Casey Kraning

From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Friday, August 30, 2024 2:27 PM
To: Nicholas Stephens; Casey Kraning; IPR52261-0005IP1
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M.; Feigenbaum, David; Zeilberger, Daniel; PH-MSD-JHU-IPR
Subject: RE: IPR2024-00240 - Motion for Additional Discovery
Attachments: IPR2024-00240 Joint Stipulation.doc

Counsel,

With respect to JHU's proposal to adjust certain due dates, Merck may be amenable to this proposal but our understanding is those adjustments would require additional scheduling adjustments because they affect other due dates set by the Board, such as the briefing for motions to exclude. To fully evaluate JHU's proposal, please send us a proposed joint stipulation considering all due dates so that there are no misunderstandings. In the meantime, Merck is willing to execute the attached joint stipulation for a scheduling adjustment.

With respect to JHU's document requests, we will not address at this time JHU's mischaracterizations and misunderstandings. Instead, we address below what JHU appears to be requesting in the form of alternative document requests.

> **Alternative JHU Request 1** appears to seek documents sufficient to show total U.S. Keytruda® sales—whether that be monthly, quarterly, or annually. To satisfy this part of Alternative JHU Request 1, Merck would be willing to produce the litigation document MSD_00728961 to be maintained as "Highly Confidential-Attorneys Eyes Only." The remaining part of Alternative JHU Request 1 appears to seek U.S. Keytruda® sales data that is supportive of the public statements identified by JHU at Paper No. 29, 5-6. That data is IQVIA claims data. Merck would be willing to produce that data to be maintained as "Highly Confidential-Attorneys Eyes Only."
>
> **Alternative JHU Request 2** appears to seek documents sufficient to show the basis for a statement of a former Merck employee more than five-and-a-half years ago. We have already explained that it is not apparent to Merck what its former employee may have relied on in making his statement, if anything specific. JHU appears to represent that it would be satisfied with U.S. sales data that is supportive of the public statements identified by JHU at Paper No. 29, 5-6. That data is IQVIA claims data. Merck would be willing to produce that data to be maintained as "Highly Confidential-Attorneys Eyes Only."

Please let us know if we have an agreement as to JHU's Alternative Requests based on our understandings stated above.

Very truly yours,

Preston

PAUL HASTINGS

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From: Nicholas Stephens <nstephens@fr.com>
Sent: Thursday, August 29, 2024 2:50 PM

To: Ratliff, Preston K. <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

The Board this morning issued the attached Order authorizing JHU's request for additional discovery. According to the Order, JHU is to serve upon Merck our documents requests as stated in the motion or alternative requests that result from an agreement between the parties about the nature of the documents to be produced, and Merck is to produce the requested documents within two weeks thereafter. The Order also allows for the possibility of Merck's submission of a sworn affidavit from, and deposition of, a Merck executive if Merck cannot produce the requested documents.

JHU respectfully submits that these developments confirm the need for an extension of the original briefing deadlines set forth in the Scheduling Order. Indeed, Merck's deadline to produce documents responsive to the requests is September 13th, which is a full week after JHU's POR original POR deadline on September 6th. As we have previously noted, JHU will also need sufficient time to review documents produced responsive to the requests and to incorporate their substance into JHU's POR. If Merck submits a sworn affidavit from an executive-level employee, JHU will also need sufficient time to take the witness's deposition, and to resolve a path forward in view of the deposition testimony. We also continue to await Merck's responses to our questions on the protective order that we sent by email on 8/26. JHU of course will be unable to access or review any produced documents until a protective order is approved for the IPR.

In light of these circumstances, JHU believes that the 4-week extension of Due Date 1 that we initially proposed on 8/19 is most appropriate and would best accommodate the parties' ability to comply with the Board's order while ensuring JHU has a fair and reasonable opportunity to review and account for Merck's document production. Accordingly, JHU proposes to extend Due Date 1 by four weeks from September 6th to October 4th, and if Merck agrees, JHU would in exchange agree to extend Due Date 2 by six weeks from December 6 to January 17. This would provide Merck with additional time to prepare its Reply while also providing additional relief from the concerns that Merck previously expressed with respect to the holiday season. We would also propose that Due Date 3 be extended from January 3rd to February 14th, as reflected in the table below. While further adjustments may become necessary, we trust that the parties would work in good faith to resolve such adjustments. Nonetheless, please let us know if Merck is amenable to stipulating to the following scheduling adjustments:

	Current Deadline	**Proposed Deadline**
DUE DATE 1: JHU's Patent Owner Response	September 6	October 4
DUE DATE 2: Merck's Reply	December 6	January 17
DUE DATE 3: JHU's Sur-reply	January 3	February 14

At minimum, if Merck cannot agree to the above proposed deadlines by COB tomorrow, August 30th, as a professional courtesy please confirm that JHU may file the stipulation previously circulated with the two-week extensions, so that we can have that in place while the parties continue to negotiate as to the proposal outlined above. That minimal extension is necessary to accommodate the deadlines in the Board's order.

