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January 7, 2026

VIA ECF

Honorable José R. Almonte
United States Magistrate Judge
District Court of New Jersey
Frank Lautenberg Post Office & U.S. Courthouse
2 Federal Square
Newark, New Jersey 07102

Re: *Halozyme, Inc. v. Merck Sharp and Dohme LLC (ES) (JRA)*
Civ. A. No. 2:25-03179 (MEF) (JRA)

Dear Judge Almonte:

This firm, together with Dechert LLP and Sidley Austin LLP, represents Defendant Merck Sharp and Dohme LLC ("Merck" or "Defendant") in the above-referenced matter. With Walsh Pizzi O'Reilly Falanga LLP and Quinn Emanuel Urquhart & Sullivan, LLP, counsel for Halozyme, Inc. ("Halozyme" or "Plaintiff") (Halozyme and Merck collectively referred to as "the Parties"), we write in accordance with Your Honor's Letter Order granting the Parties' request to submit a further status update. ECF No. 39.

Status of Post-Grant Review ("PGR") Proceedings

Over nine months ago, on April 24, 2025, Halozyme filed the instant action asserting that Merck infringes 15 patents from the same patent family: United States Patent Nos. 10,865,400, 11,041,149, 11,066,656, 11,952,600, 12,018,298, 12,037,618, 12,049,652, 12,054,758, 12,077,791, 12,091,692, 12,104,185, 12,110,520, 12,152,262, 12,195,773, and 12,264,345 (the "Asserted Patents").

Merck has filed PGRs against 12 of the 15 Asserted Patents, all of which have been instituted. Halozyme has filed its Patent Owner Responses in 5 of those PGRs, with the remainder to be filed by January 20, 2026. The final written decision ("FWD") in the first-instituted PGR (PGR2025-00003, against U.S. Patent No. 11,952,600) is expected on or before June 2, 2026.¹ All FWDs are expected to be completed on or around November 20, 2026.

¹ This deadline for issuance of the FWD is statutorily mandated. *See* 35 U.S.C. § 326(a)(11); *see also* 37 C.F.R. § 42.200(c).

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Three unchallenged patents (U.S. Patent Nos. 10,865,400, 11,041,149, and 11,066,656) are not eligible for PGR.

PLAINTIFF'S POSITIONS

Plaintiff's Position Regarding the Potential Administrative Stay of this Action

While Halozyme is prepared to begin discovery, in order to promote efficiencies and mindful of Your Honor's comments at the October 20, 2025 status conference, Halozyme will consent to an administrative stay of this action until June, 2026; Halozyme objects to Merck's request for an administrative termination, however, and respectfully requests that the Court deny the request.

As noted above, the first FWD will issue on or before June 2, 2026. Accordingly, instead of termination, Halozyme respectfully requests that the parties be ordered to meet and confer following issuance of the first FWD to discuss its impact on the litigation. Halozyme further requests that the parties be ordered to submit a joint status letter to the Court no later than June 9, 2026 informing the Court of the status of the PGRs and setting forth their positions on whether or not the stay should be continued. Finally, Halozyme requests that the Court schedule a status conference for June 16, 2026 or a convenient time shortly thereafter.

Merck contends below that Halozyme is reneging on its agreement to stay the case, but that is untrue. Halozyme expressly consents to a stay. Halozyme simply requests that the Court stay the case rather than terminate it. That is because staying this action until June 2026, rather than administrative termination, will allow the parties and the Court to proceed most efficiently while accounting for the potential impact of the FWDs on the case.

First, as set out above, an initial decision in the first set of PGRs is statutorily required to issue no later than June 2, 2026—less than six months from now. The parties have agreed that the first FWD may be informative of the scope of this matter going forward. Dkt. 34-1 (fifth and sixth "WHEREAS" clauses). Staying the matter until after the first FWD, rather than terminating, will allow the parties to efficiently update the Court regarding the progress of the PGRs and to provide their positions on whether or not the stay should be continued in view of the first FWD, without requiring inefficient motion practice to lift an administrative termination.

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Second, as noted above, there are multiple patents that Merck has not and cannot challenge via PGR. Thus, regardless of the outcome of the PGRs, this case will proceed. The FWDs will be neither binding on the Court or the parties nor dispositive of any issues as to the unchallenged patents—despite Merck’s unfounded prior claims to the contrary—given, *inter alia*, the differences in the challenged and unchallenged patents and the standards applied by the PTAB and district court.

