

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.

Case IPR 2016-00006

Patent No. 8,497,393B2

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**PETITIONER'S MOTION FOR SUPPLEMENTAL INFORMATION  
UNDER 37 C.F.R. § 42.123**

Mail Stop "Patent Board"  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Petitioner SteadyMed Ltd. (“Petitioner”) hereby moves for leave to submit supplemental information pursuant to 37 C.F.R. § 42.123. On a conference call between the parties dated May 10, 2016, the PTAB panel provided authorization for Petitioner to file this motion. Furthermore, it is noted that Patent Owner’s representative, Steve Maebius, who was on the conference call, indicated that he did not oppose the filing of this motion. The present motion seeks to submit Exhibit 1019 and Exhibit 1020 which are supplemental declarations attesting to the accuracy of the English translation of Japanese Patent Application No. 56-122328A, “Crystalline Amine Salt of Methanoprostacyclin Derivative, Manufacturing Method Thereof, and Purifying Method Thereof,” referred to as “Kawakami.”

**I. The Present Motion Complies with the Rules**

The present motion complies with the requirements of 37 C.F.R. § 42.123. First, the Board instituted the above-identified inter partes review in a Decision dated April 8, 2016. (Paper 12). Petitioner timely made a request for the authorization to file a motion to submit supplemental information within one month of the date trial was instituted, on Friday, May 6, 2016, pursuant to 37 C.F.R. § 42.123(a)(1). Second, the Decision in the present inter partes review relies on Kawakami as a key reference for invalidating at least one claim. As such, Kawakami is relevant to a claim for which the trial has been instituted, pursuant to

37 C.F.R. § 42.123(a)(2).

## **II. The Requested Supplemental Information**

As mentioned above, the present inter partes review refers to and relies on Kawakami for invalidating at least one claim. Exhibit 1006 refers to the original, Japanese language version of Kawakami, and Exhibit 1007 refers to the certified English translation of Kawakami. With its petition, Petitioner submitted Exhibit 1011, a declaration attesting to the accuracy of the English translation of Kawakami, from Mr. Boris Levine, president, owner, and chief Japanese translator at Technical Language Services, Inc. Mr. Levine, who is fluent in Japanese and English, oversaw and personally checked the English translation of Kawakami that one of his employees, Mr. James Dowdle, created. Patent Owner, however, objected to Mr. Levine's declaration (Exhibit 1007) because "there is no evidence that the translator Boris Levine has personal knowledge of the translation of Kawakami in Exhibit 1007 or even that he knows how to translate any document from Japanese to English." (Paper 20, Patent Owner's Objections to Petitioner's Evidence).

Petitioner seeks to submit two declarations: (1) Exhibit 1019 is a supplemental declaration from Mr. Levine, who served as check translator of Kawakami; and (2) Exhibit 1020 is a declaration from Mr. Dowdle, who performed the English translation of Kawakami. Both declarations certify that Mr.

Levine and Mr. Dowdle are fluent in both Japanese and English, the English translation is true and correct, and satisfies all of the formalities of 37 C.F.R. § 1.68. Petitioner submits that the English translation of Kawakami as provided in the originally filed Exhibit 1007 has not been changed, and notes, similar to the Board, that Patent Owner has not presently identified any error with the translation that would call into question its authenticity.

As additional grounds for granting this motion, Petitioner directs the Board to *Taiwan Semiconductor v. DSS Technology Management, Inc.*, IPR No. 2014-01030 (Paper 11, p. 3), where the Board, on nearly identical facts, granted a similar motion, and held that the supplemental information Petitioner sought "to submit does not change the grounds of unpatentability authorized in this proceeding, nor does it change the evidence initially presented in the Petition to support those grounds of patentability. Instead, such information merely constitutes additional evidence that allegedly confirms the accuracy of the English translation ...."

Accordingly, and for the reasons set forth above, Petitioner asks that the Board accept this motion.

Date: May 11, 2016

/s/ Stuart E. Pollack /  
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Respectfully submitted,

/s/ Lisa A. Haile /  
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## CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the attached Motion for Supplemental Information was served via electronic mail to the following:

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Date: May 11, 2016

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