

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.,
Patent Owner.

Case IPR2015-01976 (US 8,232,250 B2)
Case IPR2015-01980 (US 8,399,413 B2)
Case IPR2015-01981 (US 8,969,302 B2)¹

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and
TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

¹ This order addresses issues that are common to all three cases. We, therefore, issue a single order that has been entered in each case. For convenience, paper numbers refer to those filed in IPR2015-01976. The parties may use this style caption when filing a single paper in multiple proceedings, provided that such caption includes a footnote attesting that “the word-for-word identical paper is filed in each proceeding identified in the caption.”

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A conference call was held on November 19, 2015, among counsel for Petitioner Amneal Pharmaceuticals LLC (“Amneal”), counsel for Patent Owner Yeda Research and Development Co. Ltd. (“Patent Owner”), counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) in IPR2015-00643, IPR2015-00644, and IPR2015-00830 (collectively, “the Mylan cases”), and Judges Snedden, Yang, and Hulse.

Along with its Petitions for *Inter Partes* Review, Amneal filed Motions for Joinder to join the Mylan cases. Paper 3. In short, Amneal represents that its Petitions are substantively identical to the Petitions filed in the Mylan cases, that Amneal and Mylan have agreed to consolidate their filings, and that there will be no effect on the trial schedule for the Mylan cases. *Id.* at 5–7. The Board initiated the conference call with the parties to discuss Amneal’s motions for joinder.

During the call, Amneal stated that it has discussed the joinder issue with Patent Owner and Mylan and confirmed that as long as Mylan is an active petitioner, Mylan and Amneal will speak with one voice. Amneal also stated that the parties all agree to be bound by the schedule set forth in the Mylan cases. In response, Patent Owner confirmed that it does not oppose Amneal’s joinder motion, but stated that it currently intends to file a Patent Owner Preliminary Response to Amneal’s Petitions.

Both Amneal and Mylan stated that they were previously unaware that Patent Owner intended to file a Preliminary Response in these proceedings. The Petitioners expressed concerns about the possibility of Patent Owner filing new evidence with its Patent Owner Preliminary Response and the effect that may have on their ability to speak with one voice. The parties also asked for clarification as to whether Patent Owner is entitled to use in

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its Preliminary Response to the Amneal Petitions the cross-examination testimony from Mylan's declarant, which was taken after the filing of the Amneal Petitions.

Patent Owner's Preliminary Responses in these proceedings are due December 29, 2015. According to the Scheduling Order in the Mylan cases, Patent Owner's Response is due in two of the three cases on November 20, 2015, with the third due on November 25, 2015. IPR2015-00643 (Paper 14); IPR2015-00644 (Paper 15); IPR2015-00830 (Paper 9).² Given the Amneal Petitions are substantively identical to the Mylan Petitions, the panel expedited the briefing schedule for the Patent Owner Preliminary Response in the Amneal proceedings. The panel ordered that the Preliminary Responses to the Amneal Petitions are now due on December 8, 2015. The panel will then consider Amneal's motions for joinder promptly after the Preliminary Responses are filed to minimize any delays in the schedule, should the panel decide to join the proceedings.

Regarding the parties' question as to whether Patent Owner may use the cross-examination testimony of Mylan's declarant in its Preliminary Responses in these proceedings, 37 C.F.R. § 42.107(c) states that a preliminary response "shall not present new testimony evidence beyond that already of record, except as authorized by the Board." 37 C.F.R. § 42.107(c). Prior panels have generally held that expert witness testimony on patentability prepared after the filing of the petition is considered "new testimony evidence." *See, e.g., FLIR Sys., Inc. v. Leak Surveys, Inc.*, Case IPR2014-00434, slip op. at 33-34 (PTAB Sept. 5, 2014) (Paper 8); *C&D*

² For future reference, the Board encourages the parties to request a conference call as early as possible to discuss joinder issues.

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Zodiac, Inc. v. B/E Aerospace, Inc., Case IPR2014-00727, slip op. at 18 (PTAB Oct. 29, 2014) (Paper 15); *Amneal Pharms., LLC v. Endo Pharms., Inc.*, Case IPR2014-01365, slip op. at 2-3 (PTAB Nov. 14, 2014) (Paper 11); *B/E Aerospace, Inc. v. MAG Aerospace Indus., LLC*, Case IPR2014-01510, slip op. at 4 (PTAB Jan. 20, 2015) (Paper 13); *Stellar Energy Ams., Inc. v. TAS Energy Inc.*, Case IPR2015-00882, slip op. at 8-10 (PTAB Sept. 21, 2015) (Paper 10).

While we acknowledge that at least one panel has found that “new” testimony refers to testimony that was taken specifically for the purpose of the *inter partes* review proceeding at issue,³ we note that that decision is not binding on this panel. Moreover, we are persuaded that the circumstances of these proceedings differ because Amneal represents that it attended and fully participated in the depositions. We also understand that Patent Owner has agreed to cross-examine Petitioners’ declarant only once. Moreover, because the Petitions in the two sets of proceedings are substantively identical, it would not appear necessary in the interests of justice for Patent Owner to rely on that testimony in the Preliminary Responses to the Amneal Petitions when it can rely on that same testimony in its Patent Owner Responses to the identical arguments made in the Mylan Petitions. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012) (“New testimonial evidence may be permitted where a party demonstrates that such evidence is in the interests of justice.”).

Finally, any discussion regarding the impact on the schedule of the proceedings if the cases are joined is speculative at this time. Once the panel

³ See, e.g., *Anova Food, LLC v. Sandau*, Case IPR2013-00114, slip op. at 2-3 (PTAB June 25, 2013) (Paper 11).

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has made a determination on Amneal's motions for joinder, we encourage the parties to confer and stipulate to any changes in the schedule up through Due Date 5 to accommodate the joinder of cases, if so ordered.

ORDER

Accordingly, it is

ORDERED that Patent Owner's Preliminary Responses in IPR2015-01976, IPR2015-01980, and IPR2015-01981, which are currently due on December 29, 2015, are due on **December 8, 2015**.

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