From: <u>Trials</u>

To: White, Brandon (WDC); Trials

Cc: J. Steven Baughman; Novo-Semaglutide-IPR@groombridgewu.com; Megan Raymond; Tietz, Jonathan (WDC);

Greb, Emily J. (MSN); Beel, Bryan D. (POR); Lembo, Matthew (NYC); *Semaglutide-Ozempic

Subject: RE: IPR2023-00722 & IPR2023-00723 | request for leave to file reply to POPR

Date: Thursday, August 3, 2023 8:25:07 AM

Counsel:

From the Board -

Petitioner's request for authorization to file a Reply to Patent Owner's Preliminary Response is granted solely to address the specific issues set forth in Petitioner's e-mail. Patent Owner's request for authorization to file a Sur-reply is also granted.

The Reply and Sur-reply shall be no longer than <u>5 pages</u> each. The Reply should be filed no later than <u>5 business days</u> after the date of this e-mail. The Sur-reply should be filed no later than <u>5 business days</u> after the date the Reply is filed.

No conference call is necessary at this time.

Regards,

Esther Goldschlager Supervisory Paralegal Specialist Patent Trial & Appeal Board U.S. Patent & Trademark Office

From: White, Brandon (WDC) <BMWhite@perkinscoie.com>

Sent: Tuesday, August 1, 2023 5:17 PM

To: Trials < Trials@USPTO.GOV>

Cc: J. Steven Baughman <steve.baughman@groombridgewu.com>; Novo-Semaglutide-IPR@groombridgewu.com; Megan Raymond <megan.raymond@groombridgewu.com>; Tietz, Jonathan (WDC) <JTietz@perkinscoie.com>; Greb, Emily J. (MSN) <EGreb@perkinscoie.com>; White, Brandon (WDC) <BMWhite@perkinscoie.com>; Beel, Bryan D. (POR) <BBeel@perkinscoie.com>; Lembo, Matthew (NYC) <MLembo@perkinscoie.com>; *Semaglutide-Ozempic <Semaglutide-Ozempic@perkinscoie.com>

Subject: IPR2023-00722 & IPR2023-00723 | request for leave to file reply to POPR

CAUTION: This email has originated from a source outside of USPTO. **PLEASE CONSIDER THE SOURCE** before responding, clicking on links, or opening attachments.

Dear Board,

Pursuant to 37 C.F.R. § 42.108(c), Petitioner Mylan Pharmaceuticals Inc. requests authorization to file an eight-page reply to Patent Owner's Preliminary Response in each of IPR2023-00722 and IPR2023-0723. Petitioner has good cause for this request. Petitioner



intends to address issues of the discretionary denial under §314(a) because of the specificity of Ground 3 and discretionary noninstitution under §325(d). None of these issues could have been previously addressed

Concerning §325(d), the POPR makes arguments regarding discretionary noninstitution based on interpretations of the prosecution history and the prior art that were not previously disclosed and could not have been foreseen. Accordingly, good cause exists.

Concerning Ground 3, the POPR seeks discretionary denial under §314(a), alleging that Ground 3 is not sufficiently specific. These arguments were not previously disclosed and could not have been foreseen, particularly in view of Petitioner's clear identification of the prior art relied upon in that Ground. Moreover, the cases cited by Patent Owner do not support discretionary denial. Petitioner does not seek to reargue the merits of Ground 3. Accordingly, good cause exists.

Petitioner proposes to file a reply of no more than eight pages within seven business days of an order authorizing the reply.

Petitioner met and conferred with Patent Owner.

Patent Owner Novo Nordisk A/S opposes Petitioner's requests. To the extent Mylan is granted reply briefing, however, Patent Owner Novo requests an equal number of pages in surreply. As Patent Owner indicated to Petitioner, solely to avoid burdening the Board with a dispute, Patent Owner would be agreeable to Petitioner having 3 pages per IPR to address issues limited to 325(d) if Patent Owner receives replies of the same length. Regarding Petitioner's lengthy discussion of the substance of its arguments, Patent Owner notes its understanding Petitioner's inclusion of such argument in its email is improper and a violation of the Board's procedures. Accordingly, Patent Owner does not attempt herein to respond to the substance of those arguments, other than to note its disagreement and to indicate that it is prepared to address those arguments on any call that the Board may schedule. Pursuant to the Board's guidance regarding conference calls, Patent Owner indicates it is available for a call on Wednesday 10am-3pm, Thursday 3-5pm, or Monday 3-5pm or otherwise at the Board's convenience.

If necessary, the Petitioner is available for a call to discuss its request at the Board's convenience.

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