, Patent Owner respectfully requests that the portions indicated herein of the Patent Owner's Response, Ex. 2020, Ex. 2022, Ex. 2037, and Ex. 2051, along with the entireties of Exhibits 2052-2054, remain under seal and only the accompanying redacted versions of the Patent Owner's Response, Ex. 2020, Ex. 2022, Ex. 2037, and Ex. 2051 be made available to the public.

Date: July 13, 2016

Respectfully submitted,

/Stephen B. Maebius/

Stephen B. Maebius

Reg. No. 35,264

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Motion to Seal and accompanying documents and exhibits were served on counsel of record for Petitioner on July 13, 2016 by delivering a copy via email to Stuart Pollack and Lisa Haile (the counsel of record for the Petitioner) at the following address:

Steadymed-IPR@dlapiper.com

Date: July 13, 2016

signature: /Stephen B. Maebius/
Stephen B. Maebius