



Charles H. Chevalier
PARTNER
P: +1973.596.4611
CCHEVALIER@FTBGIBBONS.COM

June 9, 2026

Via ECF

Honorable José R. Almonte, U.S.M.J.
United States District Court
District of New Jersey
Martin Luther King Building and U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07107

Re: *Halozyne, Inc. v. Merck Sharp & Dohme Corp.*, Civil Action No. 2:25-3179 (ES) (JRA)

Dear Judge Almonte:

Per Your Honor's January 22, 2026 Order (Dkt. No. 53), the parties write jointly to provide an update on the status of the matter following proceedings at the Patent Trial and Appeal Board (the "PTAB") challenging the validity of the patents asserted, or that will be asserted, in this case. As background, Halozyne alleges that Merck's manufacture, use, sale, offers to sell, and/or importation of KEYTRUDA QLEX 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.").

Merck has filed post-grant review ("PGR") petitions challenging twelve of the fifteen Asserted Patents, all of which have been instituted. Since the parties' last update, Merck has also filed inter partes review ("IPR") petitions challenging the remaining three Asserted Patents.

Merck has also challenged three other patents in the same patent family that are currently unasserted in this action, namely U.S. Patent Nos. 12,123,035, 12,060,590, and 12,371,685. The PTAB instituted PGRs for the '035 and '590 patents. With respect to U.S. Patent No. 12,371,685, Halozyne requested that the Director discretionarily deny Merck's PGR on the grounds that by omitting Merck & Co., Inc. ("MCI") from the petition, Merck did not name all real parties-in-interest ("RPI"), and the Director denied institution "after review of discretionary and non-merits consideration." Halozyne moved to terminate each PGR based on Merck's failure to name MCI as an RPI.

In May 2026, the PTAB issued final written decisions ("FWD") on the first two PGR proceedings, finding all challenged claims of U.S. Patent Nos. 11,952,600 and 12,152,262

One Gateway Center, Newark, New Jersey 07102 +1 973.596.4500
FBT Gibbons LLP | fbtgibbons.com

Petitioner Merck, Ex. 1246, p. 1
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unpatentable, and denied all of Halozyne's motions to terminate. Yesterday, the PTAB issued the third FWD, finding all challenged claims of U.S. Patent No. 12,018,298 unpatentable. Halozyne has requested Director Review of the Board's denial of the motions to terminate. Those requests remain pending.

The parties expect that FWDs on the next nine PTAB proceedings concerning the Asserted Patents will issue between July 11, 2026 and November 19, 2026.

For the three IPR proceedings on the Asserted Patents, Halozyne has requested that the Director discretionarily deny institution, including on grounds that Merck did not name MCI as an RPI. The parties expect the Director to issue institution decisions by September 29, 2026.

In addition, Halozyne is planning to move for leave to amend the complaint to add recently issued related patents, including U.S. Patent No. 12,371,685, for which institution was denied, and to name MCI as a co-defendant. Halozyne will provide Merck with a redline of any proposed amended complaint before seeking leave to amend. Halozyne further intends to move for leave to serve updated Hague Convention requests shortly. The parties have not yet met and conferred on these issues.

Accordingly, given the status of the PTAB proceedings, the parties respectfully submit that the Court should maintain the status quo, and the parties submit a further status update by September 15, 2026 or within one week after the Director issues a first decision on Halozyne's requests for Director Review of the Board's RPI determinations, whichever comes sooner.

Respectfully submitted,

s/ Charles H. Chevalier

Charles H. Chevalier

cc: All counsel of record (via ECF and email)

SO ORDERED.

A handwritten signature in black ink, appearing to read "José R. Almonte", is written over a horizontal line.

Hon. José R. Almonte, U.S.M.J.

Date: June 10, 2026