

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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Case IPR2013-00368  
Patent 8,206,740

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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*

By email chain commencing March 14, 2014 (copy attached to this order), the parties raised several issues concerning exhibits to Supernus's Patent Owner Response. A conference call between the parties and the Board was held on March 24, 2014. Amneal provided a court reporter for the call. For a complete record of the call, see the transcript to be filed by Amneal as an exhibit.

Supernus requested authorization for late filing of Appendices A-P to Exhibit 2145. Supernus represented that their omission was an unintentional clerical error. Supernus attached the omitted exhibits to its email to the Board dated March 14, 2014, four days after the deadline to file the Patent Owner Response, and copied Amneal on the email. Supernus proposed extending Amneal's five-day objection period under 37 C.F.R. § 42.64(b)(1) by three business days. Amneal objected to allowing Supernus to file the omitted appendices late, but did not disagree that it was a clerical error on Supernus' part. In withdrawing its objection to Supernus' filing of the omitted appendices, Amneal did ask that its deadline to file a Reply to the Patent Owner Response be extended by four days. The Board noted that there is some flexibility in the schedule for this proceeding, because Supernus has not filed a Motion to Amend Claims and no filing is expected on Due Date 3. The Board authorized Supernus to file the appendices and asked the parties to work out a stipulated change to Due Date 2.

Next, Amneal sought to have Exhibit 2145 stricken on the basis that it consists entirely of expert testimony on patent examination practice, a category of evidence excluded from admissibility by 37 C.F.R. § 42.65(a). Supernus argued that Exhibit 2145 addresses the facts of this case and is not simply expert testimony on patent examination practice.

The Board agreed with Supernus that Exhibit 2145 is not directed entirely to expert testimony on patent examination practice. Rather, the declaration testimony appears to tether the discussion of the relevant patent examination practice closely to the facts of this case for the purpose of providing context. The Board takes the view that the exhibit is not inadmissible under 37 C.F.R. § 42.65(a).

Despite the Board's view, Amneal may elect to seek to exclude this evidence in a motion to exclude, as long as the motion is filed by Due Date 4. Amneal may file more than one motion to exclude. Each motion to exclude should address all evidence Amneal seeks to exclude that has accumulated in this case by the date the motion is filed, except for evidence addressed in an earlier motion to exclude. The fifteen-page limit, however, is cumulative over all motions to exclude that Amneal files. That is, the total page count of all of Amneal's motions to exclude, added together, may not exceed fifteen. Oppositions to all motions to exclude will be due by Due Date 5, regardless of when the motions were filed, and are limited to fifteen pages in aggregate. Supernus similarly may file multiple motions to exclude, subject to the deadlines and aggregate page limit mentioned above. The Board is unlikely to rule on the motions to exclude evidence prior to entry of a final written decision.

Finally, Amneal sought to have Exhibit 2141 stricken on the basis that it is a ten-page claim chart that effectively circumvents the page limit for a Patent Owner Response. Supernus argued that the claim chart was provided in this format for the sake of clarity, and that its content could have been presented in a much smaller space. Supernus acknowledged, however, that the claim chart was offered to address an issue that was not even raised in Amneal's petition (whether the Ashley '932 and Ashley '854 documents qualify as prior art under pre-AIA 35 U.S.C. § 102(b)). The Board proposed, and the parties agreed, to leave Exhibit 2141 undisturbed but to give it little

or no consideration.

Accordingly, it is

ORDERED that Supernus is authorized to file, within three days of the date this order is entered, a substitute Exhibit 2145 that includes Appendices A-P but is otherwise unmodified;

FURTHER ORDERED that Amneal must serve any evidentiary objections to the content of the appendices within five days of service of the substitute Exhibit 2145;

FURTHER ORDERED that Amneal is not authorized to file a motion to strike Exhibit 2141 or Exhibit 2145;

FURTHER ORDERED that the parties may file more than one motion to exclude, but all such motions are due by Due Date 4, and a party's motions to exclude may not exceed fifteen pages in aggregate; and

FURTHER ORDERED that all oppositions to motions to exclude are due by Due Date 5, regardless of the date on which a respective motion to exclude was filed, and are limited to fifteen pages in aggregate.

FOR PETITIONER:

Eldora L. Ellison  
Jonathan Tuminaro  
Sterne, Kessler, Goldstein & Fox P.L.L.C.

