

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS, LLC  
Petitioner

v.

SUPERNUS PHARMACEUTICALS, INC.  
Patent Owner

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IPR2013-00368 (Patent 8,206,740)  
IPR2013-00371 (Patent 8,394,405)  
IPR2013-00372 (Patent 8,394,406)

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Before LORA M. GREEN, SCOTT E. KAMHOLZ, and  
GEORGIANNA W. BRADEN, *Administrative Patent Judges.*

KAMHOLZ, *Administrative Patent Judge.*

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

Cases IPR2013-00368,  
IPR2013-00371, IPR2013-00372  
Patents 8,206,740, 8,206,740, 8,394,406

By email dated June 3, 2014 (copy attached), Amneal requested authorization to file Exhibit 1025 in cases IPR2013-00368 and -00371. Amneal represented that the exhibit had been filed in case IPR2013-00372 and also had been served on Supernus. Supernus does not oppose the request. The request is granted.

Also by email dated June 3, 2014 (copy attached), Supernus requested guidance regarding the proper way to challenge Amneal's Reply and reply evidence for exceeding the proper scope of reply. Supernus also requested assistance from the Board regarding difficulties scheduling depositions of Amneal's reply witnesses. A conference call was conducted on June 4, 2014 to discuss these matters. A transcript of the call is to be filed by Amneal.

Supernus contended that the Reply and new evidence go beyond the scope of a proper reply because Amneal raises new issues and also belatedly introduces new evidence. When asked for an example, Supernus asserted that Exhibit 1068 is a prior-art reference that was known to Amneal at the time the petitions for these cases were filed but was introduced newly into the record, in support of Amneal's obviousness arguments, only with the Reply. Supernus requested guidance from the Board as to how to challenge the Reply, given its perception that panels of the Board have not handled such challenges uniformly. Supernus proposed filing a paper summarizing the Reply arguments and evidence that it considered to exceed the proper scope of reply.

Amneal countered that its Reply and evidence do not exceed the proper scope of reply. Amneal argued that the majority of Board panels have deferred the question of reply scope to the final written decision and that there is no reason to

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deviate from that practice here. Amneal also argued that Exhibit 1068 is proper reply evidence because it is relied on to impeach the testimony of Supernus's witness, Dr. Edward M. Rudnic.

After considering the parties' contentions, we determined that the question of whether Amneal's Reply exceeds the proper scope of reply is one that we will take up in preparing the final written decisions for these cases. We declined to authorize Supernus to file its proposed listing of challenged evidence, or any other sort of challenge to the Reply, at this time.

We reminded the parties that a petitioner's reply "may only respond to arguments raised in the corresponding opposition." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (citing 37 C.F.R. § 42.23). We cautioned Amneal that a reply that raises new issues or belatedly introduces new evidence will not be considered, and we will not distinguish proper portions of the reply from improper portions. *See id.* We further cautioned Amneal that, by submitting a Reply that exceeds the proper scope of reply in any way, Amneal runs the risk that the entire Reply, and all Reply evidence, will be given no consideration in the final written decisions. *See id.*

As to the deposition issue, Supernus represented that it has had difficulty reaching agreement on deposition dates for Amneal's four reply declarants within the time window before Due Date 4 and in Supernus's preferred order. Amneal argued that it has made reasonable proposals to accommodate Supernus's preferences. We authorized the parties to stipulate to changes of Due Dates 4 and 5, but not Dues Dates 6 and 7, to help them alleviate the impasse. Any stipulation must be filed with the Board prior to any filing that depends on the stipulation for

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timeliness. The parties may contact the Board if they remain unable to agree on deposition scheduling.

Both parties expressed intent to request oral argument. The parties are directed to file those requests by June 30, 2014, even if they stipulate to a later date for Due Date 4, in order to facilitate the Board's hearing room scheduling process.

Supernus also alerted us to the dismissal of copending litigation *Galderma Laboratories Inc., et. al. v. Amneal Pharmaceuticals LLC, et. al.*, No. 1-11-cv-01106 (D.Del.). *See, e.g.*, IPR2013-00368, Paper 54 (citing Ex. 2177). The dismissal is noted. The parties indicated that settlement talks regarding the *inter partes* review proceedings have occurred but have not resulted in progress towards settlement.

Accordingly, it is hereby

ORDERED that Amneal is authorized to file Exhibit 1025 in cases IPR2013-00368 and -00371;

FURTHER ORDERED that Supernus is not authorized to file any paper or exhibit challenging the scope of Amneal's Reply;

FURTHER ORDERED that the parties are authorized to stipulate to changes in Due Dates 4 and 5, but not Due Dates 6 and 7, upon filing notice of the stipulation with the Board; and

FURTHER ORDERED that requests for oral argument must be filed by June 30, 2014, regardless of any stipulated change to Due Date 4.

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**Subject:** RE: Case IPR2013-00368; IPR2013-00371; IPR2013-00372

Dear PTAB,

Patent Owner Supernus would like to request a conference call to discuss the following:

1. Guidance on the Board's preference on how Patent Owner may point out and explain why it believes certain new evidence and arguments in Petitioner's reply violates 37 C.F.R. § 42.23(b) ("[a] reply may only respond to arguments raised in the corresponding opposition or patent owner response"); Office Patent Trial Practice Guide, 74 Fed. Reg. at 48,767 ("a reply that raises a new issue or belatedly presents evidence will not be considered"). In particular, should Patent Owner file a motion to expunge, *see* IPR2013-00141 (Paper 35) (holding that "Green and Levy Reply Declarations ... are not proper replies and should be expunged."), or instead explain why the new evidence could have been raised earlier and thus should be accorded less weight, *cf* *Kappos v. Hyatt*, 132 S. Ct. 1690, 1694 (2012) ("In deciding what weight to afford [newly-introduced] evidence, the district court may, however, consider whether the applicant had an opportunity to present the evidence to the PTO.")?
2. If unresolved by time of the call, resolution of parties' inability to agree on dates of deposition of Petitioner's **four (4)** reply witnesses, and waiver of time limits regarding same. 37 C.F.R. § 42.53(d)(2) and (d)(4).
3. Status update on co-pending district court litigation between the parties. *See* Ex. 2177 (May 19, 2014 report of dismissal).

The parties are available for a conference call tomorrow (Wednesday, June 4) on or after 2PM EST.

Respectfully submitted,

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**Subject:** Case IPR2013-00368; IPR2013-00371; IPR2013-00372

Dear PTAB:

Counsel for Petitioner Amneal requests authorization from the Board to file Exhibit 1025 in Cases IPR2013-00368 and IPR2013-00371 to correct a clerical error. Through unintentional error, Exhibit 1025 (copy attached) was not filed with Petitioner's Reply in Cases IPR2013-00368 and IPR2013-00371 on May 23, 2014. Exhibit 1025 was, however, previously filed in IPR2013-00372 and served on Patent Owner on June 20, 2013. Exhibit 1025 was also served on Patent Owner in IPR2013-00368 on May 23, 2014. Exhibit 1025 is identical in all three IPRs.

**Patent Owner has stated that it does not oppose this request.**

Respectfully submitted,

Eldora L. Ellison

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