

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. 50)**

***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 September 22, 2016 (Paper No. 50), Patent Owner had moved to seal certain portions of the deposition transcripts of Dr. Ruffolo (Ex. 2058) and Dr. Williams (Ex. 2059). In the present amended motion, Patent Owner moves to make public certain portions of Ex. 2058 and 2059 that were previously held confidential.

- (1) Accordingly, new redacted versions of Ex. 2058 and 2059 are submitted herewith, identifying the specific parts of these documents that should remain under seal: Dr. Ruffolo’s deposition transcript (Ex. 2058): pp. 76-81, 139-140, 142, 160-161, 182-184, 186, 194-196, 214, 216-218, 230, 265, 269-270, 274-277, 279-281, 308, 317-318, 320, 323, 330-333, 335-337, 339-343, 345-348, 350-351, and 353-358; and
- (2) Dr. Williams’ deposition transcript (Ex. 2059): pp. 46, 48, 50, 60, 62, 64-67, 78, 86, 91-96, 98, 100-102, 105-107, 113, 115-116, 119, 121-125, 127, 194, 196, 203, 217-219, 251, 281-284, 286, 304, and 308-309 .

Pursuant to 37 C.F.R. § 42.14, Patent Owner seeks to seal these limited portions of Ex. 2058 and Ex. 2059 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).

### **I. Good Cause Exists for Sealing Certain Confidential Information**

Each of the proposed redactions contains 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. Conclusion**

For the reasons stated above, Patent Owner respectfully requests that the portions indicated herein of Ex. 2058 and Ex. 2059 remain under seal and only the accompanying redacted versions of Ex. 2058 and Ex. 2059 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

IPR2016-00006  
Patent 8,497,393

**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 Nov. 23, 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](mailto:Steadymed-IPR@dlapiper.com)

Date: Nov. 23, 2016

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