

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

APOTEX TECHNOLOGIES, INC.,  
Patent Owner.

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

Title: USE FOR DEFERIPRONE

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**PATENT OWNER'S REPLY IN SUPPORT OF MOTION TO EXCLUDE  
PETITIONER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)**

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Petitioner's arguments in opposition to Patent Owner's Motion to Exclude are unavailing for at least the following reasons: (1) Dr. Mehta lacked the requisite training and experience in the relevant subject matter as of the filing date of the '328 patent; (2) the paragraphs of Dr. Mehta's declarations and the exhibits that are not cited in the Petition or Petitioner's Reply are not relevant to the proceeding; and (3) Petitioner failed to provide sufficient evidence to establish that Exhibits 1037, 1038, 1040-1043, and 1047-1049 are authentic under Federal Rules of Evidence (FRE) 901 or 902. Because Petitioner's arguments are flawed, the Board should grant Patent Owner's Motion to Exclude.

**I. Dr. Mehta Lacked the Requisite Training and Experience in the Relevant Timeframe**

Despite Petitioner's assertions that Patent Owner's arguments are baseless, Petitioner cannot establish that Dr. Mehta had the requisite training and experience of a person of ordinary skill in the art as of the of the filing date of the '328 patent. Indeed, as Dr. Mehta and Petitioner readily admit, Dr. Mehta stopped prescribing deferiprone in 1993 and was peripherally involved in treatment with deferiprone until 1995. But as both Petitioner's and Patent Owner's papers in this proceeding have detailed, much of the relevant publications to the '328 patent and this proceeding are post-1995. What is more, even though the challenged claims of the '328 patent relate to treating an iron overload condition of the heart and iron-induced heart disease, Dr. Mehta readily admitted that he would have consulted a

cardiologist to assess those conditions. (Ex. 2024 at 49:12 – 50:4; 53:16 – 54:2; 64:14 – 65:4; 108:3-21; 130:2-10.) For example, in both his opening and reply declarations, Dr. Mehta opines about the T2 relaxation times (“TRT”) as measured by MRI disclosed in the Olivieri 1995 Abstract (*see, e.g.*, Ex. 1002 at ¶ 75; Ex. 1060 at ¶¶ 21-28), but conceded at deposition that these tests are run and understood by a cardiologist, not a hematologist like Dr. Mehta. (Ex. 2024 at 53:16 – 54:2; 130:2-10.) Because he is unqualified, Dr. Mehta’s opinions expressed in ¶¶ 63-85 of Exhibit 1002 and ¶¶ 19-50 of Exhibit 1060 should be excluded under FRE 702 and 703.

## **II. The Paragraphs of Dr. Mehta’s Declarations and the Exhibits That Are Not Cited in the Petition or Petitioner’s Reply Are Not Relevant to the Proceeding**

Petitioner admits that the following paragraphs of Dr. Mehta’s opening and reply declarations and exhibits are not cited in the Petition or Petitioner’s Reply:

- Paragraphs 30, 31, 37-40, 63-65, 68-71, and 80-81 of Exhibit 1002;
- Paragraphs 14, 25, 28, 44, and 45 and footnotes 1, 3, and 8 of Exhibit 1060; and
- Exhibits 1005, 1006, 1022, 1024, 1026, 1028, 1030, 1031, 1033-1035, 1060, and 1063-1066.

(Paper 56 at 5.) Despite this, Petitioner argues that these paragraphs of Dr.

Mehta’s declarations and exhibits are relevant and helpful as background. (*Id.* at

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