

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, and
KRISTINA M. KALAN, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge*.

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

On October 20, 2016, Petitioner sent an electronic message to the Board requesting leave to file a Reply to Patent Owner's Preliminary Response "to allow Petitioner to respond to Patent Owner's irreconcilable positions set forth in Patent Owner's recent submissions to the Board."

Ex. A, 1. According to Petitioner, Patent Owner's Preliminary Response asserts that Petitioner's Petition is a "copy of" an earlier-filed petition in a proceeding involving the same patent. *Id.* However, according to Petitioner, Patent Owner "told the Board the opposite thing in no uncertain terms" when opposing Petitioner's Motion for Joinder. *Id.* Patent Owner has not made us aware of its position on whether Petitioner should be granted leave to file a Reply.

Based on the facts of this case, we are not persuaded that Petitioner has shown good cause to file a Reply. *See* 37 C.F.R. § 42.108(c). As indicated by Petitioner, in pointing what it believes to be Patent Owner's inconsistent positions, Patent Owner's allegedly inconsistent statements are already in the record in at least Paper 9 and Paper 14. The Board is capable of evaluating the parties' proposed positions relative to the asserted inconsistencies and related issues in this case based on the information already in the record.

ORDER

In view of the foregoing, it is hereby:

ORDERED that Petitioner's request to file a Reply to Patent Owner's Preliminary Response is *denied*.

IPR2016-01332
Patent 8,822,438 B2

FOR PETITIONER:

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EXHIBIT A

From: White, Brandon (Perkins Coie) [mailto:BMWhite@perkinscoie.com]
Sent: Thursday, October 20, 2016 11:28 AM
To: Trials <Trials@USPTO.GOV>
Cc: JANS-ZYTIGA@akingump.com; ZytigalPRTeam@sidley.com; Abiraterone@perkinscoie.com; Beel, Bryan D. (Perkins Coie) <BBeel@perkinscoie.com>; Canterbury, Crystal R. (Perkins Coie) <CCanterbury@perkinscoie.com>
Subject: Mylan v. Janssen, IPR2016-01332: Request for Reply

Dear Board,

Petitioner respectfully requests leave to file a reply in support of its Petition. As explained below, good cause exists as required by 37 C.F.R. § 42.108(c) to allow Petitioner to respond to Patent Owner's irreconcilable positions set forth in Patent Owner's recent submissions to the Board.

In its preliminary response, Patent Owner Janssen Oncology, Inc. asserts that the Board should not institute Petitioner Mylan Pharmaceuticals Inc.'s IPR because it is a "copy of" and "mere[] repetition" of an allegedly identical earlier-filed Amerigen petition. Paper No. 14 at 1-2. Janssen further claims that Mylan's declarant, Dr. Garnick, offers "substantially the same" declaration as Dr. Serels (who submitted a declaration in support of Amerigen's instituted petition for IPR). *Id.*

However, about two months ago when opposing Mylan's motion for joinder, Janssen told the Board the opposite thing in no uncertain terms. At that time, Janssen asserted in relevant part:

- 1) "[T]he Mylan IPR petition **does not advance 'identical grounds' to those instituted by the Board** in Amerigen's IPR." Paper No. 9 at 6 (emphasis added).
- 2) "Mylan relies on **new evidence and new expert testimony not presented** in the Amerigen IPR." *Id.* (emphasis added).
- 3) Criticism of Mylan's description of its petition as "congruent" with Amerigen's. *Id.* at 8.

Thus, Janssen argued it would face substantial burden and prejudice if joinder were allowed. *Id.* at 1, 8. The Board accepted Janssen's arguments, issuing an Order refusing to expedite

Janssen's preliminary response because of "the additional evidence and testimony relied upon by [Mylan] in its Petition." Paper No. 11 at 3.

In view of Janssen's about face in its preliminary response, Mylan respectfully submits that good cause exists to allow Mylan a reply to address (1) Janssen's inconsistent positions, and (2) more particularly, Janssen's claim that the Board should deny institution of Mylan's IPR because the "same or substantially the same prior art or arguments previously [were] presented to the Office." Paper No. 14 at 1. Accordingly, Mylan respectfully requests leave to file a 5-page reply within one week of the Board's decision on this request.

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