UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC

Petitioner

ν.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

Patent Owner

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

PATENT OWNER'S OBJECTIONS TO EVIDENCE PURSUANT TO 37 C.F.R. § 42.64



Pursuant to 37 C.F.R. § 42.64, Patent Owner objects to the admissibility of the documents identified below submitted by Petitioner, Coalition for Affordable Drugs VIII, LLC, for the following reasons:

- 1. Petitioner's Exhibit 1042 is objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding. This Exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 2. Petitioner's Exhibit 1043 is objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding. This Exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 3. Petitioner's Exhibit 1044 is objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding.
- 4. Petitioner's Exhibit 1045 (Supplemental Declaration of Randall M. Zusman, M.D.) is objected to as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S.



579 (1993). Dr. Zusman does not possess the requisite credentials or expertise to render opinions in this case. This Exhibit is further objected to as unreliable under Federal Rules of Evidence 702/703 because its bases are not of the type reasonably relied upon by experts in the field in forming an opinion. This Exhibit is further objected to as unreliable under Federal Rules of Evidence 702/703 to the extent that it relies on documents dated after the priority date of U.S. Patent No. 7,932,268 for any prior art teaching.

- 5. Petitioner's Exhibit 1046 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35 U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 6. Petitioner's Exhibit 1047 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35 U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 7. Petitioner's Exhibit 1048 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35



U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

- 8. Petitioner's Exhibit 1049 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35 U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 9. Petitioner's Exhibit 1050 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35 U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.
- 10. Petitioner's Exhibit 1051 is objected to under Federal Rules of Evidence 402/403 to the extent that it is relied upon as prior art under 35 U.S.C. § 102. This exhibit (including the highlighting contained within the document) is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.



11. Petitioner's Exhibit 1052 is objected to because it violates 37 C.F.R. §42.6 (d). This exhibit (Transcript of the Deposition of S. David Kimball, Ph.D. dated July 11, 2016) was previously filed by the Patent Owner as Exhibit 2304.

Date: September 14, 2016 Respectfully submitted,

/William G. James/

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