

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**COALITION FOR AFFORDABLE DRUGS VIII, LLC**

*Petitioner*

v.

**THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA**

*Patent Owner*

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**Case IPR2015-01836 (U.S. Pat. No. 7,932,268)**

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**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE**

## **I. Statement of Precise Relief Requested**

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner The Trustees of the University of Pennsylvania hereby moves to exclude Exhibits 1024, 1025, and 1046-1052, submitted by Petitioner Coalition for Affordable Drugs VIII, LLC.

## **II. Argument**

### **A. Exhibits 1024 and 1025 (website printouts)**

Exhibits 1024 and 1025 appear to be website printouts. In its Exhibit List, Petitioner describes Exhibit 1024 as “*Prices and coupons for 30 capsules of Juxtapid 5mg, 10mg, 20mg, 30mg, 40mg and 60mg (brand), GOODRX.COM, <http://www.goodrx.com/juxtapid> (last visited July 16, 2015),” and Exhibit 1025 as “*Dan Mangan, ‘Fast Money’ faux pas: Firm draws FDA warning, DOJ subpoena, CNBC.COM (Jan. 13, 2014), <http://www.cnbc.com/id/101327742> (last visited July 22, 2015).*” Paper 1 at v. Petitioner cites these exhibits on page 4 of the Petition, to support its allegation regarding the purported price of JUXTAPID. Paper 1 at 4.*

On March 21, 2016, Patent Owner timely objected to Exhibits 1024 and 1025 as lacking authentication under Federal Rule of Evidence (“FRE”) 901. Paper 9 at ¶¶ 9, 10; *see* 37 C.F.R. § 42.64(b)(1). Patent Owner further objected to Exhibit 1025 under FRE 801/802 as hearsay (subject to no exception); under FRE 402/403 as not relevant to any issue in this proceeding; and under FRE 106 as

incomplete. Paper 9 at ¶10. Petitioner did not respond to these objections with supplemental evidence or otherwise.

FRE 901 states: “To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Petitioner fails to carry its burden. Based on the description in Petitioner’s Exhibit List, it appears that Petitioner would contend that Exhibits 1024 and 1025 are webpage printouts. But the Petition makes no attempt to establish the province of these exhibits, and the face of Exhibit 1024 lacks any indication whatsoever of a website address from which the document was purportedly obtained.

“When offering a printout of a webpage into evidence to prove the website’s contents, the proponent of the evidence must authenticate the information from the website itself, not merely the printout.” *See, e.g., Standard Innovation Corp. v. LeLo, Inc.*, Case IPR2014-00148, Paper 42 at 10 (P.T.A.B. Apr. 23, 2015), *rehearing denied*, IPR2014-00148, Paper 44 (P.T.A.B. Aug. 13, 2015); *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), *as amended* (Nov. 20, 2007) (*citing United States v. Jackson*, 208 F.3d 633, 638 (7th Cir. 2000)). The Board has required that “[t]o authenticate printouts from a website, the party proffering the evidence must produce some statement or affidavit from someone with knowledge of the website . . . for example a web master or someone else with

personal knowledge would be sufficient.” *EMC Corp. v. Personalweb Techs., LLC*, Case IPR2013-00084, Paper 64 at 45-46 (P.T.A.B. May 15, 2014) (quoting *St. Luke’s Cataract & Laser Inst., P.A. v. Sanderson*, 2006 WL 1320242, at \*2 (M.D. Fla. May 12, 2006)), *a’ffd*, 612 Fed. Appx. 611 (Fed. Cir. 2015).

Here, Petitioner has failed to provide *any* witness testimony whatsoever regarding the websites from where it allegedly obtained Exhibits 1024 and 1025, let alone any testimony from a witness with personal knowledge that the printouts themselves are authentic. Because Petitioner has failed to provide any evidence to support a finding that the documents are what Petitioner claims they are, Exhibits 1024 and 1025 are inadmissible and should be excluded.

Exhibit 1025 should be excluded for three additional reasons. First, it should be excluded under FRE 801/802 as hearsay (subject to no exception). Exhibit 1025 contains out-of-court statements that are offered for the truth of the matters therein (*i.e.*, the purported price of JUXTAPID, *see* Petition, Paper 1 at 4). Petitioner has not and cannot identify any hearsay exception applicable to this document. Second, Exhibit 1025 should be excluded under FRE 106 as incomplete. Specifically, article content appears to be missing. For example, the first full paragraph of the article starts mid-sentence. Third, Exhibit 1025 should be excluded under FRE 402/403 as not relevant to any issue in this proceeding. Petitioner does not argue that the purported price of JUXTAPID, which is a

commercial embodiment of the challenged patent claims, has any relevance to whether the challenged claims are unpatentable.

**B. Exhibits 1046-1051 (Product Labels)**

Exhibits 1046-1051 purport to be product labels for various pharmaceuticals.

In its Exhibit List, Petitioner describes the documents as follows:

|      |                       |
|------|-----------------------|
| 1046 | FDA Label for Crestor |
| 1047 | FDA Label for Vytorin |
| 1048 | FDA Label for Zocor   |
| 1049 | FDA Label for Caduet  |
| 1050 | FDA Label for Lipitor |
| 1051 | FDA Label for Zetia   |

Paper 30 at vii-viii. The labels contain yellow highlighting that was presumably added by Petitioner. *See, e.g.*, Ex. 1046 at 9. Petitioner cites these exhibits in support of its contention that “at least six drugs were FDA approved for the treatment of HoFH at the time of the invention, including Crestor, Vytorin, Zocor, Caduet, Lipitor and Zetia.” Paper 30 at 20; Paper 33 at 21.<sup>1</sup>

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<sup>1</sup> Although Petitioner also cites Exhibits 1050-1055 in the Supplemental Declaration of Randall M. Zusman, M.D. (“Supplemental Zusman Declaration”, Ex. 1045), Petitioners failed to cite the relevant paragraphs of the Supplemental Zusman Declaration in Petitioner’s Reply or Opposition to the Motion to Amend.

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