

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC

Petitioner

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

Patent Owner

Case IPR2015-01835 (U.S. Pat. No. 8,618,135)

**PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO
EXCLUDE EVIDENCE**

I. Exhibits 1024 And 1025 Should Be Excluded.

For the reasons set forth in Patent Owner’s Motion to Exclude (“Motion” (Paper 38) at 1-4), the website printouts that comprise Exhibits 1024 and 1025 should be excluded at least on the basis of Federal Rule of Evidence (“FRE”) 901 as lacking authenticity.

Petitioner argues that the Marx Declaration (Exhibit 1034) authenticates Exhibits 1024 and 1025. Pet. Opp. (Paper 44) at 1. As Petitioner explains, however, the Marx Declaration attests to the respective hyperlinks where Exhibits 1024 and 1025 purportedly can be found. But Petitioner offers these exhibits to show the purported price of Juxtapid, and nothing in the Marx Declaration speaks to whether the documents accurately report this information.

Patent Owner also objected to Exhibit 1025 as hearsay. *See* Motion at 1; 3. Petitioner does not directly respond to this evidentiary challenge, but instead argues only that Patent Owner has not contested the prices in the exhibits. This misses the point. As an evidentiary matter, Petitioner bears the burden of responding to Patent Owner’s timely-made hearsay objection by showing that its proffered exhibit is subject to a hearsay exception. Petitioner has not done so.

Finally, Petitioner has failed to respond to Patent Owner’s additional arguments that Exhibit 1025 should be excluded under FRE 106 and 402/403. Motion at 3-4.

Accordingly, Exhibits 1024 and 1025 should be excluded because they lack authentication under FRE 901. Further, Exhibit 1025 should also be excluded under FRE 106, 402/403, and 801/802.

II. Exhibits 1050-1055 (Product Labels) Should Be Excluded.

For the reasons set forth in the Motion, Exhibits 1050-1055, which purport to be product labels for various pharmaceuticals, should be excluded under FRE 901 as not authenticated and under FRE 402/403 to the extent they are relied on as prior art. Motion at 4-7.

In response to Patent Owner's objections to the product labels, Petitioner relies upon the Declaration of Christopher Casieri ("Casieri Declaration" (Ex. 1060)). The Casieri Declaration simply asserts that the documents comprising Exhibits 1050-1055 may be downloaded from an FDA website, but fails to include any facts purporting to show that the documents are what Petitioner contends they are—labels for products that "were FDA approved for the treatment of HoFH at the time of the invention." Petitioner Reply (Paper 30), at 20.

In response to Patent Owner's relevance objection, Petitioner argues that the dates of availability of statins and ezetimibe are not contested facts (Opp. at 3), but this argument again misses the mark. Petitioner has used these labels to assert that "at least six drugs were FDA approved for the treatment of HoFH at the time of the invention." Motion at 4 (*citing* Paper 30 at 20; Paper 31 at 21)). Thus, the issue is

not whether statins and ezetimibe were generally commercially available prior to 2005, but instead whether Exhibits 1050-1055 themselves tend to show that the products mentioned therein were available as of 2005. Accordingly, whether these labels are what Petitioner purports them to be, as of the dates Petitioner purports them to have been publicly available, is *precisely* the issue here, and Petitioner has not proffered evidence on these points.

Accordingly, Exhibits 1050-1055 should be excluded because they lack authentication under FRE 901. Further, because they have not been established as part of the state of the art, they should be excluded under FRE 402/403 as irrelevant to any issue in this proceeding.

III. Exhibit 1056 (Kimball Deposition Transcript) Should Be Excluded.

For the reasons set forth in the Motion, Exhibit 1056 should be excluded under 37 C.F.R. §42.6(d) as an improper duplicate of Exhibit 2304. Motion at 7-8. Exhibit 2304, filed first by Patent Owner, also includes Dr. Kimball's signed errata sheet, and is thus the more complete of the two documents. Motion at 7. To the extent Petitioner cites Exhibit 1056 in its Reply, its citations can be updated to reflect Exhibit 2304 in place of Exhibit 1056 if necessary.

IV. Conclusion

For the foregoing reasons, Patent Owner respectfully requests that the Board exclude Petitioner's Exhibits 1024, 1025, and 1050-1056.

Dated: November 18, 2016

Respectfully submitted,

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