

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,  
Patent Owner.

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Cases: IPR2016-01563 (Patent 8,673,927)  
IPR2016-01564 (Patent 8,846,695)  
IPR2016-01565 (Patent 8,853,156)  
IPR2016-01566 (Patent 9,173,859)

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Before TONI R. SCHEINER, BRIAN P. MURPHY, and ZHENYU YANG  
*Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge.*

ORDER  
Conduct of the Proceeding  
*37 C.F.R. § 42.5*

IPR2016-01563 (Patent 8,673,927)  
IPR2016-01564 (Patent 8,846,695)  
IPR2016-01565 (Patent 8,853,156)  
IPR2016-01566 (Patent 9,173,859)

On November 21, 2016, Mylan Pharmaceuticals Inc. (“Petitioner”) requested a teleconference with the Board for authorization to file a reply to the Preliminary Responses of Patent Owner Boehringer Ingelheim International GmbH (“Patent Owner”). On November 30, 2016, a conference call with the parties was convened by Judges Yang, Scheiner, and Murphy.

The Petitions assert at least one ground of unpatentability in reliance on certain “FDA-approved” drug labels, and a meeting poster (IPR2016-01565), as prior art printed publications under 35 U.S.C. § 102. Pet. 21–29.<sup>1</sup> Patent Owner argues that Petitioner has not made a threshold showing to establish the drug labels and meeting poster qualify as prior art printed publications. Prelim. Resp. 21–24. A decision on whether to institute a trial proceeding has not yet been made.

During the conference call, Petitioner argued there was good cause for submission of a reply to address Patent Owner’s printed publication arguments, because Patent Owner cited a PTAB case that issued after the Petitions were filed, which addressed non FDA-approved drug labels. *See* Prelim. Resp. 21 (citing *Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH*, Case IPR2016-00649, slip op. at 22 (PTAB September 1, 2016) (Paper 10)). Petitioner also represented it was not seeking to submit any new evidence to supplement the record, only to address Patent Owner’s arguments. Patent Owner argued that the Preliminary Responses challenged only the sufficiency of Petitioner’s evidence required to meet Petitioner’s burden in the Petition to establish the drug labels and meeting poster qualify as printed publications. Patent

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<sup>1</sup> For ease of reference, all citations are to the papers in IPR2016-01563 as representative, unless otherwise stated.

IPR2016-01563 (Patent 8,673,927)  
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Owner further noted the § 315(b) one-year bar date has passed, and, therefore, it would be improper to permit Petitioner to supplement the Petition now.

Upon considering both parties' positions, we agree with Patent Owner. Petitioner does not persuade us that good cause exists to allow Petitioner to file a reply to the Preliminary Responses to address the sufficiency of Petitioner's evidence that the drug labels and meeting poster qualify as prior art printed publications. It is Petitioner's burden to make such a showing in the Petitions. We can read the *Frontier Therapeutics* case without further input from the parties and assess the arguments and evidence presented on the current record. The passing of the § 315(b) bar date also militates against granting Petitioner's request. *See Teva Pharmaceuticals USA, Inc., v. Indivior UK Limited*, Case IPR2016-00280 slip op. at 4 (PTAB May 27, 2016) (Paper 21) ("Petitioner essentially asks to significantly bolster its Petition with new substantive argument and evidence, well after a statutory bar date, in relation to an issue where it has the burden to make a threshold showing.").

With regard to IPR2016-01565, Petitioner also requested the opportunity to file a reply addressing Patent Owner's evidence and argument in support of the asserted conception and reduction to practice of the claimed invention prior to the Mikhail reference. IPR2016-01565 Paper 11, 9–11. Petitioner emphasized that the evidence presented by Patent Owner consisted of internal company reports, and that Petitioner was entitled to address the substance of Patent Owner's arguments after discovery. Patent Owner acknowledged its antedating claim and argued that Petitioner had received contention discovery in the co-pending district court proceeding, although discovery in the district court proceeding is not yet complete.

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We agree with Petitioner. Patent Owner bears the burden of proof regarding its antedating contention. Petitioner is entitled to respond to the contention after discovery. It is premature at the institution stage to address the merits of Patent Owner's antedating contention. Therefore, we see no reason for Petitioner to file a reply to that contention prior to a decision by the Board on whether to institute a trial proceeding.

In consideration of the foregoing, it is:

ORDERED that Petitioner's request is *denied*;

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