UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TARO PHARMACEUTICALS U.S.A., INC., Petitioner,

V.

APOTEX TECHNOLOGIES, INC., Patent Owner.

Case IPR2017-01446 U.S. Patent No. 7,049,328

Title: USE FOR DEFERIPRONE

PATENT OWNER'S OBJECTIONS TO EVIDENCE IN PETITIONER'S REPLY PURSUANT TO 37 C.F.R. § 42.64



Pursuant to 37 C.F.R. § 42.64 and the Federal Rules of Evidence, as applied by the Board, Patent Owner Apotex Technologies, Inc. ("Apotex") provides the following objections to Exhibits submitted by Taro Pharmaceuticals USA, Inc. ("Taro" or "Petitioner") in association with its filing of its Reply (Paper 41). These objections are timely served within five (5) business days of Petitioner's Reply.

Apotex serves Taro with these objections to provide notice that Apotex may move to exclude the challenged evidence under 37 C.F.R. § 42.64(c) unless Taro cures the defects associated with the challenged evidence identified below. In addition, Apotex reserves the right to present further objections to this or additional evidence submitted by Taro, as allowed by the applicable rules or other authority.

I. Exhibits 1037, 1038, 1040-1043, 1045, and 1047-1049

Apotex objects to Exhibits 1037, 1038, 1040-1043, 1045, and 1047-1049 as hearsay. *See* Fed. R. Evid. 801, 802.

Apotex object to Exhibits 1037, 1038, 1040-1043, 1045, and 1047-1049 for lack of authentication. *See* Fed. R. Evid. 901.

Further, Apotex objects to the relevance and probative value of Exhibits 1037, 1038, 1040-1043, 1045, and 1047-1049 as these exhibits do not contain evidence that is contradictory to any position advanced by Apotex in this proceeding. *See* Fed. R. Evid. 401, 402, and 403.



II. Exhibit 1060

Apotex objects to portions of Exhibit 1060, Expert Declaration of Dr. Jayesh Mehta In Support of Petitioner's Reply. Specifically, Apotex objects to ¶¶ 5, 14-16, 18, 20, 21-23, 36, 38-41, and 45-46 as not based on sufficient facts or data, the product of reliable principles and methods, and/or reliable application of the principles of methods and facts. *See* Fed. R. Evid. 702, 703, 705, 403; 77 Fed. Reg. at 48,763; 37 C.F.R. § 42.65.

Apotex objects to ¶¶ 44-45 of Exhibit 1060 as irrelevant as these paragraphs are not directly cited in the Reply. *See* Fed. R. Evid. 401, 402. Apotex further objects to Fn 1 and portions of ¶ 14 as irrelevant because they contain cites to Exhibit 1066, which is not cited in the Petitioner's Reply (Paper 41). *See* Fed. R. Evid. 401, 402. Apotex further objects to Fn 3 and portions of ¶ 25 as irrelevant because they contain cites to Exhibit 1065, which is not cited in Petitioner's Reply and which is inadmissible for the reasons discussed below. *See* Fed. R. Evid. 401, 402. Apotex further objects to Fn 8 and portions of ¶ 28 as irrelevant because they contain cites to Exhibits 1063-1064, which are not cited in Petitioner's Reply. *See* Fed. R. Evid. 401, 402.

Apotex objects to ¶¶ 19-50 as testimony provided on a topic which the declarant is not qualified to opine. *See* Fed. R. Evid. 702 and 703.



III. Exhibit 1065

Apotex objects to Exhibit 1065 for lack of authentication. *See* Fed. R. Evid. 901. Apotex further objects to Exhibit 1065 because it is not a printed publication. *See* 35 U.S.C. § 311(b). Apotex also objects to Exhibit 1065 as irrelevant. *See* Fed. R. Evid. 401, 402.

IV. Exhibits 1052-1054 and 1056

Apotex objects to the relevance and probative value of Exhibits 1052-1054 and 1056, which are not cited in Petitioner's Reply (Paper 41) or the Expert Declaration of Dr. Jayesh Mehta In Support of Petitioner's Reply (Ex. 1060). *See* Fed. R. Evid. 401, 402, and 403.

V. Exhibits 1063-1066

Apotex objects to the relevance and probative value of Exhibits 1063-1066, which are cited in the Expert Declaration of Dr. Jayesh Mehta In Support of Petitioner's Reply (Ex. 1060), but not cited in Petitioner's Reply (Paper 41). *See* Fed. R. Evid. 401, 402, and 403.

Respectfully submitted,

Date: June 20, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2018, I caused a true and correct copy of **Patent Owner's Objections to Evidence in Petitioner's Reply** to be served via electronic mail on the following attorneys of record:

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