As to JHU's document requests, we hope to be able to reduce Merck's burden of production by agreeing to requests that are characterized in a manner consistent with the data that Merck maintains for relevant categories of Keytruda® sales. This information is known only to Merck, not JHU, and although we have asked multiple times during meet and confers over the past month for Merck to investigate this issue, it is still not clear what, if any, investigation Merck has pursued in this regard. Please let us know if Merck is able to comply with and would agree to the following document

requests. If not, please explain why Merck would be unable to comply with these requests and let us know what further modifications would be necessary to facilitate Merck's compliance in a manner consistent with the Board's Order.

> **Request 1:** Documents sufficient to show Merck's Keytruda® sales (e.g., monthly, quarterly, or annually) at least in the United States, including sales by FDA-approved indication (or by cancer type or sub-type, or however Merck otherwise categorizes its sales data to support its public statements, including the public statements identified by JHU at Paper No. 29, 5-6); and
>
> **Request 2:** Documents sufficient to show the basis for Merck's statement in its February 1, 2019, earnings call that Merck saw "good growth in the MSI-high agnostic indication," that "represents about 5% of our [Keytruda®] business." JHU notes that this request could be satisfied, for example, by information Merck has available to support the statements in its financial press releases as identified by JHU at Paper No. 29, 5-6, or other information available to Merck, rather than the information subjectively relied upon by Mr. Clyburn, who made the quoted statement on the February 1, 2019 earnings call.

The Board's Order today requires JHU to serve its discovery requests on Merck within one business day, i.e., by Friday 8/30. We would therefore appreciate Merck's prompt attention to this matter and would ask that Merck provide its responses to the above-noted issues by 3 pm ET tomorrow.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Nicholas Stephens
Sent: Thursday, August 29, 2024 9:24 AM
To: 'Ratliff, Preston K.' <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: 'mark.stewart@merck.com' <mark.stewart@merck.com>; naveenmodi@paulhastings.com; 'Wexler, Bruce M.' <brucewexler@paulhastings.com>; 'Feigenbaum, David' <davidfeigenbaum@paulhastings.com>; 'Zeilberger, Daniel' <danielzeilberger@paulhastings.com>; 'PH-MSD-JHU-IPR' <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We are following up on our emails from 8/23 and 8/27 regarding the parties' joint stipulation to modify the scheduling order to extend Due Dates 1-3. With original Due Date 1 approaching next Friday 9/6, JHU would like to file the stipulation today to ensure JHU's in-house counsel, outside counsel, and others whom we are working with on the Patent Owner's Response can plan accordingly for the next week, including the upcoming holiday weekend. Additionally, as you know, we continue to await the Board's order on JHU's discovery motion and we await Merck's responses to our questions on the protective order that we sent by email on 8/26.

Please kindly confirm that we may file the stipulation today.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Nicholas Stephens
Sent: Tuesday, August 27, 2024 11:21 AM
To: 'Ratliff, Preston K.' <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We appreciate Merck's cooperation in agreeing to a 2-week extension of the parties' briefing deadlines. While a 4-week extension would have provided even greater assurance that the parties could resolve their outstanding discovery disputes and obtain the Board's approval of a modified protective order in sufficient time ahead of JHU's Patent Owner's Response (POR) deadline, it is currently our expectation that the 2-week extension will suffice barring unexpected delays in resolving these issues. For example, we only received Merck's proposed redlines to the default protective order on 8/23, even though we first raised it with Merck more than a month earlier. We provided feedback on the protective order yesterday, but the parties are continuing to negotiate and the Board will ultimately need to approve the protective order before we can even access any produced documents to review and incorporate their substance into JHU's POR. Our statement regarding reservation of rights simply reflects the reality that the timing of certain events related to discovery and the protective order still remains uncertain and unknowable. JHU currently has no intention to seek a further extension if these outstanding issues are resolved in sufficient time for JHU to account for the produced documents in our POR. Should there be a delay in resolving these issues, we will of course work with Merck in good faith to propose a path forward. We are mindful of the year-end holiday season and appreciate that you have raised Merck's yearly shut-down during the holidays.

If you would like to discuss further, please let us know. Please otherwise confirm that we may proceed to file the stipulation for the 2-week extension, which we believe is consistent with the parties' agreement last week.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Tuesday, August 27, 2024 10:39 AM
To: Nicholas Stephens <nstephens@fr.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Thank you for your email.

As we previously explained, in the spirit of compromise and cooperation, Merck was willing to agree to a two-week extension even though JHU's alleged timing issue is self-created. JHU's statement about reserving rights, however, presents a concern. Specifically, you write below that "JHU of course reserves all rights to seek further adjustments to the briefing schedule to the extent necessary depending on when these issues are finally resolved." Please explain what is meant by this statement as it appears to unilaterally give JHU the flexibility to negate Merck's compromise proposal, and potentially unfairly prejudice Merck by having Merck prepare its Reply during the year-end holiday season and at a time when Merck will have its yearly shut-down.

Very truly yours,

Preston

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From: Nicholas Stephens <nstephens@fr.com>
Sent: Friday, August 23, 2024 5:00 PM
To: Ratliff, Preston K. <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

JHU agrees to the proposed scheduling adjustments set forth in your email from earlier today. JHU expects that the parties will continue to work toward resolution of our outstanding discovery disputes and resolve a mutually agreeable protective order in a timely fashion. JHU of course reserves all rights to seek further adjustments to the briefing schedule to the extent necessary depending on when these issues are finally resolved.

