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Subject: RE: IPR2023-00739 - Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc.
Date: Thursday, August 10, 2023 10:46:45 AM

Counsel,

From the Board –

Petitioner’s request for authorization to file a Reply brief to Patent Owner’s Preliminary Response is granted-in-part. The Board authorizes briefing on the Petitioner’s following issues: (1) argument that the issues in the instant IPR and the Mylan Litigation overlap and weigh against institution under *Fintiv*; (2) interpretation of the challenged claims, including that they require a “fixed” dosing. Authorization for briefing on Petitioner’s proposed issue (3) (argument that explicit disclosure of every element of the Challenged Claims is required to show obviousness) is denied.

Patent Owner is similarly authorized to file a Sur-Reply to Petitioner’s Reply. Both briefs are limited to 10 pages in length. Petitioner’s Reply to be submitted no later than August 21, 2023. Patent Owner’s Sur-Reply to be submitted no later than August 31, 2023.

Regards,

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

From: Matthew Traupman <matthewtraupman@quinnemanuel.com>
Sent: Thursday, August 10, 2023 8:12 AM
To: Trials <Trials@USPTO.GOV>
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Dear Patent Trial and Appeal Board,

We represent Petitioner Samsung Bioepis Co., Ltd. (“Samsung”) in IPR2023-00739. Patent Owner, Regeneron Pharmaceuticals, Inc. (“Regeneron”), filed its Preliminary Response to Samsung’s Petition in IPR2023-00739 on July 28, 2023.

Samsung seeks leave to submit a 15-page reply to Regeneron's Preliminary Response for purposes of responding to Regeneron's (1) argument that the issues in the instant IPR and the Mylan Litigation overlap and weigh against institution under *Fintiv*; (2) interpretation of the Challenged Claims, including that they require a "fixed" dosing; and (3) argument that explicit disclosure of every element of the Challenged Claims is required to show obviousness.

There is good cause because, *inter alia*, Regeneron disclaimed a number of the Challenged Claims in response to Samsung's petition, changing the scope of the requested IPR and affecting the analysis under *Fintiv*. In particular, Regeneron mischaracterizes the arguments made in a related litigation as to the remaining, non-disclaimed claims. Samsung seeks leave to add additional context and facts regarding those arguments and why they do not overlap with the grounds Samsung presents in its petition. In addition, Regeneron relies on an interpretation of the remaining Challenged Claims to which Samsung seeks the opportunity to respond, along with Regeneron's mischaracterization of the law of obviousness.

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 will oppose this request, indicating in its response to Samsung that its position is that the alleged bases for the reply are issues that Samsung could have addressed in its Petition. Samsung could not have anticipated Regeneron's disclaimer of claims in response to the petition, nor could Samsung have addressed Regeneron's interpretation of the claims or law.

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

Respectfully,
Matt Traupman
Backup counsel for Petitioner

Matthew Traupman

Partner

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