

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC and AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC  
Petitioners,

v.

ALMIRALL, LLC,  
Patent Owner.

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Case IPR2019-00207  
Patent 9,517,219 B2

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Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ, and  
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

ORDER

*Authorizing Reply to Preliminary Response to Petitioners  
and Sur-reply to Patent Owner  
37 C.F.R. § 42.108(c)*

A conference call was held on February 27, 2019, between counsels for Petitioners and Patent Owner in the above-captioned *Inter Partes* Review (IPR). The conference call was requested by Petitioners by email to the Board on February 25, 2019, to discuss Petitioners' request to file a Reply responsive to Patent Owner's Preliminary Response (Paper No. 8) as it relates to 35 U.S.C. § 314(a) and 35 U.S.C. § 325(d). Patent Owner opposed the conference call as unnecessary, but nonetheless participated.

In the above-referenced email, and as reiterated by Petitioners during the conference call, Petitioners seek to respond to contentions in Patent Owner's Preliminary Response concerning certain alleged admissions in the Petition that Petitioners' duty of candor obligates Petitioners to correct. Further, Petitioners also contend in the email, and reiterated at the conference call, that the Petition did not (preemptively) address the contentions in the Preliminary Response relating to § 314(a) and § 325(d) because Petitioners could not reasonably have anticipated such contentions. Petitioners request the opportunity to submit a Reply to the Preliminary Response addressing these issues.

Patent Owner opposes Petitioners' request for such a Reply, at least in part, to prevent Petitioners' supplementation of the Petition.

"A petitioner may seek leave to file a reply to the preliminary response in accordance with [37 C.F.R.] §§ 42.23 and 42.24(c). Any such request must make a showing of good cause." 37 C.F.R. § 42.108(c). A denial of institution in an IPR under § 314(a) and/or § 325(d), for which Patent Owner argued in the Preliminary Response, concludes the case, generally, on the basis of redundancy and unfairness. We have the

discretion to deny institution under either statutory basis. For a discretionary denial under § 314(a), such redundancy can take the form of substantial similarities between the patents, prior art, and grounds for unpatentability asserted in a second-petitioned IPR and those asserted in a first-petitioned IPR, and the unfairness is based upon potential tactical advantages afforded a petitioner and burden on a patent owner and the Board. *See General Plastics Industrial Co. v. Canon Kabushika Kaisha*, Case IPR2016-01357, Paper No. 19, slip op. 9–10 (PTAB Sept. 6, 2017) (precedential) (identifying factors to be considered under § 314(a)). For a discretionary denial under § 325(d), such redundancy and unfairness may result from an overlap between the prior art and grounds asserted in an IPR petition and the prior art and arguments previously considered by the Office. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, Paper No. 8, slip. op. 17–18 (PTAB Dec. 15, 2017) (informative) (identifying factors to be considered under § 325(d)).

In the Petition, Petitioners devoted about a page and a half to their position that there is no basis to deny the Petition under § 314(a) or § 325(d). Petition (Paper No. 3), 63–64. Patent Owner, however, devoted the entirety of its Preliminary Response to argue that institution should be denied under § 314(a) and § 325(d). *See generally* Paper No. 8. Petitioners contend that, based on the facts of this case, they could not have reasonably foreseen arguments from Patent Owner on § 314(a) and § 325(d) so as to have addressed them in the Petition, but having now considered Patent Owner's arguments thereon, Petitioners dispute that the necessary similarities and overlaps (redundancies) exist here for § 314(a) and/or § 325(d) to apply in

this case. If Petitioners indeed could not have reasonably foreseen Patent Owner's allegations under § 314(a) and § 325(d) as presented in the Preliminary Response, Petitioners should have an opportunity to respond. We find no basis to conclude that Petitioners could have reasonably anticipated the specific arguments made by Patent Owner in the Preliminary Response. We, therefore, conclude that Petitioners contentions of surprise provide a sufficient showing of good cause for granting authorization to file a Reply in this case. During the conference call, Petitioners did not oppose a Sur-reply for Patent Owner in the event a Reply was authorized.

Accordingly, it is:

ORDERED that Petitioners are granted permission to file a Reply of no more than ten (10) pages, within five (5) business days after issuance of this Order, responsive to the allegations under 35 U.S.C. § 314(a) and 35 U.S.C. § 325(d) as set forth in Patent Owner's Preliminary Response. The Reply Brief may also address any necessary corrections regarding any alleged admissions by Petitioners alleged in the Preliminary Response.

FURTHER ORDERED that following Petitioners' filing of the aforementioned Reply, Patent Owner is granted permission to file a Sur-reply of no more than five (5) pages, within five (5) business days. The Sur-reply should address only issues addressed in the Reply.

IPR2019-00207  
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