We have attached for your review a draft of the joint stipulation to modify the scheduling order. Please let us know if the draft is acceptable and if we may proceed to file.

Best regards,
-Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Friday, August 23, 2024 12:09 PM
To: Nicholas Stephens <nstephens@fr.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We write regarding JHU's request to extend the due date of its Patent Owner Response.

Based on JHU's stated rationale, the primary reason for JHU's request for a **28 day extension** is due to the fact that JHU waited **36 days** before it raised an alleged need for Additional Discovery. We do not understand why JHU waited so long and why JHU thinks it is appropriate to point to its self-created timing issue as the ultimate basis for its extension request. Further, JHU's extension proposal would unduly prejudice Merck by placing a substantial period of Merck's time to prepare its Reply during the year-end holiday season and at a time when Merck will have its yearly shut-down. Nevertheless, in the spirit of compromise and cooperation, Merck is willing to agree to a two-week extension with Merck's Reply and JHU's Sur-Reply similarly adjusted by two weeks. The revised schedule would look as follows:

	Current Deadline	**Proposed Deadline**
DUE DATE 1: JHU Patent Owner Response	September 6	September 20
DUE DATE 2: Merck Reply	December 6	December 20
DUE DATE 3: JHU Sur-reply	January 3	January 17

Please confirm that Merck's compromise proposal works for JHU. If not, let us have JHU's availability to meet and confer this coming Monday and Tuesday.

Very truly yours,

Preston

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From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Friday, August 23, 2024 11:37 AM
To: Nicholas Stephens <nstephens@fr.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Attached is a draft protective order for this IPR proceeding. As you will see, it tracks Merck and JHU's prior agreement as to Highly Confidential Information.

With respect to JHU's request to extend the due date of its Patent Owner Response, we will get back to you shortly.

Very truly yours,

Preston

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From: Nicholas Stephens <nstephens@fr.com>
Sent: Thursday, August 22, 2024 10:38 AM
To: Ratliff, Preston K. <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

JHU's team is sized to support the nine IPRs that Merck filed on the '393 and related patents, with particular individuals primarily working on different cases and/or different phases of these cases. Among the scheduling issues that we are working to resolve, JHU's lead counsel is preparing for re-scheduled depositions and a pair of oral hearings over the next several weeks.

Moreover, and regardless of the specific dockets and schedules of individuals on our team, the present state of discovery and protective order negotiations warrants an extension. It has been more than a month since JHU raised the issue of a protective order with Merck (July 19th), but we are still awaiting Merck's proposal. The parties will need time first to reach agreement on the protective order and obtain the Board's approval, and JHU must then have reasonable time to review and account for documents produced under the protective order.

We believe our proposal to modify Due Dates 1-3 is reasonable under the circumstances, especially where there will be no impact on the stayed district court litigation. We hope that Merck will consider the proposal in good faith and we look forward to receiving Merck's redlines on the protective order and Merck's position on the proposed extensions this week.

Best regards,
-Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

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From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Wednesday, August 21, 2024 4:55 PM
To: Nicholas Stephens <nstephens@fr.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We write in reply to your email below.

First, as to JHU's request to extend the due date of its Patent Owner Response, you state that JHU's counsel have "full dockets and unanticipated travel scheduled over the next several weeks." We understand that JHU has a team of at least 11 people working on this matter. Would you please give us more information about who you are speaking about and the nature of their schedules. If we have more information it would help Merck evaluate better JHU's request.

Second, we are working on the protective order proposal and will get it to you as soon as possible this week.

Many thanks,

Preston

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---

From: Ratliff, Preston K.
Sent: Tuesday, August 20, 2024 1:38 PM
To: 'Nicholas Stephens' <nstephens@fr.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

This is to let you know that we are in receipt of your email below and will get back to you.

Very truly yours,

Preston

PAUL HASTINGS

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From: Nicholas Stephens <nstephens@fr.com>
Sent: Monday, August 19, 2024 2:40 PM
To: Feigenbaum, David <davidfeigenbaum@paulhastings.com>; Ratliff, Preston K. <prestonratliff@paulhastings.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Casey Kraning <Kraning@fr.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Following up on the parties' August 13th meet and confer, we have not yet received Merck's proposed redlines to the default Protective Order. Please share Merck's proposed edits by close of business Wednesday, August 21st.

Additionally, as you know, the Board's Scheduling Order (Paper 11) set September 6, 2024 as the deadline for filing Patent Owner's Response to the Petition (DUE DATE 1). At this time, however, briefing on JHU's discovery motion is ongoing and the parties still need to negotiate the terms of a protective order. The Board will also require time to issue an order on the discovery motion and Merck may require further time to comply with any authorized discovery. JHU's counsel also have full dockets and unanticipated travel scheduled over the next several weeks. Considering these circumstances, Patent Owner proposes that the parties jointly stipulate to extend the briefing schedule as follows:

	Current Deadline	**Proposed Deadline**
DUE DATE 1: JHU's Patent Owner Response	September 6	October 4
DUE DATE 2: Merck's Reply	December 6	January 3
DUE DATE 3: JHU's Sur-reply	January 3	January 31

JHU stipulates that it will not be filing a motion to amend in IPR2024-00240, and therefore no changes are required to deadlines related to the amendment process. Please let us know if Merck agrees with the above proposal, and JHU will circulate a draft of the stipulation for review.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Feigenbaum, David <davidfeigenbaum@paulhastings.com>
Sent: Wednesday, August 14, 2024 2:06 PM
To: Nicholas Stephens <nstephens@fr.com>; Ratliff, Preston K. <prestonratliff@paulhastings.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Casey Kraning <Kraning@fr.com>; Wexler, Bruce M.

<brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Dear Counsel,

We confirm that the paragraph below, with our revision in red, reflects the Parties' agreement reached during the August 13 meet and confer:

> Regarding JHU's Request #3, the parties met and conferred on August 13th. Prior to the meet and confer, JHU's district court litigation counsel provided a list of ten documents from Merck's Highly Confidential Keytruda® BLA to Merck on August 12, 2024 that JHU contends are responsive to JHU's Request #3. ~~Given the limited number of documents,~~ Merck agreed that JHU may produce these ten pdfs of Highly Confidential Keytruda® BLA documents in IPR2024-00240 under a "Highly Confidential—Attorneys' Eyes Only" or equivalent level of confidentiality, subject to the parties negotiating in good faith on the terms of a protective order for this IPR. These negotiations have begun and are ongoing. JHU acknowledges that Merck reserves its rights to object to JHU's reliance on these documents on evidentiary grounds and based on relevance ~~an evidentiary basis~~. The parties believe that JHU's Request #3 is sufficiently resolved and the Board need not address Request #3 in its forthcoming order.

As noted, Merck reserves its rights to object to JHU's reliance on the ten Keytruda BLA documents on evidentiary grounds and based on relevance.

Very truly yours,

David

PAUL HASTINGS

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From: Nicholas Stephens <nstephens@fr.com>
Sent: Tuesday, August 13, 2024 9:31 PM
To: Ratliff, Preston K. <prestonratliff@paulhastings.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Casey Kraning <Kraning@fr.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Following up on the parties' meet and confer earlier today, we write to confirm that on the meet and confer, the parties agreed that the scope of JHU's Request #3 are the ten documents identified by JHU's district court litigation counsel to Merck on August 12, 2024, and that Merck consents to the production of these ten documents by JHU in IPR2024-00240, subject to the parties' negotiation of a protective order in this matter. JHU understands that Merck reserves its rights to object to these ten documents on evidentiary grounds, but that the parties otherwise agree that this discovery

issue is resolved and that JHU's Request #3 does not require further adjudication by the Board. In that spirit, JHU intends to include the following paragraph in its Motion for Additional Discovery that will be filed tomorrow:

> Regarding JHU's Request #3, the parties met and conferred on August 13th. Prior to the meet and confer, JHU's district court litigation counsel provided a list of ten documents to Merck on August 12, 2024 that JHU contends are responsive to JHU's Request #3. Given the limited number of documents, Merck agreed that JHU may produce these ten documents in IPR2024-00240 under a "Highly Confidential—Attorneys' Eyes Only" or equivalent level of confidentiality, subject to the parties negotiating in good faith on the terms of a protective order for this IPR. These negotiations have begun and are ongoing. JHU acknowledges that Merck reserves its rights to object to JHU's reliance on these documents on an evidentiary basis. The parties believe that JHU's Request #3 is sufficiently resolved and the Board need not address Request #3 in its forthcoming order.

Please confirm by no later than 2pm ET tomorrow that the above paragraph reflects Merck's understanding of the agreement reached on today's meet and confer.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Tuesday, August 13, 2024 8:35 AM
To: Casey Kraning <Kraning@fr.com>; Nicholas Stephens <nstephens@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Dear Counsel,

We are available to meet and confer today at 2 pm Eastern. As to the questions that you sent us yesterday, we can discuss them during the meet and confer.

Very truly yours,

Preston

PAUL HASTINGS

Preston K. Ratliff II | **Partner and Chair of the New York Litigation Department**
Paul Hastings LLP | 200 Park Avenue, New York, NY 10166 | Direct: +1.212.318.6055 | +1.212.318.6000 | Fax: +1.212.230.7742 | prestonratliff@paulhastings.com | www.paulhastings.com

From: Casey Kraning <Kraning@fr.com>
Sent: Monday, August 12, 2024 5:48 PM
To: Nicholas Stephens <nstephens@fr.com>; Ratliff, Preston K. <prestonratliff@paulhastings.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>

Cc: mark.stewart@merck.com; Modi, Naveen <naveenmodi@paulhastings.com>; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Following up on your email below, we have provided answers to Merck's questions in red. Additionally, ahead of the meet and confer, please provide Merck's answers to the following questions from JHU:

- If Merck is maintaining that it does not maintain sales data by indication, what steps has Merck taken to investigate whether Merck maintains sales data by indication?
    - Has Merck investigated whether Merck uses third parties to collect data relating to its Keytruda sales?
    - Has Merck spoken to the relevant people who compile Merck's annual financial disclosures and press releases like EX2008 to understand the basis for Merck's statements suggesting that it tracks Keytruda sales by indication?
- What is Merck's position on whether the standard protective order in the trial practice guide will suffice? If Merck does not believe the standard protective order will suffice, what amendments is Merck proposing?
- On Request #3, now that the short list of documents has been provided by litigation counsel, does Merck maintain its objection that JHU's request is overly burdensome?

