

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 OBJECTIONS TO PETITIONER'S REPLY &
EVIDENCE SUBMITTED WITH PETITIONER'S REPLY**

Patent Owner United Therapeutics Corporation (“Patent Owner”) hereby objects to the admissibility of certain evidence cited in support of the Petitioner’s Reply to Patent Owner’s Response to Petition filed on September 27, 2016 (“Reply”), as well as to the portions of the Reply that rely upon such objectionable evidence. Patent Owner’s objections are based on the Federal Rules of Evidence (“FRE”), relevant case law, and the Patent Trial and Appeal Board (“PTAB”) Rules. Patent Owner’s objections are set forth with particularity below.

EXHIBIT 1021

Exhibit 1021 is described as “Spreadsheet of 46 batches from Exs. 2053 and 2036.” Patent Owner objects to Exhibit 1021 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.

EXHIBIT 1022

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 37 CFR 42.6(a)(3) because it contains arguments improperly incorporated by reference into the Petitioner's Reply, including paragraphs 24-48, 53-63, 65-73, 75-83, and 85-88; and

(c) 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;

(d) 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.

EXHIBIT 1024

Exhibit 1024 is described as "Stephen R. Byrn et al., *Solid-State Chemistry of Drugs*, Chapter 10, 'Polymorphs,' 143-231 (2d ed. 1999)." Patent Owner objects to Exhibit 1024, which is purported to be a chapter from a chemistry textbook, under FRE 802. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1025

Exhibit 1025 is described as “Terence L. Threlfall, ‘Analysis of Organic Polymorphs: A Review,’ Analyst 120(10): 2435 (1995).” Patent Owner objects to Exhibit 1025, which is purported to be a scientific journal article, under FRE 802. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1026

Exhibit 1026 is described as “ANDAs: Pharmaceutical Solid Polymorphism-- Chemistry, Manufacturing, and Controls Information.” Patent Owner objects to Exhibit 1026, which is purported to be a Food and Drug Administration Guidance Document, under FRE 802. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1027

Exhibit 1027 is described as “Solid-State Chemistry of Drugs, Chapter 5, ‘Thermal Methods of Analysis,’ 81-901 (2d ed. 1999).” Patent Owner objects to Exhibit 1027, which is purported to be a chapter from a chemistry textbook, under FRE 802. The Petitioner relies on this exhibit to prove the truth of the matter

asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1028

Exhibit 1028 is described as “Drawings made of the compound in the Kawakami reference.” Patent Owner objects to Exhibit 1028, which is purported to be a diagram of a chemical compound, under FRE 802. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

Petitioner further objects to this exhibit under FRE 402-403, as being irrelevant and likely to cause confusion.

PORTIONS OF PETITIONER’S REPLY

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

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