UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

APOTEX TECHNOLOGIES, INC.,
Patent Owner.

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

Title: USE FOR DEFERIPRONE

PATENT OWNER'S OBSERVATIONS ON THE CROSS EXAMINATION OF DR. JAYESH MEHTA

Pursuant to the Scheduling Order (Paper 8), Patent Owner Apotex Technologies, Inc. ("Apotex") submits the following observations on cross-examination of Dr. Jayesh Mehta.

I. Inherent Anticipation

1. In Exhibit 2040, at 18:6-17 and 20:2-16, Dr. Mehta testified that practicing the prior art methods of dosing deferiprone to blood transfusion-dependent patients will not achieve the claimed results of the '328 patent in every single patient and that a possibility or probability of something happening would meet the standard for inherent anticipation. This testimony is relevant to Dr. Mehta's opinions in paragraphs 20, 67, 74, 75, and 77 of his Declaration (Ex. 1002) and paragraphs 35 and 41 of his Reply Declaration (Ex. 1060) that "prior art may still anticipate if that element is 'inherent' in its disclosure, that is, if it is necessarily found in the prior art" (Ex. 1002 at ¶ 20), and that the administration of 75 mg/kg/day of deferiprone in Hoffbrand 1998, Olivieri Abstract 1995, and Olivieri 1995 inherently anticipates the claims of the '328 patent. The testimony is relevant because Dr. Mehta uses an improper legal standard for inherent anticipation to conduct his analysis of the prior art. The testimony is also inconsistent with Dr. Mehta's opinions that the administration of 75 mg/kg/day of deferiprone in the prior art inherently anticipates the claims of the '328 patent.

2. In Exhibit 2040, at 8:1 – 9:4, 10:8 – 12:7, and 24:24 – 27:7, Dr. Mehta

testified that the claims of the '328 patent require a therapeutically effective amount to achieve a specific outcome in individual patients, that the ability of deferiprone to bind iron and remove it from the body depends on the dose, and that 75 mg/kg/day will not bind and reduce cardiac iron in each and every patient at that dose. This testimony is relevant to Dr. Mehta's opinions in paragraphs 37, 61, 66, 67, 74, 75, and 77 of his Declaration (Ex. 1002) and paragraphs 15, 20, 27, 38, and 41 of his Reply Declaration (Ex. 1060) that "clinical experience has shown that treatment with 75/mg/kg/day of deferiprone is effective at maintaining a non-toxic level of iron in the blood of transfusion-dependent patients, thereby treating iron overload." (Ex. 1002 at ¶ 37.) This testimony is relevant because it is inconsistent with Dr. Mehta's opinions that the administration of 75 mg/kg/day of deferiprone in the prior art inherently anticipates the claims of the '328 patent.

II. Claim Construction

3. In Exhibit 2040, at 8:1 – 9:4, 10:8 – 12:7, and 16:16 –18:4, Dr. Mehta testified that, under the district court's claim construction, the "sufficient to" clauses in the claims of the '328 patent and the like define the therapeutically effective dose in the claims. This testimony is relevant because it is inconsistent with Dr. Mehta's opinions in paragraphs 55, 56, 66 and 71 of his Declaration (Ex. 1002) and paragraph 18 of his Reply Declaration (Ex. 1060) that the "sufficient to" language in the claims of the '328 patent "adds nothing to the claimed method"

and does not require a person attempting to practice the claims to, for example, change the dose administered to the patient being treated. This testimony is also relevant because it is inconsistent with Dr. Mehta's opinions that the "sufficient to" language in the claims of the '328 patent is "not limiting because the method is performed in the identical manner of whether the particular results are achieved." (Ex. 1002 at ¶ 66.)

4. In Exhibit 2040, at 24:24 – 27:7, Dr. Mehta testified that physicians would adjust a chelation regimen based on an individual patient's response to treatment, and that a physician attempting to practice the claims of the '328 patent would look at the results achieved in an individual patient in order to know if the claimed methods were successfully practiced. This testimony is relevant because it is inconsistent with Dr. Mehta's opinion that "the term 'therapeutically effective amount' must be understood to mean an amount that is in general successful, even if not successful in each and every patient treated." (Ex. 1060 at ¶ 15.) This testimony is also relevant because it also is inconsistent with Dr. Mehta's opinions that the "sufficient to" language in the claims of the '328 patent is "not limiting because the method is performed in the identical manner of whether the particular results are achieved." (Ex. 1002 at ¶ 66.)

III. MRI T2 Relaxation Time ("TRT")

5. In Exhibit 2040, at 40:15 – 46:5 and 49:16 – 55:3, Dr. Mehta

confirmed that Liu et al. (Ex. 1062) disclosed that serum ferritin does not accurately reflect the differential iron storage between the organs in the body, that in the 1994-1996 timeframe, the authors were still evaluating the usefulness of MRI TRT measurements of tissue iron, and that there were caveats to MRI TRT that required independent validation of the process in humans before wide application. This testimony is relevant because it is inconsistent with Dr. Mehta's opinions in paragraph 26 of his Reply Declaration (Ex. 1060) that the "prior art shows that clinicians in the field of iron overload treatment recognized that cardiac MRI TRT was a reliable measure of heart iron concentration."

IV. The Clinical Study Described in the '328 Patent

6. In Exhibit 2040, at 6:6 – 7:25, Dr. Mehta testified that the study described in column 14, line 43 through column 26, line 5 of the '328 patent was a retrospective study and thus it was not possible to adjust the deferiprone dose in such a study. This testimony is relevant to Dr. Mehta's opinions in paragraph 15 of his Reply Declaration (Ex. 1060) because it explains why the inventors did not adjust the dose of deferiprone in the study described in column 14, line 43 through column 26, line 5 of the '328 patent.

V. Anticipation by Hoffbrand 1998

7. In Exhibit 2040, at 35:7-13, Dr. Mehta testified that Hoffbrand and his coauthors determined that for the 5 patients that died of cardiac disease, treatment

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