Please let us know whether Merck is available in the proposed 1-3pm ET time window tomorrow.

Thank you,
Casey

From: Nicholas Stephens <nstephens@fr.com>
Sent: Monday, August 12, 2024 4:08 PM
To: Ratliff, Preston K. <prestonratliff@paulhastings.com>; Casey Kraning <Kraning@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Thank you for your email. Our team is unable to meet between 9-11 am ET tomorrow as proposed. We are, however, available tomorrow between 1-3 pm Eastern. Can you please let us know if Merck is available to meet in this timeframe?

We will also provide our responses to the remaining questions in your email below in advance of the meet and confer.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Ratliff, Preston K. <prestonratliff@paulhastings.com>
Sent: Monday, August 12, 2024 11:15 AM
To: Casey Kraning <Kraning@fr.com>; Nicholas Stephens <nstephens@fr.com>; IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Cc: mark.stewart@merck.com; naveenmodi@paulhastings.com; Wexler, Bruce M. <brucewexler@paulhastings.com>; Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Dear Counsel,

This is to let you know that we are not available to meet and confer today. We, however, are available tomorrow between 9-11 am Eastern. Please let us know if that works for you. Further, to facilitate our meet and confer, please send us in advance the answers to the following questions relating to JHU's Request for Additional Discovery.

- In the district court litigation, JHU represented that third-party companies maintain U.S. sales data for Keytruda by FDA-approved indication. Does JHU still believe third-party companies maintain such data? If so, which third-party companies? Also, has JHU sought to obtain such data from any third-party company? We understand that third-party entities such as IQVIA and IMS Health may generate reports that estimate Keytruda sales for different purposes. We understand that these third parties charge thousands of dollars for such reports and impose restrictions on the use of such information. JHU believes it would be overly burdensome for JHU to have to pay for third-party data when Merck already possesses data sufficient to meet JHU's request. Further, to avoid disputes over the integrity of third-party data, Merck is in the best position to produce the requested data for this proceeding.

- Has JHU sought to obtain any of the U.S. sales data for Keytruda that Merck has made publicly-available by virtue of its U.S. Securities and Exchange Commission disclosure statements? We understand this is available but it does not meet our discovery request for data broken down by indication.

- Why does JHU need U.S. sales data for Keytruda on a monthly basis as opposed to on a quarterly or annual basis? If Merck can produce indication-specific sales data on a quarterly or annual basis, that would sufficiently fulfill JHU's request.

Relatedly, we wrote you on August 9, August 10, and August 12 in response to JHU's request as to the Highly Confidential Keytruda BLA that Merck produced under the Discovery Confidentiality Order in the district court litigation. On this point, we have not yet heard back from you regarding the identification of each member of JHU's "district court team" and our proposal to avoid the need for troubling the district court with a motion.

Finally, as you requested, we will be happy to address during the meet and confer each of the issues identified in the Board's Order.

Very truly yours,

Preston

PAUL HASTINGS

Preston K. Ratliff II | **Partner and Chair of the New York Litigation Department**
Paul Hastings LLP | 200 Park Avenue, New York, NY 10166 | Direct: +1.212.318.6055 | +1.212.318.6000 | Fax: +1.212.230.7742 | prestonratliff@paulhastings.com | www.paulhastings.com

From: Casey Kraning <Kraning@fr.com>
Sent: Friday, August 9, 2024 7:54 PM
To: Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,
We are, in fact, requesting permission for the JHU district court team to review Merck's BLA to facilitate discovery in IPR2024-00240. JHU seeks to do this to alleviate any potential or perceived burden on Merck associated with identifying documents responsive to JHU's third request. This proposed course of action does not, in JHU's view, violate the district court protective order. The district court team will not share any of the documents or their contents with the IPR team until either Merck gives its consent or there is an Order from the Board and approval by the District Court allowing it to do so.

Once JHU's litigation team identifies the relevant documents to Merck's litigation team, we expect Merck to produce those documents in the IPR by serving them on JHU's IPR team. This set of documents would then be governed by the terms of the protective order in IPR2024-00240. Again, if Merck gives its consent now to allow JHU's litigation team to review the BLA, JHU's litigation team can identify those documents for Merck to facilitate negotiation of a protective order in IPR2024-00240.
These steps should alleviate any concern Merck may have regarding the disclosure of its confidential information. We expect that Merck and JHU will work together in good faith to facilitate this process in a timely fashion should the Board grant JHU's motion. To that end, please let us know when Merck is available to meet and confer on Monday, as previously requested.
Regards,
Casey

From: Zeilberger, Daniel <danielzeilberger@paulhastings.com>
Sent: Friday, August 9, 2024 1:09 PM
To: Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We are in receipt of JHU's email below and will get back to you as soon as practicable.

In the meantime, we are concerned with your statement that "JHU's district court team intends to review the BLA that Merck produced in the litigation to identify any specific documents or portions of the BLA that may be relevant to JHU's third request in the IPR." As you have previously acknowledged, the DCO provides that "Highly Confidential Information will be used solely for the purpose of prosecuting or defending this action, including trial and any appeals therefrom, and shall not be used in any other civil actions or for any other purpose." (DCO at ¶ 8.)

