

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL,
INC. and WOCKHARDT BIO AG,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner.

Case IPR2015-00547¹
Patent 7,765,107

**AMNEAL PHARMACEUTICALS LLC'S AND PAR PHARMACEUTICAL,
INC.'S OBJECTIONS TO EVIDENCE SUBMITTED BY PATENT OWNER
PURSUANT TO 37 C.F.R. § 42.64(B)(1)**

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¹ Case IPR2015-01820 has been joined with this proceeding.

Pursuant to 37 C.F.R. §42.64(b)(1), Petitioners Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. object as follows to the admissibility of evidence submitted by the Patent Owner on November 6, 2015:

1. **JAZZ EXHIBIT 2042** is objected to under Fed. R. Ev. 801–802 because it is offered as a statement of Dr. Robert Valuck, not made while testifying in the present trial, for the purpose of proving factual matters regarding Dr. Valuck’s expertise. **JAZZ EXHIBIT 2042** is also objected to under Fed. R. Ev. 401–402 as no statement in the exhibit is relevant to any material issue of fact in dispute in this trial. **JAZZ EXHIBIT 2042** is also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading.

2. Paragraphs 50-57 of **JAZZ EXHIBIT 2046** are objected to under Fed. R. Ev. 401–402 because they are irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. Paragraphs 50-57 of **JAZZ EXHIBIT 2046** are also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading. Paragraph 53 of **JAZZ EXHIBIT 2046** is also objected to under Fed. R. Ev. 801/802 because it contains

the statements of David A. Holdford and Craig T. Kirkwood offered for the purpose of establishing factual matters.

3. Paragraphs 36-38 of **JAZZ EXHIBIT 2047** are objected to under Fed. R. Ev. 401–402 because they are irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. Paragraphs 36-38 of **JAZZ EXHIBIT 2047** are also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading.

4. **JAZZ EXHIBIT 2049** is objected to under Fed. R. Ev. 401–402 because it is irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. **JAZZ EXHIBIT 2049** is also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading.

5. **JAZZ EXHIBIT 2050** is objected to under Fed. R. Ev. 401–402 because it is irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made

available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. **JAZZ EXHIBIT 2050** is also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading.

6. **JAZZ EXHIBIT 2052** is objected to under Fed. R. Ev. 401–402 because it is irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. **JAZZ EXHIBIT 2052** is also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading. **JAZZ EXHIBIT 2052** is also objected to under Fed. R. Ev. 901 as insufficiently authenticated. **JAZZ EXHIBIT 2052** is also objected to under Fed. R. Ev. 801/802 as containing impermissible hearsay testimony.

7. **JAZZ EXHIBIT 2053** is objected to under Fed. R. Ev. 401–402 because it is irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. **JAZZ EXHIBIT 2053** is also objected to under Fed. R. Ev. 403 because its minimal

probative value is substantially outweighed by the fact that it is misleading and needlessly cumulative. Paragraph 5 of **JAZZ EXHIBIT 2053** is objected to under Fed. R. Ev. 702 as Dr. Kirkwood's statements that he does not teach about the Federal Register in his drug literature course is not a fact or data on which an expert in the field would reasonably rely in forming an opinion on the public availability of the ACA. **JAZZ EXHIBIT 2053** is further objected to under Fed. R. Ev. 602 as there is insufficient evidence that Dr. Kirkwood possesses personal knowledge regarding the Federal Register.

8. **JAZZ EXHIBIT 2054** is objected to under Fed. R. Ev. 401–402 because it is irrelevant to the question of whether, more than one year before December 17, 2002, AMN1004–AMN1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. **JAZZ EXHIBIT 2054** is also objected to under Fed. R. Ev. 403 because its minimal probative value is substantially outweighed by the fact that it is misleading. **JAZZ EXHIBIT 2054** is also objected to under Fed. R. Ev. 801–802 because it is offered as a statement of Dr. Glenn Van Buskirk not made while testifying in the present trial, offered for the purpose of proving factual matters. **JAZZ EXHIBIT 2054** is also objected to under Fed. R. Ev. 701/702 as opinion testimony based on scientific, technical, or other specialized knowledge within the scope of Fed. R. Ev.

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