From:	Goldberg, Brian
To:	Zach Summers; Katelyn O"Reilly; Chevalier, Charles H.; Caracappa, Michael V.; Helm, Katherine; Hackman, Blaine; Shanker, Shyam; Roberts, Daniel; Merck-Halozyme-Dechert
Cc:	Liza Walsh; Lauren Malakoff; Dave Nelson; Lauren Martin; Elliot Choi; Anastasia Fernands; Nancy Zhang; Jeff Gerchick
Subject:	RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179
Date:	Thursday, October 9, 2025 5:10:55 PM
Attachments:	image001.png image002.jpg

Zach,

Thanks for the meeting yesterday and for memorializing Halozyme's proposal for consideration. Merck agrees in principle to produce limited discovery during a stipulated stay of litigation. We hope we can reach agreement on scope, with our comments and questions as follows:

We understand that Halozyme seeks a limited production of the two specific categories of items you lay out below.

With respect to the first category, we understand from your reasons below and your comments yesterday that early production of these materials would allow Halozyme to prepare more useful contentions and evaluate what additional discovery may be needed if the stay is lifted. To that end, Merck is willing to produce Modules 2 and 3 of its BLA as well as samples of the Keytruda Qlex product. As you can appreciate, Merck's BLA contains highly sensitive materials that it prepared at great expense. We take it that you would like Modules 2 and 3 (Summaries and Quality sections), which contain the information on the accused drug substance and product, the non-clinical and clinical overviews, overall quality summary, etc., for Halozyme's claims in this case. We do not believe additional modules or the IND are relevant to Halozyme's claims nor are they necessary for the purpose of this initial discovery. Some of the modules, such as the Module 5 clinical study reports, would be burdensome to produce at this stage. As you know, they have voluminous amounts of sensitive personal, HIPAA-type information that at a minimum would need to be reviewed and heavily redacted and are irrelevant to Halozyme's claims. If Halozyme has something specific in mind that it needs from the other modules or from the IND, please explain your rationale for us to consider in good faith. Please also let us know the volume / how many samples Halozyme believes it needs for testing.

With respect to the second category, we understand you wish to move forward with Hague requests to Alteogen. Halozyme has not stated what documents it seeks from Alteogen that are relevant to Halozyme's claims and it would be helpful know what Halozyme is looking for at this stage. We suggest the most productive way to move forward is for Merck to produce its agreement with Alteogen. Merck does not agree to collect communications with Alteogen at this stage. Such an unconstrained request for communications between these companies is overbroad, unduly burdensome, will certainly encompass many irrelevant documents and is unnecessary at this stage. Again, if Halozyme has something specific in mind that it is seeking in communications with Alteogen, please let us know and we will consider it.

Merck is willing to make these productions on an outside counsel eyes only basis during the pendency of the stay if Halozyme's outside counsel agrees to a basic prosecution bar,

i.e., that it will not participate or advise in Halozyme's prosecution efforts toward patents or patent applications concerning modified PH20 polypeptides or pharmaceutical products containing pembrolizumab. This would not preclude Halozyme's outside counsel from participating in PTAB proceedings, so long as outside counsel is not involved directly or indirectly in seeking amendment of any claims in any such proceedings.

Merck is also willing to limit the length of the stay along the lines you proposed below. We propose, however, that we seek a status conference with Judge Almonte after the first final written decision is issued rather than an automatic lift of the stay. We suggest this because whether and how to proceed could depend greatly on how the PTAB resolves the initial wave of petitions.

If the above is acceptable to Halozyme, we ask that you please prepare a stipulation memorializing this agreement for our review, with the goal of submitting the stip to the Court tomorrow in lieu of a Joint Discovery Plan.

We look forward to your response and are hopeful will can reach an agreement that does not burden the Court with motion practice.