As we understand it, neither the district court nor the Board has issued an order providing JHU relief from the district court DCO. If now you are requesting Merck's permission to review the Keytruda BLA that was produced as a highly confidential in the district court litigation for purposes of the IPR2024-00240 proceeding, please make that clear in writing and identify each member of "JHU's district court team." Upon receipt of that request and information, Merck will get back to you with its position as to JHU's request.

Regards,
Dan

From: Nicholas Stephens <nstephens@fr.com>
Sent: Friday, August 9, 2024 12:10 PM
To: Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

The Board this week issued the attached Order authorizing Patent Owner's motion for additional discovery. The Order identifies several issues on which the Board "strongly suggest[s]" that the parties meet and confer to address before Patent Owner's motion is due next Wednesday, August 14th.

Consistent with the Board's Order, please let us know Petitioner's availability to meet and confer Monday, August 12th. JHU is available between 9-11 am and 12-1 pm ET, but may be able to accommodate later times if needed.

For the call, please be prepared to discuss each of the issues identified in the Board's Order, including at least:

- How Merck can reasonably produce information responsive to JHU's first and second requests in a manner that "allow[s] Patent Owner to obtain the information it seeks"; and
- Merck's position on a protective order for this proceeding if JHU's discovery requests are granted.

As we have previously stated, JHU believes the Board's default protective order should suffice to protect Merck's confidential information. JHU is nonetheless willing to consider reasonable modifications to the default protective order should Merck choose to propose any. Regardless, Merck should provide its position and any proposed modifications to the default protective order as soon as possible to avoid unnecessary delays in complying with any authorized discovery.

Finally, as to the JHU's third discovery request, the Board noted that JHU's motion "should identify specific documents and their particular relevance to the arguments Patent Owner seeks to raise in its Response to the Petition" and that the motion should "address what documents are available from the related litigation that may be responsive to this request, to assist in clarifying the scope of potential discovery." In light of this instruction, JHU's district court team intends to review the BLA that Merck produced in the litigation to identify any specific documents or portions of the BLA that may be relevant to JHU's third request in the IPR. JHU's district court team will communicate that list to Merck's district court team to confirm Merck's agreement to JHU's identification and high-level descriptions of those documents in the motion sufficient to meet the instructions provided in the Board's Order.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Zeilberger, Daniel <danielzeilberger@paulhastings.com>
Sent: Tuesday, July 30, 2024 3:51 PM
To: Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We have updated the draft email, below, to reflect Merck's position. In terms of a call with the Board, we are available on Thursday at 10:00 am ET and Friday between 10:00 am and 2:00 pm ET.

We think a discussion about an appropriate protective order is premature. The Board has not granted JHU's requested discovery, much less do we know what, if any, materials are responsive to JHU's requests to allow the Parties to tailor an appropriate protective order.

****DRAFT BOARD EMAIL****

Honorable Board,

Patent Owner, The Johns Hopkins University, respectfully requests leave to move for additional discovery under 37 C.F.R. § 42.51(b)(2). PO specifically requests production of the following documents:

1. Documents sufficient to show Merck's Keytruda monthly sales in the United States, including sales by FDA-approved indication ~~and/or cancer type~~;
2. Documents sufficient to show the basis for Merck's statement in its February 1, 2019 earnings call that Merck saw "good growth in the MSI-high agnostic indication," that "represents about 5% of our [Keytruda] business"; and
3. Submissions from Merck to FDA, including correspondence, and/or presentations, ~~from Merck~~ before and including May 25, 2017 regarding the MSI-H ~~tumor agnostic~~ indication, including as related to FDA granting breakthrough therapy designation on November 2, 2015 to Keytruda for the treatment of patients with MSI-H metastatic colorectal cancer.

The requested documents are relevant to objective indicia of non-obviousness, including but not limited to commercial success, long-felt but unmet need, industry praise, unexpected results, and nexus. PO submits that additional discovery is necessary in the interest of justice and PO's motion would demonstrate that the factors set forth in *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 (PTAB March 5, 2013) (precedential) are satisfied.

The parties have met and conferred. Petitioner requested that its position be included as follows: Petitioner opposes Patent Owner's request for additional discovery. Patent Owner's request is not in the interests of justice and cannot meet the Garmin factors, particularly given the unfair burden of the request, its lack of relevance and proportionality to the issues in this proceeding.

The parties can be available for a conference call on Thursday at 10:00 am ET and Friday between 10:00 am and 2:00 pm ET.

Regards,
Dan

From: Nicholas Stephens <nstephens@fr.com>
Sent: Tuesday, July 30, 2024 4:35 PM

To: Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Please provide us with an ETA for when you will have Merck's insert. We intend to email the Board at 5 pm ET.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Zeilberger, Daniel <danielzeilberger@paulhastings.com>
Sent: Tuesday, July 30, 2024 1:50 PM
To: Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Thank you for your email. We have revisions to the draft email you have provided, and will be sending them as soon as possible today. Please refrain from emailing the Board until you have our insert containing Merck's position.

