

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

COSMO TECHNOLOGIES LIMITED,
Patent Owner.

Case IPR2018-00080
U.S. Patent No. 9,320,716

**PATENT OWNER'S OPPOSITION TO ARGENTUM
PHARMACEUTICALS LLC'S MOTION FOR JOINDER**

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Patent Trial and Appeal Board
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Patent Owner Cosmo Technologies Limited (“Cosmo”) submits this opposition to Argentum Pharmaceuticals LLC’s (“Argentum”) motion for joinder of IPR2018-00080 (the “Argentum IPR”) with IPR2017-01035 (the “Mylan IPR”).

In the Mylan IPR, Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) and Patent Owner have settled their dispute and filed a joint motion for termination. *See* IPR2017-01035, Paper 23. Pursuant to the settlement, Mylan has agreed that neither it nor its expert, Dr. Anthony Palmieri, will participate in an IPR proceeding challenging the patent at issue. *Id.* at 4 (“Petitioner represents that it will no longer participate in this *inter partes* review and will file no further papers. Petitioner has also agreed not to permit its expert witness, Dr. Anthony Palmieri, to assist Argentum or any other Petitioner in an IPR proceeding challenging the patent at issue.”).

For reasons discussed in the joint motion for termination, the Board should terminate the Mylan IPR. Termination saves the parties litigation costs and the Board administrative resources thereby furthering the AIA’s purpose of providing an efficient and less costly alternative forum for adjudicating patent disputes and encouraging settlement. If the Mylan IPR is terminated, then Argentum’s joinder request should be denied as moot. *See Ubisoft, Inc. v. Uniloc USA, Inc.*, IPR2016-00414, Paper 16 at 5 (June 2, 2016) (“Because [the first IPR] is no longer pending, it cannot serve as a proceeding to which another proceeding may be joined. We, therefore, must deny Petitioner’s Motion for Joinder.”).

There is no prejudice to Argentum if joinder is denied. Patent Owner has never brought a patent infringement lawsuit against Argentum and is unlikely to do so because Argentum has never made any drug products related to the challenged patent. *See* Ex. 2001. Argentum is not subject to any statutory bar under 35 U.S.C. § 315(b), and joinder is unnecessary for the Board to evaluate fully Argentum’s new petition and supporting evidence.

Joinder should also be denied because, in the event the Mylan IPR has not yet been terminated, joinder would prejudicially complicate the schedule in the Mylan IPR, and in fact, cannot work under the current schedule. An institution decision on Argentum’s IPR petition will not be issued until after January 31, 2018—the deadline for Patent Owner to file a preliminary response, *see* 35 U.S.C. § 314(b) (institution decision is “after” a preliminary response or the last date on which such response may be filed), 37 C.F.R. § 42.107(b) (“The preliminary response must be filed no later than three months after the date of a notice....”)—and will most likely be issued approximately three months later in **late April 2018**. In contrast, Patent Owner’s Response in the Mylan IPR is due several months before then, on December 20, 2017, and oral argument is scheduled for June 15, 2018. *See* IPR2017-01035, Paper 18 at 7 (Due Dates 1 and 7 in Scheduling Order). Joining the Argentum IPR would prejudice Patent Owner by injecting critical new evidence, e.g., unpatentability testimony from a different expert witness, late in the Mylan IPR proceeding without giving Patent Owner an adequate opportunity to respond. *See ZTE Corp. v. Adaptix Inc.*, IPR2015-01184,

Paper 10 at 5 (July 24, 2015) (denying joinder because a different expert declarant raises “new issues...[that] would adversely impact the IPR [] trial”).

Argentum’s motion for joinder states that if Mylan’s expert will not participate in the IPR, then Argentum’s expert, Dr. Hartmut Derendorf, and his accompanying declaration must be substituted in. *See* Paper 3 at 7. And as discussed above, Mylan has agreed in the settlement agreement that its expert will not assist Argentum or participate in the IPR. Joinder would, therefore, introduce a different expert witness in the Mylan IPR. While Argentum’s expert makes statements in his declaration similar to those made by Mylan’s expert, there are notable differences, including his educational background (Ex. 1006 ¶ 8), his academic work experience (*id.* ¶¶ 9, 11), his research interests (*id.* ¶ 10), his consulting work for industry (*id.* ¶¶ 12-13), and his membership in professional organizations and journals (*id.* ¶ 15, 17). Importantly, Dr. Derendorf’s prior statements and publications (more than 460 scientific publications and over 880 presentations in total) concerning targeted-drug-release pharmaceutical formulations will be critical to the issues in dispute (*id.* ¶ 16, Ex. 1007). Argentum’s expert will also inevitably provide new evidence when giving testimony in deposition. Introducing this new evidence via joinder and substituting in Argentum’s expert as the primary unpatentability expert would simply not be feasible under the Mylan IPR schedule. Indeed, because an institution decision in the Argentum IPR will not be issued until after January 31, 2018, Patent Owner is in the situation of filing its Patent Owner Response in the Mylan IPR (assuming it has not yet been terminated),

due on December 20, 2017, even before deposing Argentum's expert. Such an outcome would unfairly prejudice Patent Owner.

Argentum's joinder motion remarkably does not propose any modification to the schedule in the event that Mylan and its expert do not participate in the IPR (which has turned out to be the situation here), and, therefore, Argentum has failed to meet its burden of proof in establishing that joinder is appropriate under 37 C.F.R. § 42.20(d). *See Sierra Wireless Am., Inc. v. M2M Sols. LLC*, IPR2016-00853, Paper 16 (Sept. 20, 2016) (denying joinder because "Petitioner does not explain specific modifications to the schedule that would be necessary to account for the additional issues, grounds, and prior art raised in the Petition"). Argentum should not be allowed to propose any schedule modifications in its reply brief as that would be improper new argument. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016) (affirming the Board's decision to reject a reply brief that was "presenting a new argument for the first time"), *citing* 37 C.F.R. § 42.23(b) ("All arguments for the relief requested in a motion must be made in the motion.").

If trial is instituted in the Argentum IPR, then it should proceed on its own schedule. A separate trial for the Argentum IPR, if instituted, would not require additional Board resources because the Mylan IPR should be terminated. Therefore, even if joinder is denied, only one IPR proceeding on the patent at issue will remain.

It will not prejudice Argentum for this Board to consider Argentum's new IPR petition and supporting evidence on its own schedule. Argentum will be afforded full

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