

**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. Samsung Bioepis Co., Ltd.,  
and Samsung Biologics Co., Ltd.*, Civil  
Action No. 1:24-cv-08417 (CPO)(EAP)

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

(MDL 3138)

**CONSENT ORDER AND JUDGMENT**

WHEREAS Amgen Inc. and Amgen Manufacturing Limited (collectively, “Amgen” or “Plaintiffs”), and Samsung Bioepis Co., Ltd. and Samsung Biologics Co., Ltd, (collectively, “Samsung” or “Defendants”) were involved in litigation in the United States District Court for the District of New Jersey, MDL Case No. 1:25-md-03138, associated with Civil Action No. 1:24-cv-08417-CPO-EAP (the “Samsung Denosumab Litigation”) involving Amgen’s patents covering its denosumab antibody, pharmaceutical compositions containing denosumab, and methods of manufacture, stemming from Samsung Bioepis’ filing of a BLA No. 761392 seeking FDA approval of certain denosumab-dssb biosimilar products, as well as other conduct therein alleged;

WHEREAS Amgen and Samsung settled the Samsung Denosumab Litigation, executing a Confidential Settlement Agreement on September 4, 2025 (the “Agreement”);

WHEREAS, as a part of the Agreement, the parties agreed that the Court would enter judgment;

WHEREAS the definitions and terms of the Agreement shall apply to any disputes between the parties regarding the enforcement of this order but are not restated here for reasons of convenience and confidentiality;

WHEREAS, the findings set forth below are made solely to effectuate the parties' settlement, shall not constitute an admission by Samsung other than for purposes of this action, enforcement of this Consent Order and Judgment, and any disputes arising under or related to the Confidential Settlement Agreement;

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. For the purposes of this action only, 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 and the parties' Agreement dated September 4, 2025.

4. Solely for purposes of this action, and subject to and pursuant to the terms of the Agreement and as to the Samsung Denosumab Biosimilar Products, the asserted claims of United States Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,058,418; 8,460,896; 8,680,248; 9,012,178; 9,320,816; 9,359,435; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,822,630; 11,098,079; 11,254,963; 11,292,829; 11,634,476; and 11,685,772 ("Asserted Patents") are deemed valid, enforceable and infringed by making, using, selling, or offering to sell Samsung Denosumab Biosimilar Products in the United States of America, its territories, possessions, protectorates and the Commonwealth of Puerto Rico ("Territory"), or by the import of Samsung Denosumab Biosimilar Products into the Territory.

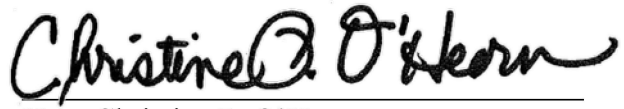
5. Subject to the terms of the Agreement, the parties' remaining claims and counterclaims in the above-captioned matter are dismissed with prejudice.

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: 9/5/25

A handwritten signature in black ink, reading "Christine P. O'Hearn". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

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