UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII, LLC,
Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,
Patent Owner.

Case IPR2015-01835

Patent 8,618,135

PATENT OWNER'S OBSERVATIONS ON CROSS-EXAMINATION OF PETITIONER'S REPLY WITNESS

Dr. Zusman's Reply Deposition Transcript (Ex. 2306)

1. In Ex. 2306, on page 44, lines 9-15, in response to the question "And it was generally known that for lomitapide, side effects increase with dose, correct?," Dr. Zusman testified that "That dose was one of the factors that was associated with side effects in the previously conducted trials." This testimony is relevant to Petitioner's assertion that a person of ordinary skill in the art (POSA) would have been motivated to dose lomitapide according to the increasing dose titration regimen in Pink Sheet, purportedly with a reasonable expectation of success. *See, e.g.*, Petitioner's Reply (Paper 30) at pages 12-15. This testimony is relevant because it demonstrates that contrary to Petitioner's assertion, a POSA would not have been motivated to use lomitapide—which was known to have dose-dependent side effects—in an increasing dose titration regimen.

2. In Ex. 2306, on page 50, line 22 – page 51, line 14, Dr. Zusman agreed that Exhibit 1015 (Chang) states that "similar AST and ALT elevations of a magnitude sufficient to halt the development of BMS-20138 [lomitapide] were also reported." This testimony is relevant to Petitioner's contention that a POSA purportedly would have understood that "BMS abandoned lomitapide for business reasons." *See, e.g.*, Petitioner's Reply (Paper 30) at pages 11 and 21. This testimony is relevant because it demonstrates that a POSA would have understood that BMS discontinued lomitapide due to liver toxicity, undercutting any purported

motivation to restart development of lomitapide.

3. In Ex. 2306, on page 51, line 15 – page 54, line 14, Dr. Zusman admits that Exhibit 2001, which includes the Technology Donation Agreement, is dated "May 19, 2006" (*see* Ex. 2306, page 52, lines 3-6) and "is not prior art." (*See* Ex. 2306, page 53, line 6.) This testimony is relevant to Petitioner's contention that based on the Technology Donation Agreement, a POSA would have known that "BMS abandoned lomitapide for business reasons," and to Dr. Zusman's contention that BMS discontinued the development of lomitapide "based on existing market conditions." *See, e.g.*, Petitioner's Reply (Paper 30) at pages 11, 21. This testimony is relevant because it demonstrates that a POSA would not have had access to the Technology Donation Agreement as of the claimed priority date, and thus this document could not have influenced a POSA's decision on whether to restart lomitapide development following BMS's discontinuation of the drug.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PATENT OWNER'S OBSERVATIONS ON CROSS-EXAMINATION OF PETITIONER'S REPLY WITNESS was served electronically via e-mail on October 28, 2016 on the following:

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