

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

MERCK SHARP & DOHME LLC,
Petitioner,

v.

HALOZYME, INC.,
Patent Owner.

PGR2025-00017
Patent 12,110,520 B2

Before COKE MORGAN STEWART, *Acting Under Secretary of
Commerce for Intellectual Property and Acting Director of the United States
Patent and Trademark Office.*

DECISION
Referring the Petition to the Board

Halozyme, Inc. (“Patent Owner”) filed a request for discretionary denial (Paper 17, “DD Req.”) in the above-captioned cases, and Merck Sharp & Dohme LLC (“Petitioner”) filed an opposition (Paper 20, “DD Opp.”).

After considering the parties’ arguments and the record, and in view of all relevant considerations, discretionary denial of institution is not appropriate in this proceeding. This determination is based on the totality of the evidence and arguments the parties have presented.

In particular, the projected final written decision due date is September 11, 2026. DD Opp. 23–24. The district court has not yet scheduled a trial date, and the time-to-trial statistics suggest trial would not begin until May 2030. *Id.* As such, it is likely that a final written decision in this proceeding will issue nearly four years before the district court trial occurs. Furthermore, the challenged patent issued on October 8, 2024, and Petitioner filed its Petition on January 17, 2025. Accordingly, Petitioner challenges the patent early in the life of the patent. Early challenges favor robust, predictable patent rights and weigh against discretionary denial. Additionally, Petitioner provides persuasive reasoning, supported by evidence, that discretionary denial under 35 U.S.C. § 325(d) is not appropriate. *See id.* at 11–23. These factors weigh against discretionary denial.

Although certain arguments are highlighted above, the determination not to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petition is referred to the Board to handle the case in the normal course, including by

PGR2025-00017
Patent 12,110,520 B2

issuing a decision on institution addressing the merits and other non-discretionary considerations, as appropriate.

In consideration of the foregoing, it is:

ORDERED that Patent Owner's request for discretionary denial is *denied*;

FURTHER ORDERED that the Petition is referred to the Board; and

FURTHER ORDERED that neither party shall file a request for rehearing or Director Review of this decision until the Board issues a decision on institution.

PGR2025-00017
Patent 12,110,520 B2

FOR PETITIONER:

Jeffrey Kushan
SIDLEY AUSTIN LLP
jkushan@sidley.com

Mark Stewart
MERCK SHARP & DOHME LLC
Mark.stewart@merck.com

FOR PATENT OWNER:

Eldora Ellison
R. Wilson Powers III
Jennifer Meyer Chagnon
David H. Holman
Tyler C. Liu
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
Eellison-ptab@sternekessler.com
Tpowers-ptab@sternekessler.com
Jchagnon-ptab@sternekessler.com
Dholman-ptab@sternekessler.com
Tliu-ptab@sternekessler.com

David J. Kappos
CRAVATH, SWAINE & MOORE
dkappos@cravath.com

Aubrey Haddach
HALOZYME, INC.
ahaddach@halozyme.com