

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: DENOSUMAB PATENT
LITIGATION

This Document Relates To:

Amgen Inc. and Amgen Manufacturing Limited LLC v. Shanghai Henlius Biotech, Inc., Shanghai Henlius Biologics Co., Ltd., Organon LLC, and Organon & Co., Civil Action No. 1:25-cv-12160 (CPO)(EAP)

Civil Action No. 1:25-md-03138 (CPO)
(EAP)

(MDL 3138)

CONSENT ORDER AND JUDGMENT

WHEREAS Amgen Inc. and Amgen Manufacturing Limited (collectively, “Amgen” or “Plaintiffs”), and Shanghai Henlius Biotech, Inc. and Shanghai Henlius Biologics Co., Ltd. (collectively, “Henlius”) and Organon LLC and Organon & Co. (collectively with Henlius, “Defendants”) were involved in litigation in the United States District Court for the District of New Jersey, MDL Case No. 1:25-md-03138-CPO-EAP, associated with Civil Action No. 1:25-cv-012160-CPO-EAP (the “Henlius Denosumab Litigation”) involving Amgen’s United States patents covering its denosumab antibody, pharmaceutical compositions containing denosumab, and methods of manufacture, stemming from Henlius’s filing of a BLA seeking FDA approval of BILDYOS[®] (denosumab-nxxp) and BILPREVDA[®] (denosumab-nxxp) (“Henlius Biosimilar Products”);

WHEREAS Amgen and Defendants reached an amicable resolution of the Henlius Denosumab Litigation;

WHEREAS, the parties agreed that the Court would enter judgment;

WHEREAS, the findings set forth below are made solely to effectuate the parties' resolution of this matter, and shall not constitute an admission by Defendants other than for purposes of resolving this action, enforcement of this Consent Order and Judgment, and any disputes arising under the parties' resolution; and

WHEREAS the parties have waived the entry of findings of fact and conclusions of law under Rule 65 of the Federal Rules of Civil Procedure;

THEREFORE based on the parties' stipulation and consent, it is ORDERED, ADJUDGED, and DECREED as follows:

1. The Court has jurisdiction over the subject matter of the above-captioned case pursuant to 28 U.S.C. §§ 1331 and 1338(a).

2. The Court has personal jurisdiction over the parties, and venue is proper as to all parties pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400 (b).

3. The Court retains jurisdiction to enforce or supervise performance under this Consent Order and Judgment.

4. As to the Henlius Biosimilar Products, the asserted claims of United States Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,053,236; 8,217,153; 8,460,896; 8,680,248; 9,228,168; 9,359,435; 10,106,829; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,894,972; 11,077,404; 11,098,079; 11,192,919; 11,254,963; 11,319,568; 11,434,514; 11,459,595; 11,492,372; 11,946,085; 11,952,605; and 12,084,686 ("Asserted Patents") are valid and enforceable and are infringed by making, using, selling, or offering to sell Henlius Biosimilar Products in the United States of America, its territories, possessions, protectorates and the Commonwealth of Puerto Rico ("Territory"), or by the import of Henlius Biosimilar Products into the Territory.

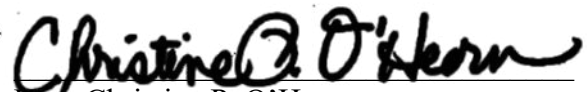
5. The parties' remaining claims and counterclaims in the above-captioned matter are dismissed with prejudice.

6. Judgment is entered with respect to the Asserted Patents, and this order fully resolves the remaining claims and counterclaims.

7. Each party shall bear its own costs.

IT IS SO ORDERED.

Dated: 3/31/2026


Hon. Christine P. O'Hearn
United States District Judge