Regards,

Brian

Brian Goldberg
Partner

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From: Zach Summers <zachsummers@quinnemanuel.com>
Sent: Wednesday, October 8, 2025 8:56 PM
To: Katelyn O'Reilly <KOReilly@walsh.law>; Goldberg, Brian <Brian.Goldberg@dechert.com>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <lwalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Brian and Kathy:

Thank you for the productive discussion on Monday (10/6) and again today (10/8). To follow up per your request, we wanted to memorialize Halozyme's position regarding Merck's intent to request a stay, which Merck raised during the Monday meet and confer. Given the fact that there will be remaining patents no matter the outcome of the PGRs as well as numerous issues that will be unaffected by their outcome, Halozyme believes that the most efficient course of action is to move forward with the case on the schedule we have proposed as Exhibit 1 to the Joint Discovery Plan. Of course, if Merck has further suggestions as to that schedule, please let us know. In the interests of seeking compromise however, and without prejudice to our position, we are open to considering a stay if Merck is willing to agree to produce a few specific items that will be relevant to the case no matter the outcome of the PGRs. This limited production will allow for the case to move forward efficiently should a stay be entered.

Specifically, please let us know if Merck is willing to produce:

1. The BLA/IND for Keytruda Qlex, and samples of Keytruda Qlex
2. Merck's agreements and communications with Alteogen. As part of this request, we would request that the Court allow us to make a motion for discovery of Alteogen under the Hague Convention after we have a chance to evaluate the production.

As noted during the meet and confer, the above discovery is limited, and it will provide important information that will be relevant no matter the outcome of the PGRs.

Category 1 will allow for Halozyme to determine, *inter alia*, what information about Keytruda Qlex already exists and what potential follow up discovery will be necessary after any stay is lifted. And the provision of samples will allow for Halozyme to proceed with testing, which can be time consuming. Providing the information in Category 1 is standard, and it increases the likelihood that the case moves forward smoothly after any stay is lifted.

Category 2 will allow Halozyme to move forward with Hague process discovery of Alteogen in the most efficient way possible. As you know, such discovery takes a long time. Starting it after a stay would be inefficient. The requested materials will allow us to craft the Hague requests, and they are standard asks that should not be burdensome to collect and produce. Additionally, as we noted Monday, production of the materials will also allow us to determine the extent to which Merck has possession, custody, or control of Alteogen's documents and other information—and, in particular, Merck's duty to collect and preserve that information. Alteogen is a third party in a foreign jurisdiction and, to our knowledge, without a US presence. We are concerned that highly relevant information will be lost during the pendency of the stay.

Lastly, as we noted, we would request Merck's agreement that any stay would be lifted automatically after the first Final Written Decision issues, absent agreement of the parties. We would agree to a joint request to the Court at that time to hold a status conference on how best to proceed.

We understood your position on the call to be that no discovery should take place during Merck's proposed stay. We disagree for at least the reasons articulated above. We did not understand you to argue the above discovery is burdensome or outside the scope of the case. Merck also articulated that it believes the resolution of the PGRs will effectively resolve the litigation; as we stated, that is not the case, legally or factually, given the patents Merck has not challenged and the differences between, *inter alia*, the standards applied by the PTAB and district court, as well as the claims at issue in the challenged and unchallenged patents. Finally, we also understood your position to be that any stay would continue through the pendency of any appeal, regardless of outcome. As we expressed, that substantially lengthens the proposed stay and is not acceptable to Halozyme.

Please let us know if Merck is willing to reconsider its position. Otherwise, we are certain the parties can productively address the issues at the upcoming status conference.

Best,
Zach

From: Katelyn O'Reilly <KOReilly@walsh.law>
Sent: Wednesday, October 8, 2025 5:44 PM
To: Zach Summers <zachsummers@quinnemanuel.com>; Goldberg, Brian <Brian.Goldberg@dechert.com>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <lwalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

[EXTERNAL EMAIL from koreilly@walsh.law]

All,
As discussed on our call, please find attached a draft of the joint discovery plan and proposed schedule. I'm also attaching a draft protective order; as you'll see, per Judge Almonte's judicial preferences, we used the DNJ template and made proposed revisions thereto in redline.
We look forward to your comments.
Thanks,
Katelyn

From: Zach Summers <zachsummers@quinnemanuel.com>

Sent: Wednesday, October 8, 2025 1:14 PM
To: Goldberg, Brian <Brian.Goldberg@dechert.com>; Katelyn O'Reilly <KOReilly@walsh.law>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <LWalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Thanks, Brian. 4pm works.

From: Goldberg, Brian <Brian.Goldberg@dechert.com>
Sent: Wednesday, October 8, 2025 9:49 AM
To: Zach Summers <zachsummers@quinnemanuel.com>; Katelyn O'Reilly <KOReilly@walsh.law>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <lwalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: Re: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

[EXTERNAL EMAIL from brian.goldberg@dechert.com]

Zach,

Kassie and I can speak after 4pm. Let us know if that works for you and we'll send an invite.

