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October 14, 2025

VIA ECF
Honorable Jose R. Almonte, U.S.M.J.
U.S. District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: ***Halozyme, Inc. v. Merck Sharp & Dohme LLC***
Civil Action No. 2:25-cv-03179 (ES) (JRA)

Dear Judge Almonte:

This firm, together with Quinn Emanuel Urquhart & Sullivan, LLP, represents Plaintiff Halozyme, Inc. in the above-referenced matter.

Enclosed for the Court's consideration is a Stipulation and Proposed Order. If the Stipulation and Proposed Order meets with Your Honor's approval, we respectfully request that Your Honor execute and have it entered on the docket.

We thank the Court for its consideration of the attached and are available should Your Honor or Your Honor's staff have any questions or need anything further.

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

Enclosure
cc: All Counsel of Record (via ECF and E-Mail)

Halozyme EX2024
Merck v. Halozyme
IPR2026-00312

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HALOZYME, INC., Plaintiff, v. MERCK SHARP AND DOHME LLC, Defendant.	**Civil Action No. 2:25-03179(ES)(JRA)** **Initial Scheduling Conference: October 20, 2025**

STIPULATION AND (PROPOSED) ORDER

This stipulation is made by and between Plaintiff Halozyme, Inc. ("Halozyme" or "Plaintiff") and Defendant Merck Sharp and Dohme LLC ("Merck" or "Defendant") (Halozyme and Merck collectively referred to as "the Parties") in this matter ("Litigation").

WHEREAS, on April 24, 2025, Halozyme filed this patent infringement action, alleging that Merck's current and/or imminent manufacture, use, sale, offers to sell, and/or importation of its Keytruda Qlex product infringes each of 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.");

WHEREAS, on July 14, 2025, Merck filed its Answer;

WHEREAS, Merck has filed Post Grant Review proceedings ("PGRs") with the Patent Trial and Appeal Board ("PTAB") against 12 of the 15 Asserted Patents;

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

WHEREAS, PGRs against 7 of the Asserted Patents have been instituted;

WHEREAS, the PTAB will render a Final Written Decision ("FWD") on the first instituted PGR (as to U.S. Patent No. 11,952,600) no later than June 2, 2026;

WHEREAS, the Parties agree that the FWD may impact the scope of the Litigation;

WHEREAS, in order to conserve resources and promote efficiencies for the Parties and the Court until issuance of the FWD, the Parties have agreed to engage in limited discovery, as specifically set forth below, and otherwise stay this litigation until after the issuance of the first FWD.

NOW THEREFORE, Halozyme and Merck, by and through their respective undersigned counsel, and subject to approval of the Court, stipulate and agree as follows:

1. This Litigation is stayed subject to the conditions set forth herein and further Order of the Court;
2. The parties shall submit a proposed discovery confidentiality order ("DCO"), or if unable to reach agreement on a DCO, a joint letter setting forth any disputes relating to same, by November 5, 2025;
3. Merck shall produce the following discovery by December 5, 2025[1]:
    a. Merck's Biologics License Application ("BLA") 761467 Modules 2 and 3;
    b. 15 unexpired vials of Merck's 2.4mL 395mg KEYTRUDA QLEX™ product and 15 unexpired vials of Merck's 4.8mL, 790mg KEYTRUDA QLEX™ product;
    c. Merck's license agreement, and any amendments thereto with Alteogen,

[1] If the parties submit a dispute on the DCO, and that dispute remains pending as of December 5, 2025, the discovery set forth herein shall be produced "for outside counsel's Attorney's Eyes Only, solely for purposes of the pending case and shall not be disclosed to the client or any other person," in accord with Local Patent Rule 2.2, until such time as a DCO is entered by the Court.

Inc. ("Alteogen"), and

d. Documents located after a targeted search, to the extent any exist, regarding materials that Alteogen initially provided to Merck to consider its partnership prior to entering confidential negotiations (e.g., PowerPoint presentation, testing data, berahyaluronidase-alfa development history etc.).

4. The Parties are continuing to confer regarding (1) Merck's production of its BLA 761467 Module 1 and related investigational new drug application, (2) the number and types of samples (*i.e.,* formulated product versus berahyaluronidase-alfa) Merck will produce and (3) agreements with Alteogen besides the license agreement and amendments thereto and production of documents located after a targeted search regarding materials that Alteogen provided to Merck to consider its partnership (e.g., PowerPoint presentation, testing data, berahyaluronidase-alfa development history etc.), including documents provided under a confidentiality agreement. If the Parties are unable to reach agreement, the Parties shall submit a joint dispute letter regarding same by November 5, 2025.

5. Merck will not object to Halozyme pursuing discovery of third-party, Alteogen Inc., a South Korean company, pursuant to the Hague Convention or any similar method during this stay.

6. The parties jointly request that the Court set a status conference on June 16, 2026, or on a date and time convenient for the Court in mid-to-late June, 2026.

Dated: October 14, 2025

Respectfully submitted,

/s/ *Liza M. Walsh* Liza M. Walsh Katelyn O'Reilly Lauren R. Malakoff WALSH PIZZI O'REILLY FALANGA LLP Three Gateway Center 100 Mulberry Street, 15th Floor Newark, New Jersey 07102 (973) 757-1100 lwalsh@walsh.law koreilly@walsh.law lmalakoff@walsh.law	/s/ *Charles H. Chevalier* Charles H. Chevalier Michael V. Caracappa GIBBONS P.C. One Gateway Center Newark, New Jersey 07102-5310 (973) 596-4611 cchevalier@gibbonslaw.com mcaracappa@gibbonslaw.com
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PURSUANT TO THE ABOVE STIPULATION
IT IS on this _____ day of October, 2025
SO ORDERED.

A status conference shall be held on June _____ 2026, at _____.

_____
Honorable Jose R. Almonte, U.S.M.J.