Thus, no matter the outcome of the PGRs, this case will move forward with at least the three unchallenged patents. Halozyme should not be required to seek to reopen the case to prosecute claims that will proceed regardless of the outcome of the PGRs. And that is exactly what Merck contemplates—under Merck’s proposal, the parties would wait until November 2026, five months after the FWD, to provide their positions on whether the case should be “restored.” Halozyme respectfully submits that it would be better and more efficient to stay the case until after the first FWDs, which may be informative of the scope of the case going forward, including whether the PGR patents will or will not be part of the remaining case.

Third, as set out below, there are still open disputes regarding Merck’s production and issues of confidentiality, including any DCO. Additionally, as the Court is aware, the Court granted Halozyme’s motion to issue Letters Rogatory to the appropriate authorities in the Republic of Korea (Dkt. 49); Halozyme appreciates the Court’s prompt ruling on its motion, and will proceed with service of the Letters Rogatory in accordance with the provisions of the Hague Convention. Halozyme notes that further follow up action from the Court may nonetheless be required at some future time, depending on whether the Central Authority of Korea accepts or requests modifications to the requests or raises other issues. For instance, the Convention dictates that “[i]f the Central Authority considers that the request does not comply with the provisions of the present Convention, it shall promptly inform the authority of the State of origin which transmitted the Letter of Request, specifying the objections to the Letter,” at which time corrections are typically made by the requesting party, if necessary. *See* Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters, T.I.A.S. 7444, 23 U.S.T. 2555 (“Hague Evidence Convention”), *reprinted in* 28 U.S.C. § 1781. Administrative termination may complicate that procedure unnecessarily.

Halozyme’s proposed course of action would allow the Court to most efficiently address these and other issues, if necessary, without burdensome motion practice over a termination.

Plaintiff’s Position Regarding the Status of Pre-Discovery Document Production

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The Parties' agreement regarding discovery was presented to the Court on November 14, 2025 (*see* ECF No. 38), and the Court entered the Parties' proposed stipulation governing limited pre-discovery document production on November 17, 2025, pursuant to Local Patent Rule 2.2 (ECF No. 40). Pursuant to the Parties' agreement, Merck was required to produce product samples as well as limited documents (*id.*). As to the former, the parties are coordinating regarding logistics; as to the latter, the documents produced by Merck contain improper redactions to information that Merck claims relates to "third party confidential information," which is purportedly not relevant.

Regarding the redactions, after the parties met and conferred extensively to narrow Merck's initial production and, after Merck rejected Halozyme's repeated requests to enter a full DCO, Merck stipulated to an outside counsel's eyes-only production under Local Patent Rule 2.2 to address Merck's confidentiality concerns, including concerns about use outside this case. That stipulation should have eliminated any need for redactions by resolving any confidentiality concerns. At no point during the parties' extensive negotiations did Merck indicate it intended to redact the agreed-upon materials, whether for confidentiality or relevance.

Merck redacted substantial portions of relevant information from its production, however, including financial terms with Alteogen and portions of Alteogen's presentation to Merck (*see, e.g.,* MSD-0031593-596 and MSD-031650-031652). This information is directly relevant to the nature and scope of Merck's relationship with Alteogen, the supplier of berahyaluronidase alpha in Merck's accused product, and the categories of documents and custodians likely to exist.

Merck has indicated it is not asserting any privilege over these materials; instead, it merely claims that they are allegedly "third-party confidential materials" that are not relevant. But there should be no confidentiality concerns given the parties' agreement regarding production under Local Patent Rule 2.2. And "[u]nilateral redactions based on one party's subjective view of relevancy are improper." *Columbus Life Insurance Company v. Wilmington Trust, N.A.*, 344 F.R.D. 207, 216 (D.N.J. 2023) (citation omitted); *General Motors LLC v. Ashton*, No. 20-cv-12659, 2023 WL 1765711, at *4-5 (D.N.J. Feb. 3, 2023) (finding unilateral relevancy redactions inappropriate); *Rodriguez-Ocasio v. Midland Credit Mgmt., Inc.*, No. 17-cv-3630, 2019 WL 3821769, at *2 (D.N.J. July 23, 2019) (affirming the magistrate judge's finding that unilateral redactions are improper). That is because "Federal Rule of Civil Procedure 34 concerns the production of entire documents—not particular pictures, graphics, paragraphs, sentences, or words. Thus, absent special

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circumstances, courts view entire documents as either relevant or irrelevant; they do not weigh the relevance of particular provisions.” *Rodriguez-Ocasio*, 2019 WL 3821769, at *2 (D.N.J., 2019)(internal citations omitted).

