From: <u>Trials</u>

To: <u>Matthew Traupman</u>; <u>Trials</u>

Cc: Brausa, Adam R.; Durie, Daralyn J.; Davis, Kira A; Weires, Rebecca; Regeneron-MoFo-IPR@mofo.com; Ray

Nimrod; Landon Smith; QE - Samsung Bioepis

Subject: RE: IPR2023-00884 -- Request for leave to file Reply to POPR

Date: Wednesday, September 6, 2023 4:08:42 PM

Counsel,

From the Board -

Petitioner's email of September 5, 2023 (below), requests authorization to file a 10-page Reply to Patent Owner's Preliminary Response to address "newly submitted evidence" concerning the priority to be accorded the '572 patent's claims in light of changes to the Patent Act per the AIA. That the parties met and conferred on this matter prior to reaching out to the Board for relief is appreciated. We understand that Patent Owner opposes Petitioner's request, but we find good cause exists to grant it because certain evidence cited by Patent Owner in its Preliminary Response and the related arguments appear to have been previously unknown and not available outside of Patent Owner (see, e.g., Paper 7 – PO Motion to Seal describing evidence as internal or non-public). Accordingly, Petitioner is authorized to submit a 10-page Reply to address evidence cited in the Preliminary Response on this issue that was not previously available to Petitioner and to explain its opposition to Patent Owner's positions on prior conception/reduction to practice in view of Petitioner's asserted prior art. Patent Owner is authorized to file 5-page Sur-reply to Petitioner's Reply. No new arguments or evidence is authorized.

Petitioner's Reply is due no later than September 18, 2023.

Patent Owner's Sur-reply is due no later than September 28, 2023.

This email will be entered into the record as Board's Exhibit 3001. No conference call is believed necessary on this issue, but if the parties disagree or have any questions, they should contact the Board.

Regards,

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

From: Matthew Traupman <matthewtraupman@quinnemanuel.com>

Sent: Tuesday, September 5, 2023 11:37 AM

To: Trials < Trials @ USPTO.GOV>

Cc: Brausa, Adam R. <ABrausa@mofo.com>; Durie, Daralyn J. <DDurie@mofo.com>; Davis, Kira A <KiraDavis@mofo.com>; Weires, Rebecca <RWeires@mofo.com>; Regeneron-MoFo-IPR@mofo.com; Ray Nimrod <raynimrod@quinnemanuel.com>; Landon Smith



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Dear Patent Trial and Appeal Board:

We represent Petitioner Samsung Bioepis Co., Ltd. ("Samsung") in IPR2023-00884 concerning U.S. Patent No. 11,253,572. Patent Owner, Regeneron Pharmaceuticals, Inc. ("Regeneron"), filed its Preliminary Response to Samsung's Petition in IPR2023-00884 on August 25, 2023.

Samsung seeks leave to submit a 10-page reply to Regeneron's Preliminary Response for purposes of responding to Regeneron's newly submitted evidence and argument that: (1) the claims of the '572 patent are allegedly subject to the first-to-invent provisions of pre-AIA 35 U.S.C. §§ 102 and 103, rather than post- AIA versions of 35 U.S.C. §§ 102 and 103, because the claims of the '572 patent are supported by the January 21, 2011 provisional application; and (2) Regeneron's 2010 press releases are not prior art because the subject matter claimed the '572 patent was allegedly conceived and reduced to practice before those references were published or were derived from the inventor himself.

There is good cause because, *inter alia*, Regeneron bears the burden of production on both of these issues, and Regeneron includes new, confidential exhibits in support of the alleged inventorship of the '572 patent by Dr. Yancopoulos. For instance, Samsung did not have the opportunity to address confidential internal email communications and presentations that Regeneron alleges show conception and the alleged inventorship of Dr. Yancopoulos. Samsung seeks leave to address this previously unavailable evidence and why Regeneron has not shown sufficient conception and reduction to practice for purposes of swearing behind its 2010 press releases. *See, e.g., Medtronic Inc., et al. v. Teleflex Innovations S.A.R.L.,* IPR2020-00132, Paper 22 at 10-11; *Associated British Foods, plc et al v. Cornell Research Foundation, Inc.,* IPR2019-00577, Paper 25 at 31. In addition, Regeneron argues that a single paragraph in the January 21, 2011 provisional application provides a literal description of the invention recited in claim 25. Samsung seeks the opportunity to respond to Regeneron's characterizations of the disclosures in the '572 patent and the January 21, 2011 provisional application, which Samsung believes contain several inaccurate statements.

If the Board grants this request, Samsung proposes submitting the reply 10 days after the Board's order. Samsung would not oppose Regeneron's filing of a sur-reply of equal length due 10 days after the filing of Samsung's reply. Regeneron has indicated that it is amenable to a 5-page reply, limited to the evidence and argument that Regeneron's 2010 press releases are not prior art. Regeneron opposes Samsung's request as to the issue of whether the claims of the '572 patent are allegedly subject to the first-to-invent provisions of pre-AIA 35 U.S.C. §§ 102 and 103, rather than the AIA, because Regeneron contends Samsung could, and should have raised that issue in its Petition. Samsung maintains its position that it could not have anticipated Regeneron's mischaracterization of the disclosures of the '572 patent and the January 21, 2011 provisional application, and a 10-page



reply addressing both issues outlined above is warranted.

If a conference call would be helpful to the Board, we are happy to propose times when both parties are available.

Regards, Matt Traupman Backup Counsel for Petitioner Samsung Bioepis

Matthew Traupman Partner Quinn Emanuel Urquhart & Sullivan, LLP

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