From: <u>Trials</u>

To: <u>J. Steven Baughman</u>; <u>Trials</u>

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Semaglutide-IPR@groombridgewu.com; Megan Raymond

Subject: RE: IPR2023-00724 - Request for Conference Call **Date:** Wednesday, November 29, 2023 10:56:55 AM

Dear Counsel,

From the Board -

The time for filing a request for rehearing in the above-referenced case has expired. We do not agree that the addition of Petitioner Mylan as a party to a trial that may begin a few days before our final written decision is due or the filing of two additional petitions by other petitioners constitutes good cause for the waiver of the request for rehearing deadline. Also, we noted in our Institution Decision that "Patent Owner does not address Petitioner's assertions that a trial here would most likely conclude before the parallel Delaware litigation, and Petitioner's stipulation 'that if the Board institutes, Petitioner will not pursue in the district court any instituted grounds against the originally-issued claims unless a change in law otherwise permits." Paper 10, 16. Patent Owner's request for leave to file a request for rehearing of institution is denied. No call is necessary at this time.

Regards,

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

From: J. Steven Baughman <steve.baughman@groombridgewu.com>

Sent: Monday, November 27, 2023 7:58 PM

To: Trials < Trials@USPTO.GOV>

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Subject: IPR2023-00724 - Request for Conference Call

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Patent Owner writes to request leave to file a request for rehearing of institution, or other comparable briefing as the Board may deem appropriate, to address changes in circumstances that have arisen since institution and that impact the *Fintiv* factors, including that (1) after an October 31, 2023 stipulation and order by the district court adding Mylan to a trial that was originally scheduled



only for other parties, Mylan is now scheduled for trial before the FWD in this IPR would be due (without regard to whether the last sentence of 35 U.S.C. §315(b) becomes applicable), and (2) there are two pending copycat petitions. Patent Owner requests 5 pages of briefing to address these issues. Patent Owner has, alternatively, requested that Petitioner agree to provide a Sotera stipulation, but Petitioner has declined. To the extent Patent Owner's request for additional briefing is granted, Patent Owner would not oppose an opposition brief from Petitioner of equal length. Regarding Petitioner's assertions below arguing its positions, 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 and in the requested briefing. Petitioner states its position as follows: Patent Owner's request for leave rests on two alleged "change[s] in circumstances that have arisen since institution." But there are no changed circumstances, and Patent Owner's request is untimely. First, Petitioner's trial date is not a "change in circumstances." Although Patent Owner asserts that Petitioner is "now" scheduled for trial late in 2024, the Delaware trial was scheduled on June 30, 2022, and that trial date was addressed in the Petition. See Pet. at 65; see also Ex. 1082. It remains the case that "a final written decision should issue before a decision is expected to be issued by any district court" as stated in the Petition. Second, while two copycat petitions have been filed, Patent Owner has indicated it intends to file preliminary responses, and there has been no joinder ruling. The mere existence of copycat petitions is not a changed circumstance for this trial. Third, Patent Owner's request is an untimely attempt to do by rehearing what Patent Owner did not do before: address the Fintiv factors on the merits. Petitioner addressed Fintiv in its Petition and offered a Sand Revolution stipulation, Pet. at 65-66, but Patent Owner's Preliminary Response addressed neither Fintiv nor the stipulation. It is also too late for Patent Owner to address Fintiv now because any request for rehearing should have been filed by October 18, 2023. For all these reasons, Petitioner respectfully requests that the Board deny the request for leave to file for rehearing.

The parties are available for the requested call at 4pm ET on Thursday (November 30), Friday (December 1), or Monday (December 4), or as the Board may otherwise direct. (These times reflect that counsel for Patent Owner are presently on business travel in Asia.)

Respectfully submitted,
J. Steven Baughman
Counsel for Patent Owner

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