Putting aside the impropriety of the redactions and reserving all rights to seek relief with respect to same, Halozyme respectfully submits that Merck’s approach to these redactions merely highlights the need for a DCO that will govern discovery in this case going forward.² Halozyme respectfully submits that there is no reason that the parties cannot move forward with such negotiations; to the contrary, requiring the parties to do so where there is no question that litigation will proceed once the stay is lifted – as is the case here – is efficient, prudent, and consistent with the practice in this District to allow negotiations over discovery frameworks to continue while discovery is stayed. *See, e.g., Gibly v Best Buy Co., Inc.*, No. 21-14531, 2022 WL 2413906 (D.N.J. Mar. 7, 2022) (granting stay of discovery after discovery confidentiality order was entered and ordering parties to negotiate ESI protocol during stay). Merck’s suggestion that doing so will result in the Court having to decide disputes during the pendency of the stay is incorrect; rather, the parties will not have to submit anything to the Court until after June 9, which is also Halozyme’s proposed deadline to update the Court on the first FWD and whether a stay should continue.

Accordingly, Halozyme requests that the Court direct the parties to meet and confer regarding a DCO and submit a DCO, or if unable to reach agreement on a DCO, a joint letter setting forth any disputes relating to same, by June 9, 2026, ahead of the proposed status conference.

Conclusion to Plaintiff’s Position

For the reasons set forth above, Halozyme respectfully requests that, to the extent the Court is not inclined to proceed at this juncture, the Court order (1) an administrative stay of this action until June, 2026, (2) that the parties meet and confer regarding a DCO, (3) the parties meet and confer after the PTAB issues the first FWD in order to submit a joint status letter to the Court no later than June 9, 2026 informing the Court of the status of the PGRs and setting forth their respective positions on whether or not the stay should

² Contrary to Merck’s suggestion, Halozyme’s position has always been that the parties should negotiate a full DCO regardless of whether discovery is stayed, which is consistent with the parties’ prior stipulation (Dkt. 34-1).

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be continued. Halozyme further requests that the Court order a status conference for June 16, 2026 or a convenient time shortly thereafter.

DEFENDANT'S POSITIONS

Defendant's Position Regarding the Status of Pre-Discovery Document Production

The Court held an initial scheduling conference on October 20, 2025, at which the Court indicated that it believed administrative termination of the case was appropriate, pending resolution of Merck's PGRs. ECF No. 36. Merck agreed that administrative termination of the case was appropriate without the need for any document production, as the results of Merck's 12 instituted PGRs would weigh heavily on the future of the case and would greatly simplify the issues in the case. Merck's position was consistent with this District's precedent that routinely stays actions pending the outcome of all relevant PTAB proceedings, even when fewer than all patents or claims are challenged. *See, e.g., Depomed Inc. v. Purdue Pharma L.P.*, No. 13-0571 (JAP), 2014 WL 3729349, at *5 (D.N.J. July 25, 2014) (issue simplification can occur even where "some or all of the claims are found not invalid"); *SPG Dry Cooling USA, LLC v. Evapco Dry Cooling, Inc.*, No. 3:20-20131 (FLW) (LHG), ECF No. 48, at *2 (D.N.J. Feb. 17, 2022) ("Given that the IPR proceedings may have a critical impact on the scope of the litigation, allowing discovery to proceed as to only one of the patents would risk waste of resources, both of the parties and of the Court. . . . The Court further instructs the Clerk's Office to administratively terminate the matter pending completion of the IPR."); *Cochlear Ltd. v. Oticon Med. AB*, No. 3:18-6684 (BRM) (DEA), ECF No. 121, at *5-6 (D.N.J. Nov. 5, 2019) (finding that IPR would narrow and simplify the issues for the Court when the "PTAB will be reviewing twenty-five (25) of the forty-eight (48) claims" of the asserted patent; administratively terminating the case pending resolution of the IPR); *Canfield Scientific, Inc. v. Drugge*, No. 2:16-4636 (JMV), ECF No. 90, at *7-10 (D.N.J. June 13, 2018) (finding that IPR would narrow and simplify the issues for the Court when plaintiff sought review of 11 out of 41 asserted claims; staying and administratively terminating the case pending the completion of PTAB proceedings).

In the interest of compromise, however, Merck agreed to produce certain pre-discovery documents to Halozyme in order to avoid burdening the Court with motion practice. Halozyme represented that it needed certain documents from Merck to facilitate Halozyme's preparation of a letter of request pursuing Hague Discovery of third party Alteogen Inc. ("Alteogen"), a South Korean company, and samples of Merck's KEYTRUDA QLEX product so it could begin product testing. *See* ECF No. 34-1. The Parties' agreement regarding discovery was presented to the Court on November 14, 2025

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(see ECF No. 38), and Your Honor entered the Parties' proposed stipulation governing limited pre-discovery document production on November 17, 2025, pursuant to Local Patent Rule 2.2 (ECF No. 40).

