

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 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, during the preliminary proceedings, for the following reasons:

1. Petitioner's Exhibit 1002 (Declaration of Randall M. Zusman) 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. 8,618,135 ("the '135 Patent") for any prior art teaching.

2. Petitioner's Exhibit 1003 (Declaration of Michael Mayersohn) is objected to as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Dr. Mayersohn 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 the '135 Patent for any prior art teaching.

3. Petitioner's Exhibit 1004 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 is further objected to under Federal Rules of Evidence 702/703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) to the extent it is offered as improper expert testimony. The form of this Exhibit violates 37 C.F.R. § 42.63.

4. Petitioner's Exhibit 1005 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 is further objected to under Federal Rules of Evidence 702/703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) to the extent it is offered as improper expert testimony. The form of this Exhibit violates 37 C.F.R. § 42.63.

5. Petitioner's Exhibit 1007 is objected to under Federal Rules of Evidence 402/403 because it is cumulative over Exhibit 1001.

6. Petitioner's Exhibit 1013 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 is further objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding.

7. Petitioner's Exhibit 1014 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 is further objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding. This Exhibit is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

8. Petitioner's Exhibit 1023 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 is further objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding. This Exhibit is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

9. Petitioner's Exhibit 1024 is objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

10. Petitioner's Exhibit 1025 is objected to under Federal Rule of Evidence 106 as incomplete. This Exhibit is further objected to under Federal Rules of Evidence 402/403 because it is not relevant to any issue in the above-captioned proceeding. This Exhibit is also objected to as hearsay (subject to no exception) under Federal Rules of Evidence 801/802. This Exhibit is further objected to because it has not been properly authenticated as required by Federal Rule of Evidence 901.

11. Petitioner's Exhibit 1026 is objected to under Federal Rule of Evidence 106 as incomplete.

12. The form of Petitioner's Exhibit 1028 violates 37 C.F.R. § 42.63.

13. The form of Petitioner's Exhibit 1030 violates 37 C.F.R. § 42.63.

14. Petitioner's Exhibit 1034 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 is further objected to under Federal Rules of Evidence 702/703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) to the extent it is offered as improper expert testimony. This Exhibit is further objected to because it has not been

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