From:	Faegenburg, Russell W.
To:	Baumgarten, Elise; Fisher, Stanley; Malik, Jitty; Mahaffy, Shaun; Pacchioli, Alissa M.; West, Christopher W.; Radeke, Heike Simone; Pacchioli, Alissa M.; Van Buskirk, Tedd W.; Teschner, Michael H.; Wong, Jovial; Fundakowski, Claire (CFundakowski@winston.com); Fischer, Sarah; Zullow, Keith A
Cc:	Merck-Sitagliptin
Subject:	RE: IPR2020-00040, IPR2020-01045, IPR2020-01060, IPR2020-01072
Date:	Tuesday, July 7, 2020 3:19:15 PM

Elise,

This is in response to your email below, on behalf of Joinder Petitioners Teva, Sun and DRL.

With respect to item 2. of your email, Joinder Petitioners agree that they will withdraw their respective opening expert declarations once Dr. Chorghade is deposed on his opening declaration. As discussed previously, however, Joinder Petitioners reserve the right to use their own experts on reply if, for example, Mylan settles before the need for a reply declaration or after a reply declaration but before the declarant is deposed.

With respect to item 5.c., because the proceeding has not yet begun, Joinder Petitioners cannot anticipate all party-specific issues that may require a response. Joinder Petitioners, therefore, decline to limit their rights to provide evidence, or to respond, on party-specific issues to only those issues you have identified in your email. Furthermore, because, as you acknowledge, discovery is premature at this stage, Petitioners decline to adopt particular procedures for discovery, particularly where no discovery has been propounded, much less authorized by the Board, and Merck's ability to obtain discovery is speculative.

Finally, your statement that "Merck understands that, unless otherwise indicated in its email, Joinder Petitioners agree with the conditions outlined in its June 26 letter" is incorrect. Our July 1 email set forth the conditions to which Joinder Petitioners agree for purposes of joinder, and our silence should not be construed as an agreement to any particular condition.

Sincerely yours,
Russ

From: Baumgarten, Elise [mailto:EBaumgarten@wc.com]
Sent: Thursday, July 2, 2020 1:45 PM
To: Faegenburg, Russell W.; Fisher, Stanley; Malik, Jitty; Mahaffy, Shaun; Pacchioli, Alissa M.; West, Christopher W.; Radeke, Heike Simone; Pacchioli, Alissa M.; Van Buskirk, Tedd W.; Teschner, Michael H.; Wong, Jovial; Fundakowski, Claire (CFundakowski@winston.com); Fischer, Sarah; Zullow, Keith A

Cc: Merck-Sitagliptin
Subject: RE: IPR2020-00040, IPR2020-01045, IPR2020-01060, IPR2020-01072

[EXTERNAL E-MAIL]
Russ,

I write in response to your email dated July 1 on behalf of Teva, Watson, DRL, and Sun. Merck would like to clarify a few points raised in your email.

2. You state that Joinder Petitioners will "withdraw their respective experts once Dr. Chorghade has submitted all necessary declarations."

- Merck understands that each Joinder Petitioner will withdraw any expert declaration from their expert immediately after Dr. Chorghade is deposed. Once Dr. Chorghade is deposed on his currently submitted declaration, Ex. 1002, Merck expects that the Joinder Petitioners will immediately withdraw all currently filed expert declarations in this case.
- Please confirm that Joinder Petitioners withdrawal of their experts will not be discretionary. In other words, once Dr. Chorghade is deposed, Joinder Petitioners agree to immediately withdraw their own experts.

5.c. Joinder Petitioners state that each Joinder Petitioner reserves the right to address any party-specific issues with its own evidence.

- Merck understands that each party reserves the right to present arguments related to party-specific discovery issues. In other words, Teva will present argument if Merck seeks discovery from Teva; no other party will present argument on an issue specific to another party.
- Merck also understands that each Joinder Petitioner reserves the right to address substantively any party-specific discovery. For example, if Merck obtains discovery from Teva, Teva reserves the right to request to address that discovery in a substantive written submission. Merck reserves the right to request additional briefing to address any such arguments.
- Merck understands that these are the only party-specific issues that the Joinder Petitioners may raise.

