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 OBSERVATIONS

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Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
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Response to Observation 1:

In his Reply Declaration (Ex. 1060), Dr. Mehta opined on the inherent anticipation of claims 6-10[1]: for patients in Olivieri 1995 and Hoffbrand 1998 who were successfully treated (i.e., their results showed a decrease in cardiac iron), this meant that "to the extent that deferiprone preferentially chelated cardiac iron in the claimed population as of the filing date of the patent, deferiprone administered to the claimed population resulted in preferential chelation as of the publication date of [the prior art]." (Ex. 1060 at ¶ 35; *see also id*. at ¶ 41.)

On page 18 of his second deposition (Exhibit 2040), Dr. Mehta provided his opinion that the "intended results" "will occur in some patients, and [] will not occur in other patients." (Ex. 2040 at 18:15-17.) Dr. Mehta explained that it would be unrealistic to believe that every patient responds the same way to treatment, "just like give you give antibiotics for pneumonia, and not every single patient always responds." (*Id.* at 19:4-6.) This testimony is not inconsistent with Dr. Mehta's opinions expressed in his Reply Declaration where Dr. Mehta focused on successfully treated patients, and opined on the behavior of deferiprone in the bodies of those successfully treated patients.

[1] Patent Owner states that Dr. Mehta opined that "the prior art inherently anticipates the claims of the '328 patent." To be clear, Dr. Mehta offered opinions on inherent anticipation only with respect to claims 6-10 of the '328 patent. He opined that claims 1, 2, 4, and 5 are expressly anticipated by the prior art.

On page 20 of Exhibit 2040, Dr. Mehta testified about the standard for inherent anticipation. He also expressed the standard for inherent anticipation in his First Declaration (*see* Ex. 1002 at ¶ 20), and he used this standard in forming his opinions in this matter. Dr. Mehta's testimony about probabilities and possibilities is not inconsistent with his opinions expressed in his Reply Declaration, which focused on successfully treated patients.

Response to Observation 2:

Dr. Mehta did not testify that the "claims of the '328 patent require a therapeutically effective amount to achieve a specific outcome in individual patients," as asserted by Patent Owner in Observation 2. Patent Owner takes Dr. Mehta's testimony at 8:1-9:4 and 10:8-12:7 out of context: Dr. Mehta agreed that he had provided certain testimony in a *different deposition*, for the parallel district court litigation, where a *different claim construction standard* applies, and where the district court entered a *different claim construction* than that adopted by the Board in this proceeding.[2]

Even under the different claim interpretation, Dr. Mehta never testified that the claims "require" an effect in "individual patients." (*See* Ex. 2040 at 8:1-9:4 and 10:8-12:7.) Dr. Mehta similarly did not testify in the other cited portion of his

[2] Patent Owner has admitted that statements regarding the claim construction adopted by the district court "have no probative value should the PTAB maintain its preliminary construction adopted in instituting these proceedings." (Paper 44 at 6.)

testimony (*id.* at 24:24-27:7) that the claims "require a therapeutically effective amount to achieve a specific outcome in individual patients." He testified that when treating patients, physicians tweak individual patient's treatments, depending on how the individual's disease behaves (*id*. at 25:12-23), and that physicians always look at results in individual patients (*id*. at 27:2-3).

Dr. Mehta's deposition testimony about whether deferiprone works in "each and every patient" is not inconsistent with the opinions in his declaration, in which he focused on individual patients who were successfully treated with a therapeutically effective dose of 75 mg/kg/day of deferiprone, and whose cardiac iron was preferentially chelated (to the extent that is how deferiprone works in the body of a successfully treated patient). (Ex. 1060 at ¶¶ 22-23, 30-31, 34, 38-40.)

Response to Observation 3:

In the referenced testimony at 8:1-9:4, 10:8-12:7, and 16:16-18:4, Dr. Mehta confirmed his testimony—taken at a *different deposition*, for the parallel district court litigation, where a *different claim construction standard* applies, and where the district court entered a *different claim construction* than that adopted by the Board in this proceeding—that the intended results define the therapeutically effective dose of the claims. Dr. Mehta's opinions here that the intended results clauses of the claims are *not* limiting, however, are consistent with the Board's claim construction, the Board's rejection of Patent Owner's proposed construction

in the Institution Decision (*see* Paper 7 at 6-9), and the Board's finding that 75 mg/kg/day of deferiprone "necessarily constitutes a value that is a 'therapeutically effective amount' as recited in claims 1, 2, and 4-10." (*Id*. at 7.)

The testimony cited by Patent Owner is not relevant to claim construction in this proceeding as it does not reflect the "broadest reasonable construction" in light of the specification which determines the proper claim construction in an IPR. (*See* 37 C.F.R. § 42.100(b) ("A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.").)

Response to Observation 4:

Patent Owner's observation does not reflect Dr. Mehta's testimony. In the first part of the testimony cited by Patent Owner, Dr. Mehta testifies on the unremarkable proposition that doctors treat individual patients. (Ex. 2040 at 24:24-25:23.) In the second part of the cited testimony, Dr. Mehta answers Patent Owner's counsel's question about a physician "trying to understand if they were successfully practicing the claim[ed] method" of claim 1. In other words, Dr. Mehta was asked to assume that claim 1 requires "successfully practicing" the method, which is not consistent with the Board's claim construction. For the same reasons as discussed above in the Response to Observation 3, the testimony cited

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