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

Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

Inter Partes Review No. IPR2017-01446

EXPERT DECLARATION OF DR. JAYESH MEHTA IN SUPPORT OF PETITIONER'S REPLY

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

2. I am the same Jayesh Mehta who submitted declarations dated May 14, 2017, and December 27, 2017, in support of Taro Pharmaceuticals U.S.A., Inc.'s positions in this matter. I submit this third declaration to respond to assertions made in Exhibits 2001, 2003, 2026, and 2035, the expert declarations of Drs. Pennell and Coates submitted in this proceeding. I reserve the right to further respond to these declarations and to further supplement my opinions in this matter.

3. As of the earliest priority date of the '328 patent (June 30, 2000), 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 this 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 review of the cited prior art.

4. In my first declaration, I provided my understanding of the relevant legal principles. My understanding of these principles has not changed since I wrote my first declaration.

A. An Iron Overload Condition of the Heart

5. The '328 patent repeatedly uses the term "an iron overload condition of the heart." (*See, e.g.*, Ex. 1001 at 11:34-35, 11:45, 12:11-12, 12:19-20, 12:27-28, 12:36-37.) In these citations, the patent discusses the prevention, treatment, or reversal of heart disease in patients having "an iron overload condition of the heart." The patent's use of both terms "heart disease" and "an iron overload condition of the heart" in a single sentence implies that these terms have different meanings. Further, because the patent discusses the **prevention**, treatment, and reversal of heart disease in a patient with an iron overload condition of the heart, the term "iron overload condition of the heart" must encompass patients who are at risk for, but do not already have, heart disease (disease that will allegedly be prevented by the method) as well as patients who already have heart disease (disease that will allegedly be treated and/or reversed by the method).

6. Thus, the term "iron overload condition of the heart," which appears in claims 1, 2, 6, 7, 8, and 9, is a broad term that encompasses patients who have a condition on the spectrum of heart disease and patients who have iron in the heart with no measureable heart disease. I explained this meaning in my deposition on this matter. (*See* Ex. 2024 at 175:3-177:7.)

B. The Patent Contains a Single Example Using 75 mg/kg/day of Deferiprone

7. The ’328 patent includes one example, in the “DETAILED DESCRIPTION OF THE EMBODIMENTS” section. The example describes a retrospective study that compares the “prevalence and progression of cardiac disease” and “the survival of patients” treated, for 4 or more years, with either deferiprone or deferoxamine. (Ex. 1001 at 14:34-42.) The patients were transfusion-dependent. (*Id*. at 14:57-58.)

8. Patients were assessed for iron overload, which consisted of monthly determinations of iron input from transfusions and quarterly serum ferritin measurements. (*Id*. at 15:1-3.) Some patients had an annual assessment of liver iron concentration (LIC). (*Id*. at 15:3-6.)

9. Patients were also periodically assessed for cardiac function by a cardiologist, consisting of a physical examination, an echocardiogram and, if indicated, 24-hour electrocardiographic Holter monitoring. (*Id.* at 15:7-11.) The first cardiac assessment was the baseline value used for each patient. (*Id*. at 15:7-25.)

10. The deferiprone-treated patients were administered a dose of 25 mg/kg of body weight, three times per day, for a total of 75/mg/kg per day. (*Id*. at 15:28-30.) The deferoxamine patients were treated with 20 to 60 mg/kg per day, 4 to 7 days a week. (*Id*. at 15:30-33.)

11. The patent reports that, at the first assessment, the prevalence of cardiac disease was "similar" for both groups, with 10% of the 48 patients on deferiprone having cardiac disease and 14% of the 78 patients on deferoxamine having cardiac disease. (*Id*. at 18, Table 1.) The patent further reports that "the percentage of patients who had more than 50% of their serum ferritin values above the apparent threshold for cardiac disease (2500 µg/L) throughout the review period was similar between the 2 groups." (*Id*. at 19:18-21.)

12. For patients with cardiac disease at the first assessment, the patent reports an improvement in 2 out the 5 patients treated with deferiprone, and in 3 out of the 11 patients treated with deferoxamine. (*Id*. at 20:19-23.) Among patients who had cardiac disease at the first assessment, cardiac disease worsened over the treatment period for 1 of the 11 patients treated with deferoxamine and for none of the 5 patients treated with deferiprone. (*Id*. at 20:23-54.) Two patients treated with deferiprone had newly diagnosed cardiac disease during the course of the treatment period, as did nine patients treated with deferoxamine. (*Id*. at 20:54-61.)

13. The patent states that "[c]ardiac disease, as defined by the heart functional capacity classification developed by the New York Heart Association, was an end point in this study . . . Data to establish the diagnosis and progression of cardiac disease were obtained from the medical records of patients, noting in

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