As to other conditions that Merck sought from Joinder Petitioners to ensure that they served the true role of a silent understudy (see, e.g., 5.d.i., 5.d.iii, 5.d.vii, 5.d.viiii), Merck understands that, unless otherwise indicated in its email, Joinder Petitioners agree with the conditions outlined in its June 26 letter.

Joinder Petitioners appear to have taken the position that Merck is not entitled to party discovery. Merck believes that any formal request for party discovery (and Joinder Petitioners' substantive position in response) is premature. Currently, the issue is whether joinder is appropriate. As such, Merck seeks to ensure that it will have sufficient opportunity and time to seek any party discovery to which it believes it is entitled if joinder occurs. It is Joinder Petitioners' burden to show that joinder is appropriate, and they must account for the schedule in so doing.

In the interest of transparency, Merck previewed some of the discovery it intends to seek should joinder be granted. That Merck referenced certain patent office filings is not surprising, as

those are the documents to which Merck has access at this time. Merck will have specific, particularized requests related to that work (which include multiple declarations submitted by Teva's declarant here Len Chyall), and can further confer with Teva on the inconsistencies and pertinence of the discovery in due course. If needed, Merck can file an application for discovery. However, at this stage, an application is premature because Teva is not a party to any instituted IPR. Similarly, Merck will have requests for DRL and Sun, but saw (and still sees) it as premature to raise them before institution. For example, as to DRL and Sun, their own patents and related publications, on salts and polymorphs of sitagliptin (e.g., U.S. Patent No. 8,309,724 and WO2013001457A1), characterizes the relevant disclosures of the '871 patent, which is the subject of several Grounds, in a manner that is inconsistent with the positions taken in the Petitions. Merck believes it is entitled to discovery relevant to these inconsistencies as a matter of right, and alternatively, if not of right, to request discovery related to these issues if the Board orders joinder. If joinder is ordered, the parties can confer on the appropriateness of specific discovery requests related to these inconsistencies and, if no agreement is reached, Merck will seek authorization from the Board for such discovery.

Please let us know immediately if Merck's statements above do not align with Joinder Petitioners' understanding.

Thanks,

Elise

Elise M. Baumgarten
Williams & Connolly LLP
725 Twelfth Street, N.W., Washington, DC 20005
(P) 202-434-5894 | (F) 202-434-5029
ebaumgarten@wc.com | www.wc.com/ebaumgarten

From: Faegenburg, Russell W. <rfaegenburg@lernerdavid.com>
Sent: Wednesday, July 1, 2020 12:23 PM
To: Fisher, Stanley <SFisher@wc.com>; Malik, Jitty <jitty.malik@katten.com>; Mahaffy, Shaun <SMahaffy@wc.com>; Pacchioli, Alissa M. <alissa.pacchioli@katten.com>; West, Christopher W. <christopher.west@katten.com>; Radeke, Heike Simone <heike.radeke@katten.com>; Pacchioli, Alissa M. <alissa.pacchioli@katten.com>; Van Buskirk, Tedd W. <tvanbuskirk@lernerdavid.com>; Teschner, Michael H. <mteschner@lernerdavid.com>; Wong, Jovial <JWong@winston.com>; Fundakowski, Claire (CFundakowski@winston.com) <CFundakowski@winston.com>; Fischer, Sarah <SFischer@goodwinlaw.com>; Zullow, Keith A <KZullow@goodwinlaw.com>
Cc: Merck-Sitagliptin <MerckSitagliptin@wc.com>
Subject: RE: IPR2020-00040, IPR2020-01045, IPR2020-01060, IPR2020-01072

Stan,

This is in response to your June 26, 2020 letter concerning the joinder motions filed by Teva, DRL and Sun ("Joinder Petitioners"). Our firm represents DRL,

but I write on behalf of all three Joinder Petitioners.

