

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Taro Pharmaceuticals U.S.A., Inc.,

v.

Apotex Technologies, Inc.

Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

SUPPLEMENTAL DECLARATION OF JAYESH MEHTA, M.D.

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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 ("the '328 patent), and a declaration dated June 13, 2018, in support of Taro Pharmaceuticals U.S.A., Inc.'s Reply In Support of its Petition for *inter partes* review. I submit this supplemental declaration to respond to objections that Patent Owner submitted on June 20, 2018, regarding my June 13, 2018, 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 May 14, 2017, 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 declarations 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, including my administration of deferiprone to blood transfusion dependent patients prior to June 30, 2000, 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 5, 14-16, 18, 20, 21-23, 36, 38-41, 45-46 of my June 13, 2018, 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.” (Paper 43 at 2.) I disagree because these paragraphs contain (1) statements from the ’328 patent, (2) statements from the cited references, (3) information that would have been understood by a person of ordinary skill in the art based on a review of the ’328 patent and the cited references, (4) facts regarding thalassemia, blood transfusions, iron overload, serum ferritin, liver iron concentration, and iron-induced cardiac disease that were common knowledge to a person of ordinary skill in the art as of June 30, 2000, (5) statements of my own knowledge as of June 30, 2000, or (6) statements of my own opinion, from the perspective of a person of ordinary skill in the art as of June 30, 2000.

4. In paragraph 5, I discuss the meaning of the claims based on the meaning of the included term “prevention.” The dictionary definition of “prevention” is “the act of preventing or impeding.” (*See* Exhibit 1067 at 3.) “Prevent,” in turn, is defined as “to keep from happening.” (*Id.*) In this context, “prevention,” means to keep from developing iron-induced cardiac disease.

Indeed, Patent Owner confirmed this meaning of “prevention” during prosecution of the application that issued as the ’328 patent. In a response to an Office Action, the Patent Owner (then the “Applicant”) stated: “To clarify Applicant’s meaning with respect to the term “prevention” it is intended that the iron loading on the heart of a transfusion dependent patient would ultimately affect the function of the heart to a level beyond that which is normal. It is submitted that the use of deferiprone will prevent abnormal functioning of the heart because of the removal of the iron stores therein.” (*See* Exhibit 1004 at 380 of 435 (Response to Office Action dated Sep. 29, 2005 at 12).) My conclusion regarding the meaning of “iron overload condition of the heart,” which includes patients who are at risk for but do not already have iron-induced heart disease, is thus supported by this definition.

5. Patent Owner also objected to paragraphs 44-45, footnote 1, portions of paragraph 14, footnote 3, portions of paragraph 25, footnote 8, and portions of paragraph 28 of my June 13, 2018, declaration as “irrelevant,” because they “are not directly cited in the Reply,” or because they cite to exhibits that are not cited in Petitioner’s Reply. (Paper 43 at 2.) Patent Owner further objected to Exhibits 1063-1066 because they are not cited in the Reply. (*Id.*) I do not agree that any of the statements made in these paragraphs, footnotes, or any of these Exhibits are irrelevant to the facts and opinions presented in my June 13, 2018 declaration.

6. These paragraphs, footnotes, and Exhibits offer background information that is required to understand the facts and opinions presented in my June 13, 2018, declaration. Some these paragraphs, footnotes, and Exhibits are included for ease of understanding and organizational purposes. The fact that the paragraphs, footnotes, and Exhibits are not cited in the Reply that is supported by my declaration does not render the paragraphs, footnotes, or Exhibits “irrelevant”; I drafted my June 13, 2018, 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 as of June 30, 2000.

7. Patent Owner objected to Exhibit 1065 as irrelevant and because it is allegedly not a printed publication. (Paper 43 at 3.) I did not rely on Exhibit 1065 as evidence that MRI TRT (T2) and MRI T2* are related. My reliance on Exhibit 1065 was to support my independent knowledge of the relationship between MRI TRT and MRI T2*. Thus, Exhibit 1065 corroborates my opinion about MRI TRT (T2) and MRI T2*.

8. Patent Owner objected to Exhibit 1065 as not authenticated. As I explained in my Declaration dated June 13, 2018, in footnote 3, paragraph 25, I downloaded Exhibit 1065 from <http://mriquestions.com/t2-vs-t2.html> (a webpage entitled “Questions and Answers on MRI: T2 vs T2*, What is the difference between T2 and T2*?”) on June 13, 2018.

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