

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

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Case IPR2015-00547

Patent 7,765,107

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**JAZZ PHARMACEUTICALS, INC.'S OBJECTIONS TO  
EVIDENCE SUBMITTED DURING THE PRELIMINARY  
PROCEEDING PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Jazz Pharmaceuticals, Inc. objects as follows to the admissibility of evidence submitted during the preliminary proceeding:

| <b>Evidence</b>   | <b>Objections</b>   |
|---|---|
| AMN1007 at ¶¶ 21, 42, 45, 134, and any other paragraph addressing the public accessibility/availability of AMN1003-1006 | <p><b>FRE 602:</b> No evidence supports a finding that Dr. Valuck has personal knowledge of the public accessibility/availability of the Advisory Committee Art (AMN1003-1006).</p> <p><b>FRE 702:</b> Dr. Valuck's assertions regarding the alleged public accessibility/availability of AMN1003-1006 are improper expert testimony at least because: (1) Dr. Valuck is not qualified as an expert on the subject of public accessibility/availability; (2) Dr. Valuck's specialized knowledge is not helpful to the trier of fact to understand or determine the public accessibility/availability of AMN1003-1006; and (3) Dr. Valuck's testimony regarding the alleged public accessibility/availability of AMN1003-1006 is not based on sufficient facts or data and is not the product of reliable principles and methods reliably applied by Dr. Valuck.</p> |
| AMN1028   | <p><b>FRE 802:</b> The exhibit is inadmissible hearsay if it is offered to prove the truth of the matter asserted therein, including, but not</p>   |

| Evidence | Objections  |
|----------|---|
|          | <p>limited to, any alleged public accessibility/availability of AMN1003-1006.</p> <p><b>FRE 901:</b> Petitioners have not produced evidence sufficient to support a finding that the exhibit is what Petitioners claim it is.</p> |

Date: August 11, 2015

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certify that JAZZ PHARMACEUTICALS, INC.'S OBJECTIONS TO EVIDENCE SUBMITTED DURING THE PRELIMINARY PROCEEDING was served on August 11, 2015 by filing this document through the Patent Review Processing System, as well as e-mailing a copy to [mruedy@meiplaw.com](mailto:mruedy@meiplaw.com) and [smaddox@meiplaw.com](mailto:smaddox@meiplaw.com).

Date: August 11, 2015

Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

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