

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.,

v.

Apotex Technologies, Inc.

Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

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**SUPPLEMENTAL DECLARATION OF JAYESH MEHTA, M.D.**

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

I, Jayesh Mehta, M.D., declare as follows:

1. I am the same Jayesh Mehta who submitted a declaration dated May 14, 2017, in support of Taro Pharmaceuticals U.S.A., Inc.'s Petition for *inter partes* review of U.S. Patent No. 7,049,328 ("my first declaration"). I submit this supplemental declaration to respond to objections that Patent Owner submitted on December 12, 2017, regarding my first declaration. I reserve the right to further respond to those objections and to further supplement this declaration.

2. As of the earliest priority date of the '328 patent, my relevant experience was that of a person of at least ordinary skill in the art, based either on the definition of that term that I proposed in my first declaration at paragraph 17 or on the definition of that term proposed by Dr. Coates in his September 8, 2017, declaration at paragraph 27. All of the statements of my opinion set forth in my first declaration are presented from the perspective of the hypothetical person of ordinary skill of the art, and I am qualified to opine from this perspective due to my extensive training in blood disorders, my years of experience treating patients with blood disorders, my research into blood disorders, and my investigation and analysis of the cited prior art.

3. Patent Owner objected to paragraphs 26, 27, 28, 30, 33, 34, 36, 37, 40, 55, 56, 60, 64, 66, 67, 72, 74, 75, 76, 80, 82, 83, 84, and 85 of my first declaration 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.”

(Patent Owner’s Objections to Evidence at 1.) I disagree because these paragraphs contain (1) statements from the cited references, (2) information that would have been understood by a person of ordinary skill in the art based on a review of the cited references, (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 my own knowledge as of June 30, 2000, or (5) statements of my own opinion, from the perspective of a person of ordinary skill in the art as of June 30, 2000.

4. I note that Patent Owner’s own expert, Dr. Coates, included statements in his September 8, 2017, declaration that make points similar or even identical to those I made in certain paragraphs in my first declaration to which Patent Owner objected. (*Compare* Coates Declaration (Ex. 2001) at ¶¶ 16-20 to my first declaration at ¶¶ 26-28 and 30; Coates Declaration at ¶¶ 21-23 to my first declaration at ¶ 33; Coates Declaration at ¶ 24 to my first declaration at ¶ 34.)

5. Patent Owner objected to paragraphs 31, 34, 37-40, 63-65, 68-71, and 80-81 of my first declaration as “irrelevant,” because they “are not directly cited in the Petition and the relevance of the paragraphs is not apparent.” (Patent Owner’s Objections to Evidence at 1.) Patent Owner also objected to paragraph 30 of my first declaration as “irrelevant because it contains a cite to Exhibit 1028, which is

not cited in the Petition.” (*Id.*) Patent Owner further objected to Exhibits 1028, 1029, 1031, and 1033-1035 because they are not cited in the Petition. (*Id.* at 2.) I do not agree that any of the statements made in these paragraphs or any of these Exhibits are irrelevant to the facts and opinions presented in my first declaration.

6. These paragraphs and Exhibits offer background information that is required to understand the facts and opinions presented in my first declaration. Some these paragraphs and Exhibits are included for ease of understanding and organizational purposes. The fact that the paragraphs and Exhibits are not cited in the Petition that is supported by my declaration does not render the paragraphs “irrelevant”; I drafted my first declaration to be a stand-alone document that contains the relevant facts and my opinions, presented from the perspective of a person of ordinary skill in the art.

7. Patent Owner objected to paragraphs 63-85 of my first declaration as “testimony provided on a topic which the declarant is not qualified to opine.” (Patent Owner’s Objections to Evidence at 1.) These paragraphs present my opinions on anticipation and obviousness, and also include my understanding of the cited prior art. I am qualified to opine on these matters due to my qualifications, which render me at least a person of ordinary skill in the art.

8. As I explained in my first declaration, counsel explained the standards for anticipation and obviousness to me before I arrived at my opinions, and my

opinions are based on those standards and presented from the perspective of a person of ordinary skill in the art. Dr. Coates, similarly, stated that he relied on counsel for his understanding of the relevant legal concepts, and presented his opinions, purportedly from the perspective of a person of ordinary skill in the art. (See Declaration of Dr. Coates at ¶¶ 8-15.)

9. Patent Owner also objected to my first declaration because it does not disclose my compensation. (Patent Owner’s Objections to Evidence at 1.) I have already publicly stated that Petitioner is compensating me at the rate of \$800 per hour for my work related to the ’328 patent in a document that I understand was served on Patent Owner. (See Declaration of Jayesh Mehta M.D. in Support of Defendant’s Responsive Claim Construction Brief, *ApoPharma, Inc. v. Taro Pharmaceutical Industries, Ltd.*, No. 16-00528 (E.D.Texas) (D.I. 59-14) (Apr. 5, 2017) at 12.)

10. Patent Owner objected to “the relevance of Exhibits 1005, 1006, 1022, 1024, 1026, and 1030 in the obviousness section” of my first declaration (specifically citing ¶ 83) because “the Petition failed to identify any combination of references in the obviousness analysis.” (Patent Owner’s Objection to Evidence at 2.) Patent Owner is incorrect: the Petition states that the obviousness analysis is based on each of the “Primary References” in view of the knowledge of a person of ordinary skill in the art. (See Petition at 43-44 (“these claims are rendered obvious

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