

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

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Case IPR2015-00554<sup>1</sup>

Patent 7,668,730

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**PATENT OWNER'S NOTICE REGARDING  
NEW ARGUMENTS AND EVIDENCE IN PETITIONERS' REPLY**

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<sup>1</sup> Case IPR2015-01818 has been joined with this proceeding.

Pursuant to the Board's March 3, 2016 e-mail, Patent Owner Jazz

Pharmaceuticals, Inc. ("Jazz") identifies the following arguments and evidence raised for the first time in Petitioners' Reply filed on February 19, 2016 (Paper 46) to which Jazz had no opportunity to respond or address:

1. With the exception of two sentences, Pages 2-4, under the section entitled "FDA was required to make Exs. 1004-1006 available to the public prior to or at the ACM, and there is no evidence that FDA violated the law," contain new arguments and evidence alleging that Exs. 1004-1006 were publicly available. Petitioners rely on Ex. 1057 (along with new arguments about how this new exhibit relates to previously submitted evidence), which was available to Petitioners but not cited or mentioned in the Petition or supporting declarations. The two unchallenged sentences in this section are: on page 2, "Jazz argues there is insufficient evidence to conclude that Exs. 1004-1006 would have been available from FDA's website prior to the critical date. Response at 12-13."; and on page 3, "The FACA requires that 'documents which were made available to or prepared for or by each advisory committee *shall be made available for public inspection.*' 5 U.S.C. app. 2 § 10(b) (2001) (emphasis added)."

2. Page 4, under the section entitled "Ex. 1003 further corroborates the availability of Exs. 1004-1006 at the ACM," contains new arguments alleging that Exs. 1004-1006 were publicly available. Petitioners rely on Ex. 1003 at 12, 179,

284, 330, and 342, which were available to Petitioners but not cited or mentioned in the Petition or supporting declarations, for statements allegedly related to the availability of Exs. 1004-1006.

3. Page 5, lines 5-11, beginning with the word “Following,” and ending with “*See id.*,” contains new arguments regarding alleged updates of links only in Ex. 1017, which lead to links in Ex. 1018, which lead to further links in Ex. 1019. The new arguments regarding the alleged updates to Ex. 1017 could have been, but were not, mentioned in the Petition or supporting declarations.

Date: March 10, 2016

Respectfully submitted,

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Case IPR2015-00554<sup>2</sup>

Patent 7,668,730

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**CERTIFICATE OF SERVICE**

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<sup>2</sup> Case IPR2015-01818 has been joined with this proceeding.

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