Paper 14 Date: June 25, 2025

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

CELLTRION, INC., Petitioner,

v.

REGENERON PHARMACEUTICALS, INC., Patent Owner.

IPR2025-00456 Patent 11,084,865 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

Granting Patent Owner's Request for Discretionary Denial and Denying Institution of *Inter Partes* Review

Regeneron Pharmaceutics, Inc. ("Patent Owner") filed a request for discretionary denial (Paper 7, "DD Req.") in the above-captioned case, and Celltrion, Inc. ("Petitioner") filed an opposition (Paper 9, "DD Opp."). With authorization, Patent Owner filed a Reply (Paper 10, "DD Reply"), and Petitioner filed a Sur-reply (Paper 12, "DD Sur-reply").

After considering the parties' arguments and the record, and in view of all relevant considerations, discretionary denial of institution is appropriate in this proceeding. This determination is based on the totality of the evidence and arguments the parties have presented.

In particular, other forums—the Northern District of West Virginia and the U. S. Court of Appeals for the Federal Circuit—have already adjudicated the validity of the challenged patent claims. DD Req. 2–4. Additionally, there is a parallel proceeding involving the parties and the challenged patent in district court, and there has been substantial investment by the parties and the court in that proceeding. *Id.* For example, briefing and discovery relating to a preliminary injunction motion has already resulted in the district court issuing an order granting a preliminary injunction. DD Req. 2–4; DD Opp. 14. These circumstances favor discretionary denial.

Although certain arguments are highlighted above, the determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petition is denied under 35 U.S.C. § 314(a).

In consideration of the foregoing, it is:

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

FURTHER ORDERED that the Petition is *denied*.

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