FOR PATENT OWNER:

Stephen B. Maebius  
Sunit Talapatra  
Andrew S. Baluch  
Foley & Lardner LLP

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From: Eldora Lynn Ellison [mailto:EELLISON@skgf.com]  
Sent: Friday, March 21, 2014 2:43 PM  
To: Baker, Patrick; Trey Powers; Jonathan Tuminaro; David H. Holman; Keeto Sabharwal; Paul A. Ainsworth; smaebius@foley.com; stalapatra@foley.com; abaluch@foley.com; Trials  
Cc: PTAB Account  
Subject: RE: Conference Call - IPR2013-00368, -00371, -00372

PTAB,

Thank you for arranging a conference call regarding the issues raised below. Petitioner also respectfully requests permission to discuss, during Monday's call, the propriety of submitting a claim chart as an exhibit rather than as part of a pleading (see, e.g., Supernus's Exhibit 2141).

Thank you,  
Eldora L. Ellison  
Counsel for Petitioner

From: Baker, Patrick [mailto:Patrick.Baker@USPTO.GOV]  
Sent: Tuesday, March 18, 2014 12:41 PM  
To: Eldora Lynn Ellison; Trey Powers; Jonathan Tuminaro; David H. Holman; Keeto Sabharwal; Paul A. Ainsworth; smaebius@foley.com; stalapatra@foley.com; abaluch@foley.com  
Cc: PTAB Account  
Subject: Conference Call - IPR2013-00368, -00371, -00372

Greetings.

A conference call has been scheduled for 11:00 AM Eastern Time on Monday, March 24, 2014, for IPR2013-00368, IPR2013-00371, and IPR2013-00372.

The call in number for the conference call is 877-934-8037 and the passcode is 9450035. If you have any questions, please feel free to contact me.

Thank you.

Patrick E. Baker  
Trial Paralegal  
USPTO  
Patrick.baker@uspto.gov  
Direct: 571-272-6192  
Patent Trial and Appeal Board: 571-272-7822

From: Eldora Lynn Ellison [mailto:EELLISON@skgf.com]  
Sent: Monday, March 17, 2014 10:41 AM  
To: ABaluch@foley.com; Trials  
Cc: Trey Powers; SMAebius@foley.com; STalapatra@foley.com; Gregory Morris; Evan D. Diamond; Paul A. Ainsworth; Keeto Sabharwal; Trey Powers; David H. Holman

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Subject: RE: IPR2013-00368, -00371, -00372 - replacement Ex. 2145 -- request for conference call

Dear PTAB,

Counsel for Petitioner requests a conference call with the PTAB regarding Patent Owner's request made in the email below regarding the Declaration the Patent Owner submitted from Stephen G. Kunin (Ex. 2145). Petitioner seeks permission to oppose the Patent Owner's request.

Additionally, Petitioner seeks a conference call with the PTAB to discuss the propriety of Mr. Kunin's Declaration under 37 CFR 42.65(a) ("Testimony on United States patent law or patent examination practice will not be admitted."). The Declaration states that it "provide[s] expert analysis and testimony with respect to United States patent practice and procedures...." (Ex. 2145, pg. 2).

Counsel for Petitioner is available for a conference call on Tuesday, Wednesday afternoon, Thursday, or Friday of this week.

Thank you,  
Eldora L. Ellison  
Counsel for Amneal

-----Original Message-----

From: ABaluch@foley.com [mailto:ABaluch@foley.com]  
Sent: Friday, March 14, 2014 12:16 AM  
To: Trials@uspto.gov  
Cc: Eldora Lynn Ellison; Trey Powers; SMAebius@foley.com; ABaluch@foley.com; STalapatra@foley.com; Gregory Morris; Evan D. Diamond  
Subject: IPR2013-00368, -00371, -00372 - replacement Ex. 2145

Dear PTAB,

Counsel for Patent Owner Supernus has noticed that the as-filed Kunin Declaration (Ex. 2145) filed on March 10 in the above-captioned IPRs does not contain the lettered appendices A through P that are cited and described in the Kunin Declaration and that were intended to be appended to same.

A copy of the true and complete Kunin Declaration (including appendices A-P) that should have been filed in the IPRs on March 10 is attached hereto. The Declaration and appendices are identical in all three IPRs.

Patent Owner respectfully requests permission to substitute the attached exhibit as a replacement for Exhibit 2145.

Patent Owner agrees to extend the deadline for Amneal's evidentiary objections with respect to Exhibit 2145 by 3 business days, and thereby eliminate any prejudice caused by this substitution.

Respectfully submitted,  
Andrew Baluch  
Counsel for Patent Owner

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