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: IPR2023-00724 | request for leave to file reply to POPR

Date: Thursday, August 3, 2023 8:29:17 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: IPR2023-00724 | request for leave to file reply to POPR

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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 IPR2023-00724. Petitioner has good cause for this request. Petitioner intends to address issues of claim



construction and discretionary non-institution under §325(d). These issues could have been previously addressed

On July 20, 2023, the District Court entered a claim construction order construing, *inter alia*, the preamble of the '462 patent that is the subject of this proceeding. *See In re Ozempic (Semaglutide) Patent Litigation*, No. MDL No. 22-cv-3038 (D. Del.), ECF No. 148. Petitioner contends that arguments regarding the degree of efficacy allegedly required by the claims in the POPR are inconsistent with that order and the positions taken by Patent Owner during claim construction proceedings. The District Court's construction could not have been previously addressed. Accordingly, good cause exists.

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.

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 to address issues limited to 325(d) if Patent Owner receives a reply of the same length. Petitioner disagrees with Petitioner's assertions about claim construction and Petitioner's assertions about the foreseeability of Patent Owner's arguments and 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.

Brandon White | Perkins Coie LLP

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