

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 EXCLUDE

I. INTRODUCTION

Under 37 C.F.R. § 42.64(c) and the Scheduling Order (Paper 13), United Therapeutics Corporation (“Patent Owner”) moves to exclude Petitioner’s Exhibit 1022 and the objected-to portions of Exhibits 1009, 1022 and 2059 on the following grounds:

Exhibit	Description	Reason to Exclude
Ex. 1009	Declaration of Jeffrey D. Winkler, Ph.D. (¶¶3, 31, 46, 48, 54, 57, 63, 71, and 72)	Expert not qualified to make these conclusory statements
Ex. 1017	A website printout entitled “Getting Started in HPLC,’ Section 4D: Precision and Accuracy”	Hearsay and not authenticated
Ex. 1022	Dr. Robin D. Rogers Declaration	Exceeds scope of PO Response and does not rely on facts and data in the record
Ex. 2059	Certain portions of Deposition Transcript of Dr. Robert M. Williams, Ph.D	Likely to create confusion and mislead

Petitioner relied on these exhibits as pointed out below in its Petition (Paper No. 1) and Petitioner's Reply (Paper No. 52). Patent Owner also moves to exclude the portions of Petitioner's Petition and Reply, which rely on these exhibits.

II. PATENT OWNER TIMELY OBJECTED

Patent Owner timely objected, on April 22, 2016, to Exhibits 1009 and 1017, which were submitted with the Petition, which was instituted on April 12, 2016. *See* Paper 19. Likewise, Patent Owner timely objected, on October 3, 2016, to Exhibits 1022 and 2059, which were submitted with the Reply, which was filed on September 27, 2016. *See* Paper 55. Petitioner did not supplement or authenticate any of its evidence in response to these specific objections.

A. Ex. 1009

Specifically, Patent Owner objected to Ex. 1009 in Paper No. 19 for the following reasons:

Exhibit 1009 is described as "Declaration of Jeffrey D. Winkler, Ph.D." Patent Owner objects to Exhibit 1009, under FRE 701, because the opinion testimony contained in this exhibit reaches legal conclusions for which the declarant has not established that he is capable of providing, for example, paragraphs 3, 31, 46, 48,

54, 57, 63, 71, and 72 each recite an unsupported legal conclusion and, thus, should not be considered by the Board in this proceeding.

B. Ex. 1017

Patent Owner objected to Ex. 1017 in Paper No. 19 for the following reasons:

Exhibit 1017 is described as “‘Getting Started in HPLC,’ Section 4D: Precision and Accuracy, available at <http://www.lcresources.com/resources/getstart/4d01.htm> (accessed Sept. 29, 2015).” Patent Owner objects to Exhibit 1017 under FRE 901 as not being properly authenticated. Petitioner relies on the exhibit to prove the truth of the matter asserted therein, but the exhibit fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

C. Ex. 1022

Patent Owner objected to Ex. 1022 in Paper No. 55 for the following reasons:

Exhibit 1022 is described as “Dr. Robin D. Rogers Declaration.”

(a) Patent Owner objects to Exhibit 1022 under 37 CFR 42.23 because the opinion testimony contained in this exhibit contains opinions, including paragraphs 44-48, that are not responsive to the Patent Owner Response and, thus, should not be considered by the PTAB in this proceeding. *See* 37 C.F.R. § 41.41(b);

(b) Patent Owner objects to Exhibit 1022 under FRE 702-703 as including opinions, including paragraphs 84-86, that rely on facts and data that are not in the record as to how a melting point was calculated;

(c) Patent Owner objects to Exhibit 1022 under FRE 702-703 as including opinions, including paragraph 87, that rely on facts and data that are not in the record to conclude that a melting point range is narrow.

D. Ex. 2059

Patent Owner objected to Ex. 2059 in Paper No. 55 for the following reasons:

Patent Owner objects to the Reply at pages 2, 3, 4, 7, 8, and 24 for citing portions of Ex. 2059 (Williams deposition transcript at 112-113 and 217-219) under FRE 402-403 as being likely to cause confusion pursuant to the objection made at the deposition at p. 112 of the transcript that the questions mischaracterized earlier testimony and documents shown to the witness.

Patent Owner objects to the Reply at page 15 for citing portions of Ex. 2059 (Williams deposition transcript at 180) under FRE 402-403 as being likely to cause confusion pursuant to the objection made at the deposition at p. 181 of the transcript that the earlier questions misrepresented the document shown to the witness.

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