Regards,

Brian

Brian Goldberg
Partner

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From: Zach Summers <zachsummers@quinnemanuel.com>
Sent: Wednesday, October 8, 2025 12:16:23 PM
To: Goldberg, Brian <Brian.Goldberg@dechert.com>; Katelyn O'Reilly <KOReilly@walsh.law>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <lwalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Brian:

I will give you a call this afternoon if there is a good time. We intend to circulate at least a draft today or early tomorrow, but a discussion makes sense first.

Best,
Zach

From: Goldberg, Brian <Brian.Goldberg@dechert.com>
Sent: Tuesday, October 7, 2025 12:50 PM
To: Katelyn O'Reilly <KOReilly@walsh.law>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <lwalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Zach Summers <zachsummers@quinnemanuel.com>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

[EXTERNAL EMAIL from brian.goldberg@dechert.com]

Counsel,

Thank you for the call yesterday. Please let us know when you expect to share a draft of the joint discovery plan as well as Halozyme's response on the issues regarding a stay of the case pending PTAB proceedings. Our team has some travel conflicts on Friday, so we'd like to get the submission ready by Friday morning if possible.

Regards,

Brian

Brian Goldberg
Partner

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dechert.com

From: Katelyn O'Reilly <KOReilly@walsh.law>
Sent: Wednesday, October 1, 2025 10:04 PM
To: Goldberg, Brian <Brian.Goldberg@dechert.com>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <LWalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Zach Summers <zachsummers@quinnemanuel.com>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Hi Brian,
Thanks for providing your group email; we'll be sure to include that going forward. For Monday, our team is available 4-5pm ET. Let us know if that works for you.
Thanks,
Katelyn

From: Goldberg, Brian <Brian.Goldberg@dechert.com>
Sent: Wednesday, October 1, 2025 5:20 PM
To: Katelyn O'Reilly <KOReilly@walsh.law>; Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>; Merck-Halozyme-Dechert <Merck-Halozyme-Dechert@dechert.com>
Cc: Liza Walsh <LWalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Zach Summers <zachsummers@quinnemanuel.com>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: RE: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Katelyn,

We are unavailable tomorrow with the holiday and the times you propose on Friday do not work for us. We are confirming windows on our end, but are you available Monday other than 2-4 pm?

I've also copied our e-mail group (merck-halozyme-dechert@dechert.com). We would appreciate if you could include that email on correspondence going forward to make sure everything gets to the right people.

Regards,

Brian

Brian Goldberg
Partner

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brian.goldberg@dechert.com
dechert.com

From: Katelyn O'Reilly <KOReilly@walsh.law>
Sent: Wednesday, October 1, 2025 2:14 PM
To: Chevalier, Charles H. <cchevalier@gibbonslaw.com>; Caracappa, Michael V. <mcaracappa@gibbonslaw.com>; Helm, Katherine <khelm@dechert.com>; Goldberg, Brian <Brian.Goldberg@dechert.com>; Hackman, Blaine <Blaine.Hackman@dechert.com>; Shanker, Shyam <Shyam.Shanker@dechert.com>; Roberts, Daniel <Daniel.Roberts@dechert.com>
Cc: Liza Walsh <LWalsh@walsh.law>; Lauren Malakoff <LMalakoff@walsh.law>; Zach Summers <zachsummers@quinnemanuel.com>; Dave Nelson <davenelson@quinnemanuel.com>; Lauren Martin <laurenmartin@quinnemanuel.com>; Elliot Choi <elliotchoi@quinnemanuel.com>; Anastasia Fernands <anastasiafernands@quinnemanuel.com>; Nancy Zhang <nancyzhang@quinnemanuel.com>; Jeff Gerchick <jeffgerchick@quinnemanuel.com>
Subject: Halozyme, Inc. v. Merck Sharp & Dohme LLC - DNJ No. 25-3179

Counsel:

Please let us know your availability for the Fed. R. Civ. P. 26(f) conference. We are available Thursday between 1:00 and 5:00 p.m. ET and Friday 12-2 and 3-4:30 p.m. ET.

Thanks,
Katelyn

Katelyn O'Reilly

Partner

D: 973.757.1023 | O: 973.757.1100 | koreilly@walsh.law
Three Gateway Center, 100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
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