Regards,
Dan

From: Nicholas Stephens <nstephens@fr.com>
Sent: Tuesday, July 30, 2024 8:08 AM
To: Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Below is a draft of the email that we intend to send to the Board by 3 pm ET this afternoon. The edits in red further clarify aspects of the request discussed during our call on Friday (but will be removed in the email to the Board).

As previously requested, please let us know in due course whether Merck will agree to use of the PTAB's default protective order should discovery be granted. Please also let us know Merck's availability for a conference call with the Board Wednesday-Friday this week so that we can provide our mutual availability in the email to the Board.

****DRAFT BOARD EMAIL****

Honorable Board,

Patent Owner, The Johns Hopkins University, respectfully requests leave to move for additional discovery under 37 C.F.R. § 42.51(b)(2). PO specifically requests production of the following documents:

1. Documents sufficient to show Merck's Keytruda monthly sales in the United States, including sales by FDA-approved indication ~~and/or cancer type~~;
2. Documents sufficient to show the basis for Merck's statement in its February 1, 2019 earnings call that Merck saw "good growth in the MSI-high agnostic indication," that "represents about 5% of our [Keytruda] business"; and
3. Submissions from Merck to FDA, including correspondence, and/or presentations, ~~from Merck~~ before and including May 25, 2017 regarding the MSI-H ~~tumor agnostic~~ indication, including as related to FDA granting breakthrough therapy designation on November 2, 2015 to Keytruda for the treatment of patients with MSI-H metastatic colorectal cancer.

The requested documents are relevant to objective indicia of non-obviousness, including but not limited to commercial success, long-felt but unmet need, industry praise, unexpected results, and nexus. PO submits that additional discovery is necessary in the interest of justice and PO's motion would demonstrate that the factors set forth in *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 (PTAB March 5, 2013) (precedential) are satisfied.

The parties have met and conferred and Petitioner indicates that it opposes JHU's request. The parties can be available for a conference call at [INSERT PARTIES' AVAILABILITY].

Best Regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Zeilberger, Daniel <danielzeilberger@paulhastings.com>
Sent: Monday, July 29, 2024 3:35 PM
To: Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We have considered the materials you shared on Friday. Merck intends to oppose JHU's motion for additional discovery. As previously requested, please share a draft of the email you intend to send to the Board so that we may ensure it reflects Merck's position.

Regards,
Dan

From: Nicholas Stephens <nstephens@fr.com>
Sent: Friday, July 26, 2024 8:12 PM
To: Zeilberger, Daniel <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We are also attaching Merck's 5/25/2017 news release referenced during today's call.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Nicholas Stephens
Sent: Friday, July 26, 2024 7:03 PM
To: 'Zeilberger, Daniel' <danielzeilberger@paulhastings.com>; 'Feigenbaum, David' <davidfeigenbaum@paulhastings.com>; 'PH-MSD-JHU-IPR' <PH-MSD-JHU-IPR@paulhastings.com>; 'mark.stewart@merck.com' <mark.stewart@merck.com>
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Attached are copies of the documents requested during this afternoon's meet and confer.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Nicholas Stephens
Sent: Thursday, July 25, 2024 11:33 AM
To: 'Zeilberger, Daniel' <danielzeilberger@paulhastings.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com

Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

JHU's discovery request stems entirely from publicly available information indicating that Merck possesses documents relevant to each request for production. No confidential information has been shared in violation of the district court protective order, and your insinuations to the contrary are both baseless and unproductive. Moreover, and importantly, Merck has not explained why production of the requested documents would be overly burdensome or whether Merck has already produced the requested documents in the district court case. Please let us know promptly.

It is unclear why your last email signaled a window of availability "Thursday afternoon," but that you are now only available after COB today when our team unfortunately has a conflicting obligation. We are nonetheless available for the meet and confer at 2 pm ET on Friday. We will circulate a meeting invite with a dial-in number for that time.

Best regards,
Nick

From: Zeilberger, Daniel <danielzeilberger@paulhastings.com>
Sent: Thursday, July 25, 2024 9:58 AM
To: Nicholas Stephens <nstephens@fr.com>; Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Thank you for your reply, however, you did not answer our questions as to the issue you raised concerning JHU's "district court team." Please let us know as soon as possible because you have raised a serious concern about whether there has been a violation of the district court's Discovery Confidentiality Order.

With respect to meeting and conferring, we asked for your availability for the afternoon today ***and*** tomorrow. You, however, only commented on your availability today. Unfortunately, we are not available at the times you are available today. We are available today at 5:30 pm Eastern time and tomorrow at 12-1pm and 1:30-4 pm Eastern time to meet and confer. Please let us know if there is a time during those windows that you are available.

Many thanks,
Dan

From: Nicholas Stephens <nstephens@fr.com>
Sent: Wednesday, July 24, 2024 5:57 PM
To: Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

We are available for a call to meet and confer tomorrow at 1, 1:30, or 3 pm EDT. Please let us know which of these times you prefer.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Feigenbaum, David <davidfeigenbaum@paulhastings.com>
Sent: Wednesday, July 24, 2024 1:50 PM
To: Nicholas Stephens <nstephens@fr.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

Thank you for your reply.

