

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 MOTION TO EXCLUDE EVIDENCE

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United States Patent and Trademark Office
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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), the Board's Scheduling Order (Paper 8), and the Federal Rules of Evidence, Petitioner Taro Pharmaceuticals U.S.A., Inc. hereby moves to exclude Exhibits 2006, 2008, 2010, 2014, 2015, and 2016 submitted by Patent Owner Apotex Technologies, Inc.

II. IDENTIFICATION OF ORIGINAL OBJECTIONS

Petitioner timely objected to Exhibits 2006, 2008, 2010, 2014, 2015, and 2016 on December 12, 2017. (Paper 10.)

III. EXHIBIT 2006 IS INADMISSIBLE HEARSAY AND SHOULD BE EXCLUDED FROM THE RECORD

Exhibit 2006 is a purported copy of an article titled "*Longitudinal analysis of heart and liver iron in thalassemia major*," dated 2008. Exhibit 2006 is not prior art to the '328 patent, which has an earliest effective priority date of June 30, 2000. Patent Owner relied on Exhibit 2006 in its Preliminary Response as alleged evidence that "the liver and heart have different mechanisms of iron uptake and release." (Paper 6 at 2.) Exhibit 2006 is thus relied on for the truth of the matter stated therein. Exhibit 2006 does not contain any independent indicia of trustworthiness and is therefore inadmissible hearsay not within any hearsay exception. The Board should therefore exclude and not consider Exhibit 2006. FRE 802, 803.

IV. EXHIBIT 2008 IS IRRELEVANT, NOT AUTHENTICATED, AND INADMISSIBLE HEARSAY AND SHOULD BE EXCLUDED FROM THE RECORD

The Board should exclude and not consider Exhibit 2008 for at least three independent reasons.

First, Exhibit 2008 is not authenticated. Exhibit 2008 is a document titled “*FDA Approves Ferriprox to Treat Patients with Excess Iron in the Body.*” Patent Owner’s Exhibit list states that Exhibit 2008 is an “internet publication” (Paper 6 at Exhibit List), but Patent Owner provides no authenticating evidence for this proposition. Thus, Exhibit 2008 is unauthenticated and the Board should therefore exclude and not consider this exhibit for that reason. FRE 901.

Second, Exhibit 2008 is not relevant to this proceeding. Patent Owner relied on Exhibit 2008 as evidence that Ferrirpox[®] was allegedly approved by FDA in 2011 after an accelerated review. (Paper 6 at 9.)¹ The FDA approval of Ferriprox[®] is not relevant to any issues in this proceeding, which concerns only the unpatentability of the ’328 patent, and does not concern any particular product. Moreover, no record evidence establishes that the methods claimed in the ’328

¹ Apotex did not disclose that it first filed its application for approval for Ferriprox on December 21, 2006, and that it took five years to gain FDA approval for that drug. See https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021825Orig1s000SumR.pdf.

patent are embodied by the FDA's approval of Ferriprox[®]. Thus, the Board should exclude and not consider Exhibit 2008 under FRE 402 because it is not relevant under FRE 401. In the alternative, the Board should exclude and not consider Exhibit 2008 under FRE 403 because any probative value is substantially outweighed by the danger of unfair prejudice or confusing the issues.

Third, Exhibit 2008 is inadmissible hearsay. Patent Owner relied on Exhibit 2008 for the truth of the matter asserted therein. Exhibit 2008 does not contain any independent indicia of trustworthiness and is therefore inadmissible hearsay not within any hearsay exception. The Board should therefore exclude and not consider Exhibit 2008 for this reason. FRE 802, 803.

V. EXHIBIT 2010 IS IRRELEVANT AND SHOULD BE EXCLUDED FROM THE RECORD

Exhibit 2010 is a copy of the Claim Construction Opinion and Order issued in district court litigation Case No. 2:16-cv-00528 (E.D. Tex), in which the validity of the '328 patent is one of many contested issues. The district court construed the contested claim terms under the *Phillips* standard, as appropriate in district court. The Board, however, must construe the claims according to the broadest reasonable interpretation in light of the specification of the '328 patent. 37 C.F.R. § 42.100(b). Because these two claim construction standards are different, the court's claim construction order is irrelevant to the instant proceedings under FRE 401, and should not be considered by the Board as controlling, or even as

persuasive. The Board should therefore exclude and not consider Exhibit 2010 under FRE 402, or under FRE 403 because any probative value is substantially outweighed by the danger of unfair prejudice or confusing the issues.

VI. EXHIBIT 2014 IS NOT AUTHENTICATED AND INADMISSIBLE HEARSAY AND SHOULD BE EXCLUDED FROM THE RECORD

The Board should exclude and not consider Exhibit 2014 for at least two independent reasons.

First, Exhibit 2014 is not authenticated. Exhibit 2014 is a document titled “*Canadian Scientists Honored for Role in Breakthrough drug.*” Patent Owner’s Exhibit list states that Exhibit 2014 is an “internet publication” (Paper 6 at Exhibit List), but Patent Owner provides no authenticating evidence for this proposition. Thus, Exhibit 2014 is unauthenticated and the Board should therefore exclude and not consider this exhibit for that reason. FRE 901.

Second, Exhibit 2014 is inadmissible hearsay. Patent Owner relied on Exhibit 2014 as evidence that named inventor Dr. Michael Spino was allegedly praised by others for his work related to the ’328 patent. (Paper 6 at 59.) Exhibit 2014 is thus relied on for the truth of the matter stated therein. Exhibit 2014 does not contain any independent indicia of trustworthiness and is therefore inadmissible hearsay not within any hearsay exception. The Board should therefore exclude and not consider Exhibit 2014. FRE 802, 803.

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