On November 5 and 19, Merck requested that Halozyne provide shipping information for the KEYTRUDA QLEX samples and received no response until January 6, 2026. On November 21, 2025, Merck completed its document production encompassing 31,654 pages of documents on Halozyne. This production included Modules 2 and 3 of Merck's Biologics License Application ("BLA") for KEYTRUDA QLEX, Merck's license agreement with Alteogen and amendments thereto, and a document Merck received from Alteogen for Merck to consider its partnership with Alteogen. Merck redacted limited third-party confidential information in three documents, including information related to Alteogen products not at issue here (which is clear from the context of the unredacted portions of the document) and specific financial terms of Merck's agreement with Alteogen. The content of these limited redactions to third-party confidential information has no bearing on the purpose of this pre-discovery production, which was ostensibly to facilitate Halozyne's Hague discovery. Indeed, Halozyne filed its motion for issuance of a letter of request to Alteogen pursuant to the Hague Convention on December 19, 2025. ECF No. 48. The Court granted Halozyne's motion on January 7, 2026. ECF No. 49.

Defendant's Position Regarding the Administrative Termination of this Action

Halozyne's above position reneges on its agreement to stay the case and would defeat the entire purpose of this Court administratively terminating the action. For example, Halozyne now states that there are outstanding issues regarding Merck's pre-discovery production that require the Court to remain available. Merck disagrees and respectfully submits that Halozyne's issues with Merck's production reinforces why the Court should administratively terminate this action pending final written decisions on the PGRs. With respect to the samples of Merck's KEYTRUDA QLEX product, Halozyne says the parties "are coordinating logistics." Merck disagrees, and the shipping of samples should not impact the Court's decision to administratively terminate the action. In fact, the shipment would have been completed by now had Halozyne timely provided shipping information that Merck has asked for since November 5. Halozyne only responded on January 6, 2026, with an address as well as a request for additional information to accompany the production of samples including "how each sample was prepared." Merck will do what it agreed to and ship samples to the address Halozyne provided.

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With respect to the redactions Merck made to only three documents of Merck's entire production to Halozyme, Halozyme waited nearly one month after Merck completed the production to raise any issues. Two days later, Halozyme nonetheless filed its motion for issuance of letters rogatory which the Court has now granted. With the purpose behind Halozyme's pre-discovery production request fulfilled, it cannot now claim prejudice with respect to Merck's limited redactions. And the cases Halozyme cites are inapposite because this case is not in discovery, and involves confidential information of a third-party.

Further, for the first time on January 6, 2026, the day before this letter was due to be filed, Halozyme raised the prospect of keeping the case open for the parties to negotiate a DCO and for the Court to handle some ambiguous "action" relating to Hague discovery "at some future time." Halozyme never conferred with Merck regarding this request before agreeing and submitting a stipulation to *stay* the case and only raised it for the first time in this letter. Merck objects to Halozyme springing these issues in a joint letter at the eleventh hour.

Despite Merck's objection to Halozyme raising these issues in this status update, there is no reason for the parties to negotiate a DCO at this point. Merck insisted on the confidentiality provisions that the parties agreed to because the agreement involved a one-sided production of highly confidential materials, such as Merck's Biologic License Application. Merck demanded these restrictions because Halozyme is actively prosecuting patents attempting to capture Merck's KEYTRUDA QLEX product and is initiating (including through Halozyme's counsel Quinn Emanuel) proceedings globally that seek to prevent Merck from marketing its product. By contrast, there is no need for the Court to resolve issues that would be associated with entry of a full DCO when Halozyme is not producing any documents.

In sum, Merck has provided all the pre-discovery documentation it committed to provide to address any perceived prejudice to Halozyme from administrative termination of the case, and Halozyme has submitted its motion for a letter of request. Accordingly, the Parties' agreement is complete, and the Court should administratively terminate the case pending a FWD on each of the challenged patents. By contrast, adopting Halozyme's proposal to keep the case open to continue negotiations over Merck's completed pre-discovery production, Halozyme's completed Hague motion, and a DCO and thereafter raise new issues with Your Honor would defeat the purpose of an administrative termination and the purpose of the Parties' agreement. Merck proposes that the Parties

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provide an update to the Court in November 2026 with the outcomes of each of the PGRs and the Parties' positions with respect to whether or not the case should be restored to the active docket.

* * *

The Parties thank the Court for its time and assistance in this matter. If the Court would like to discuss anything further, the Parties will make themselves available at the Court's convenience.

Respectfully submitted,

s/Charles H. Chevalier
Charles H. Chevalier
Director

cc: Counsel of Record (via ECF and e-mail)