

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 No.: IPR2017-01446

Patent No. 7,049,328

**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE**

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Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

A. Dr. Mehta Is Qualified To Provide the Opinions Set Forth in Paragraphs 63-85 of Exhibit 1002 and Paragraphs 19-50 of Exhibit 1060

Patent Owner asserts that Dr. Mehta is not qualified to offer the opinions provided in paragraphs 63-85 of his opening declaration (Ex. 1002) and in paragraphs 19-50 of his reply declaration (Ex. 1060) because “he lacks the relevant expertise.” (PO Motion to Exclude at 2 and 10.) Patent Owner’s assertions are baseless. Dr. Mehta’s training and experience fits within either party’s definition of the person of ordinary skill in the art. (Ex. 2020 at ¶ 2; Ex. 1068 at ¶ 2.) As the Board found in its Institution Decision, a person of ordinary skill in the art “includes M.D.’s with clinical experience with iron chelators in treatment of transfusion patients with iron overload.” (Paper 7 at n. 8.) Dr. Mehta earned his M.D. from Bombay University in 1990, and he has extensive experience with iron chelators, including deferiprone, in the treatment of transfusion patients with iron overload. (Ex. 1003 at 1.)

As Dr. Mehta testified in his opening declaration, he was directly involved with the care of several transfusion-dependent patients who received deferiprone while practicing in India from 1989-1991. (Ex. 1002 at ¶ 8.) And even after he left India, he continued to be involved in the treatment of these patients through at least 1995. (*Id.*) Since 1995, he has treated many patients with iron chelators, and continued to follow the literature describing treatment of blood transfusion-dependent patients with deferiprone. (*Id.*)

During Dr. Mehta's second deposition, he agreed with counsel for Patent Owner that "Dr. Olivieri was one of the foremost researchers in the 1990s in the treatment of thalassemia major." (Ex. 2040 at 65:20-24.) Counsel then asked Dr. Mehta whether it was "fair to say" that "as of the mid 1990s, Dr. Olivieri had more experience than just about anybody else in the field in terms of administering deferiprone in an attempt to treat thalassemia major patients." (*Id.* at 65:25-66:4.) Dr. Mehta testified as follows: "I would say she probably had more experience than most, but there are exceptions...And I think it's fair to say that, purely the experience with managing patients who are on deferiprone goes, I think there was a time when I was more experienced than Nancy Olivieri." (*Id.* at 66:5-14.)

In contrast to Dr. Mehta's experience treating thalassemia patients with deferiprone, Patent Owner's expert Dr. Pennell admitted that he has never administered an iron chelator to a thalassemia patient. (Ex. 1059 at 33:21-34:1; *see also id.* at 15:9-12 (testimony that Dr. Pennell's only involvement with thalassemia patients was in performing heart scans).) And, in contrast to Dr. Mehta's use of deferiprone in the 1990s, i.e., prior to the filing date of the '328 patent, Patent Owner's other expert, Dr. Coates, testified that he did not use deferiprone until after 2000. (Ex. 1058 at 24:9-11.) Thus, of all the experts involved in this proceeding, Dr. Mehta has the most hands-on experience as of the June 30, 2000 priority date.

Because Patent Owner's objections to Dr. Mehta are unfounded, and because Dr. Mehta is qualified to testify from the perspective of a POSA, the Board should deny Patent Owner's motion to exclude these paragraphs of Exhibit 1002 and Exhibit 1060.

B. Dr. Mehta's Opinions in Paragraphs 26-28, 30, 33, 34, 36, 37, 40, 55, 56, 60, 64, 66, 67, 72, 74-76, 80, and 82-85 of Exhibit 1002 and Paragraphs 5, 14-16, 18, 20, 21-23, 36, 38-41, and 45-46 of Exhibit 1060 Are Well Supported and Reliable

Patent Owner objected to the listed paragraphs of Dr. Mehta's declarations 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 lack merit." (PO Motion to Exclude at 3, 10.) Patent Owner is wrong.

As examples of the facts in Exhibit 1002 that supposedly lack any basis, Patent Owner recited "background information on thalassemia and red blood cells," "iron overload as a result of treating thalassemia," "the side effects of subcutaneous infusions of desferrioxamine," and "that most therapeutic agents for most diseases are given in combination with excipients." (PO Motion to Exclude at 3-4.) None of these facts are contested in this proceeding, and the background section of the '328 patent itself describes these facts. (*See* Ex. 1001 at, e.g., cols. 1-2.) And, Patent Owner's expert Dr. Coates described these same facts in his opening declaration, without citing to a single reference aside for the patent itself. (*See* Ex. 2001 at ¶¶ 16-23.)

In response to Patent Owner’s original objections, Petitioner served Patent Owner with supplemental declarations in which Dr. Mehta clarified that these paragraphs contain (1) statements from the cited references and the ’328 patent, (2) information that would have been understood by a person of ordinary skill in the art based on a review of the cited references and the ’328 patent, (3) facts regarding thalassemia, blood transfusions, iron overload, desferrioxamine or deferiprone that were common knowledge to a person of ordinary skill in the art as of June 30, 2000, (4) statements of his own knowledge as of June 30, 2000, or (5) statements of his own opinion, from the perspective of a person of ordinary skill in the art as of June 30, 2000. (Ex. 2020 at ¶ 3; Ex. 1068 at ¶ 3.) Dr. Mehta also pointed out that Dr. Coates made “points similar or even identical to” points that Dr. Mehta made. (*Compare* Ex. 2001 at ¶¶ 16-20 to Ex. 1002 at ¶¶ 26-28, 30; Ex. 2001 at ¶¶ 21-23 to Ex. 1002 at ¶ 33; Ex. 2001 at ¶ 24 to Ex. 1002 at ¶ 34.)

Moreover, with respect to paragraph 36 of Exhibit 1060, Dr. Mehta explained his reasoning that a person of ordinary skill in the art would have known that Olivieri 1995 discloses the treatment of blood transfusion-dependent patients who had an iron overload condition of the heart as follows: “The serial serum ferritin and liver iron concentration measurements are the same measurements as those used in the ’328 patent to measure iron overload. The patients with serum ferritin and liver iron concentrations higher than the given thresholds had iron

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