As an initial matter, we ask that JHU please refrain from placing on us unreasonably short and arbitrary deadlines. For example, JHU is demanding now that we provide a response within less than 24 hours and where you sent your response yesterday after the close of business.

With respect to the additional discovery that you seek, we disagree that it is narrowly tailored, easily understandable, and in Merck's possession. To the extent understood, it is unduly burdensome, seeks litigation positions, is not pertinent to, or at best has speculative relevance to, the issues in the IPR, and/or is equivalent to information JHU can generate on its own.

With respect to JHU's suggestion that its "district court team" would search through and use highly confidential documents produced by Merck under the Discovery Confidentiality Order in that case, that would be inappropriate and in violation of the DCO which provides "Highly Confidential Information will be used solely for the purpose of prosecuting or defending this action, including trial and any appeals therefrom, and shall not be used in any other civil actions or for any other purpose." (DCO at ¶ 8.) On this point, please identify the members of JHU's "district court team" who are members of its PGR team, and confirm whether any individuals from either of those teams have been looking at and/or considering documents that Merck produced in the federal court litigation in Maryland for purposes other than the district court case, in violation of the Discovery Confidentiality Order.

Finally, let us know your availability to meet and confer regarding JHU's request on Thursday afternoon and Friday of this week. And to the extent JHU intends to reach out to the Board without conducting a meet-and-confer, please share your draft email so that we may add Merck's position to the email. We reserve the right to inform the Board regarding any lack of cooperation in this regard.

Regards,

David

From: Nicholas Stephens <nstephens@fr.com>
Sent: Tuesday, July 23, 2024 5:07 PM
To: Feigenbaum, David <davidfeigenbaum@paulhastings.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-

IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] RE: IPR2024-00240 - Motion for Additional Discovery

Counsel,

JHU's requests are narrowly tailored and seek production of a limited set of documents in Merck's possession. The documents are pertinent to objective indicia of non-obviousness, including but not limited to commercial success, long-felt but unmet need, industry praise, unexpected results, and the underlying nexus—all of which the Board must consider in its analysis.

JHU is not seeking Merck's litigation positions, the requests are easily understandable and not overly burdensome, and JHU is unable to generate equivalent information on its own. The requests accordingly meet each of the *Garmin* factors.

To further mitigate any burden on Merck, JHU's district court team would be willing to provide a list of specific documents that JHU seeks to the extent the district court team is aware of them, if Merck agrees that doing so would not violate the protective order.

Please confirm no later than 3 pm ET tomorrow whether Merck would like JHU's district court team to provide the above-referenced list of documents and whether Merck will oppose JHU's request for leave to move for additional discovery.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

From: Feigenbaum, David <davidfeigenbaum@paulhastings.com>
Sent: Tuesday, July 23, 2024 7:55 AM
To: Nicholas Stephens <nstephens@fr.com>; PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: RE: IPR2024-00240 - Motion for Additional Discovery

[This email originated outside of F&R.]

Counsel,

We are in receipt of the email that you sent us after the close of business on Friday evening. In order for us to adequately consider JHU's request for additional discovery, please explain why JHU is seeking the extremely broad categories of discovery listed in its email and why JHU believes this would meet the *Garmin* factors if JHU so believes. Please note that we may not be able to get back to you within the short timeframe that you requested. The answers to our questions will help us discuss this request with our client, and make a meet and confer with you more productive to the extent a meet and confer is needed.

Regards,

David

From: Nicholas Stephens <nstephens@fr.com>
Sent: Friday, July 19, 2024 6:07 PM
To: PH-MSD-JHU-IPR <PH-MSD-JHU-IPR@paulhastings.com>; mark.stewart@merck.com
Cc: IPR52261-0005IP1 <IPR52261-0005IP1@fr.com>
Subject: [EXT] IPR2024-00240 - Motion for Additional Discovery

Counsel,

JHU intends to seek authorization from the Board to file a motion for additional discovery from Merck in the subject IPR. Specifically, JHU intends to request production of the following documents:

i. Documents sufficient to show Merck's Keytruda monthly sales, including sales by FDA-approved indication and/or cancer type;
ii. Documents sufficient to show the basis for Merck's statement in its February 1, 2019 earnings call that Merck saw "good growth in the MSI-high agnostic indication," that "represents about 5% of our [Keytruda] business"; and
iii. Submissions to FDA, including correspondence, and/or presentations, from Merck before and including May 25, 2017 regarding the MSI-H tumor agnostic indication, including as related to FDA granting breakthrough therapy designation to Keytruda for the treatment of patients with MSI-H metastatic colorectal cancer.

To protect the confidentiality of Merck's information, JHU proposes that the parties agree to the default protective order provided in the Patent Trial and Appeal Board Consolidated Trial Practice Guide (November 2019) at 117-122, recognizing that the parties are simultaneously still bound by all of the provisions in the protective order entered in the district court litigation (D.I. 56), including the prosecution bar.

Please let us know whether Merck opposes this request by COB on Tuesday, July 23rd. If Merck opposes, please provide availability to meet and confer. Additionally, please let us know whether Merck will agree to the default protective order.

Best regards,
Nick

Nicholas Stephens
Principal ■ Fish & Richardson P.C.

T: 612 766 2018 | nstephens@fr.com | Bio

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