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 REPLY IN SUPPORT OF MOTION TO EXCLUDE

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United States Patent and Trademark Office
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A. Exhibits 2006, 2015, and 2016 Should Be Excluded

Patent Owner relies on the alleged facts discussed in these non-prior art references for claim construction purposes, as part of its attempt to import a limitation of measuring cardiac iron by MRI T2* into the claims. (*See* Patent Owner Response, Paper 17 at, *e.g.*, 32 ("It was not until 2000 that cardiac MRI T2* was capable of quantitatively assessing cardiac iron levels. Thus, at the time of the invention, a POSA would not have viewed [other data] as demonstrating that the patients in that study were experiencing an iron overload condition of the heart.").) But, references that are not prior art cannot be included in the claim construction inquiry. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 ("A court construing a patent claim seeks to accord a claim the meaning it would have had to a [POSA] at the time of the invention.") (emphasis added). The alleged facts reported in these Exhibits were not part of the knowledge of a POSA as of June 30, 2000, and therefore may not be considered for claim construction.

Patent Owner's citation of MPEP § 2124 is inapposite. MPEP § 2124 provides limited situations when later-arising facts may be considered, but none are analogous to claim construction. The MPEP explicitly prohibits the use of post art to inform an analysis of the claims at the time of the invention. For example, the MPEP makes clear that "it is impermissible to use a later factual reference to determine whether the application is enabled," which must be judged as of the

priority date. *Id*. *See* MPEP § 2164.05(a); *see also Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). Thus, MPEP § 2124 does not provide a basis for the Board to consider this post art to construe the claims.

Patent Owner admits that it relies on Exhibits 2006, 2015, and 2016 for the truth of the matters reported in those exhibits, making them hearsay. Patent Owner argues that Exhibits 2006, 2015, and 2016 qualify as an exception to the rule against hearsay "under FRE 703," but, FRE 703 does not present exceptions to the rule against hearsay. Rule 703 allows an expert to rely on "facts or data" even if those facts or data are not admissible. Fed. R. Evid. 703. Here, the exhibits are inadmissible hearsay, and Patent Owner's experts have not established that the facts or data are those upon which "experts in the particular field would reasonably rely," as required by FRE 703. Further, Exhibits 2006, 2015, and 2016 cannot be properly considered for claim construction, and thus, the prejudicial effect of their admission substantially outweighs any probative value of these Exhibits.

The proposed use of these exhibits is not permitted by MPEP § 2124 (or any other section of the MPEP), and the exhibits are not within any recognized hearsay exception. The Board should therefore exclude and not consider these exhibits.

B. Exhibit 2008 Should Be Excluded

Patent Owner has not provided any information on the source of Exhibit 2008. Patent Owner relies on alleged "hallmarks of authenticity under FRE 901(b)(4)"

(Paper 53 at 5), but Patent owner merely lists the information in the document without explaining how these features support authenticity. "[T]he mere recitation of the contents of documents does not authenticate them or provide for their admissibility." *Mathin v. Kerry*, 782 F.3d 804, 812 (7th Cir. 2015). Exhibit 2008 is therefore not authenticated and should be excluded and not considered.

Exhibit 2008, discussing the FDA approval of Ferriprox®, is also not relevant to the instant proceeding, which concerns only the unpatentability of the '328 patent. Patent Owner contends that Ferriprox® is relevant because it allegedly embodies the claims of the '328 patent. (Paper 53 at 5.) But, whether the '328 patent is listed in the FDA's Orange Book as covering Ferriprox® is irrelevant to the validity of the patent, and the truth of this assertion is currently contested at the district court in the parallel litigation.[1] Exhibit 2008 is titled "FDA Approves Ferriprox to Treat Patients with Excess Iron in the Body," and does not mention cardiac iron. The Board should therefore exclude Exhibit 2008.

Last, contrary to Patent Owner's assertions, Petitioner identified the statement in Exhibit 2008 on which Patent Owner relied in this proceeding. (*See* Paper 48 at

[1] At the district court, Petitioner denies Patent Owner's assertion that Petitioner's generic version of Ferriprox will infringe the '328 patent because, *inter alia*, the prescribing information for this product does not instruct the treatment of cardiac iron.

2.) Patent Owner has not identified a single hearsay exception that applies. The Board should therefore exclude Exhibit 2008 as inadmissible hearsay.

C. Exhibit 1010 Should Be Excluded

Exhibit 1010, the claim construction order from the parallel district court litigation, was decided under a different claim construction standard than applies here.[2] 37 C.F.R. § 42.100(b). And, as the Supreme Court has explained while upholding the PTAB's use of the broadest reasonable interpretation standard for claim construction, the different standards that apply in district court and at the PTAB "mean that the possibility of inconsistent results is inherent to Congress' regulatory design." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016). Thus, neither the district court's ultimate order, nor its reasoning that led to the order, are relevant to this proceeding. The district court's claim construction order is irrelevant, and the Board should exclude Exhibit 1010 under FRE 402.

Further, Patent Owner admitted that statements regarding the district court's claim construction "have no probative value should the PTAB maintain its preliminary construction adopted in instituting these proceedings." (Paper 44 at 6.)

[2] Petitioner recognizes that there may be changes to the standard for claim construction used in IPRs, but this proposed rulemaking is pending and subject to change, and therefore should not impact this proceeding.

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