Joinder Petitioners agree to a "silent understudy" role as previously stated, and with respect to items 2, 5 and 6 of your letter, Joinder Petitioners agree as follows:

> 2. Joinder Petitioners will withdraw their respective experts once Dr. Chorghade has submitted all necessary declarations (including any reply declaration) and has been deposed with respect to all of them. In that instance, Joinder Petitioners intend to rely solely on Dr. Chorghade's opinions and testimony. (Joinder Petitioners have the same comments in response to item 5.b.)
>
> 5.a. Joinder Petitioners will not raise any new grounds not already instituted by the Board in the Mylan IPR.
>
> 5.c. Joinder Petitioners will not present any additional arguments or IPR briefs. To the extent there is a party-specific issue, each Joinder Petitioner reserves the right to address that issue with its own evidence.
>
> 5.d. Mylan will be Lead Petitioner, file all substantive written submissions, conduct all argument at hearings and examine and defend witness depositions. Joinder petitioners will not file additional pages to Mylan's papers. The deposition timeframes for one party will apply. Joinder petitioners will be bound by discovery agreements between Mylan and Merck. Joinder petitioners will not serve objections to discovery requests served on Mylan and will not serve discovery requests in the Mylan IPR.
>
> All of these conditions regarding item 5.d. apply other than with respect to party discovery on Joinder Defendants or any issue involving a Joinder Petitioner that is specific to that Petitioner. For example, although Joinder Petitioners generally agree not to file substantive papers in the Mylan IPR, each Joinder Petitioner reserves the right to file papers relating to any party-specific issue that applies to that Petitioner, and will seek Board authorization to file any such paper or to take any action on its own. Likewise, if Merck were to seek party discovery from one of the Joinder Petitioners, that Petitioner would reserve the right to respond appropriately, including by resisting such discovery and by issuing its

own request for discovery.

6. Joinder Petitioners confirm that if Mylan is no longer a party, they will meet and confer to select a new Lead Petitioner to step into Mylan's shoes and Joinder Petitioners will be bound by the same conditions already in place.

With respect to items 1, 3 and 4 of your letter, Joinder Petitioners disagree that Merck has identified any basis to seek party discovery, and the discovery matters you discuss are, therefore, premature and not pertinent to the joinder inquiry.

You have only purported to identify a basis for discovery from Teva, not from either DRL or Sun. Even as to Teva, you have not identified specifically what you are seeking beyond documents and testimony readily available from public patent office proceedings, or even how any of the information from such proceedings is inconsistent with Teva's invalidity arguments in the present IPR. Teva is willing to further meet and confer with Merck to understand the specific discovery Merck will be seeking from Teva.

Given that Merck has not yet established any right to party discovery, and its ability to obtain party discovery is speculative, Merck has not established a basis to alter the schedule in the Mylan IPR based on proposed joinder. As stated above, and in Joinder Petitioners' motion papers, Joinder Petitioners are "me too" Petitioners and have agreed to the same "understudy" conditions on which the Board has previously relied in permitting joinder. If Merck wishes to pursue discovery, either now or at some time in the future, it is free to make a motion for discovery and, if it chooses, to make an application to extend the IPR schedule. Joinder Petitioners, if joined, will comply with any change that the Board orders with respect to the schedule in the Mylan IPR.

Sincerely yours,

Russ

From: Fisher, Stanley [mailto:SFisher@wc.com]
Sent: Wednesday, July 1, 2020 8:54 AM
To: Malik, Jitty; Mahaffy, Shaun; Pacchioli, Alissa M.; West, Christopher W.; Radeke, Heike Simone; Pacchioli, Alissa M.; Van Buskirk, Tedd W.; Teschner, Michael H.; Faegenburg, Russell W.; Wong, Jovial; Fundakowski, Claire (CFundakowski@winston.com); Fischer, Sarah; Zullow, Keith A
Cc: Merck-Sitagliptin
Subject: RE: IPR2020-00040, IPR2020-01045, IPR2020-01060, IPR2020-01072

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