

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

IN RE: AFLIBERCEPT PATENT LITIGATION MDL No.: 1:24-md-3103-TSK

THIS DOCUMENT RELATES TO:

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:22-cv-61-TSK

MYLAN PHARMACEUTICALS, INC.
and BIOCON BIOLOGICS, INC.,

Defendants.

ORDER GRANTING MOTION FOR
TEMPORARY RESTRAINING ORDER [ECF NO. 70]

Pending before the Court is Plaintiff's Motion for Temporary Restraining Order [ECF No. 70]. Defendants filed a Response in Opposition to that motion [ECF Nos. 105] which the Court has considered.

After a nine-day bench trial, this Court held that Defendants Mylan Pharmaceuticals Inc., and Biocon Biologics Inc. (collectively, "Defendants") infringed claims 4, 7, 9, 11, and 14-17 of U.S. Patent No. 11,084,865 (the '865 Patent) and that Defendants did not demonstrate by clear and convincing evidence that claims 4, 7, 9, 11, and 14-17 of the '865 Patent are anticipated or obvious in light of the prior art or invalid under 35 U.S.C. § 112 for lack of written description, lack of

enablement, or indefiniteness, it is ordered, pursuant to Federal Rule of Civil Procedure 65, Plaintiff's Motion for Temporary Restraining Order is **GRANTED**.

Pursuant to Federal Rule of Civil Procedure 65(d)(1), the Court makes the following findings of fact and conclusions of law based upon the record developed in connection with Regeneron's pending motion.

1. Defendants sought FDA approval via their Biologics License Application No. 761274 to market a biosimilar version of Regeneron's drug EYLEA®. Defendants' product that is the subject of this BLA is also known as "YESAFILI."

2. After a nine-day bench trial, the Court determined that Defendants would infringe claims 4, 7, 9, 11, and 14-17 of the '865 Patent by making, using, selling, or offering for sale YESAFILI, or importing YESAFILI into the United States.

3. After the same nine-day bench trial, the Court determined that Defendants did not demonstrate by clear and convincing evidence that claims 4, 7, 9, 11, and 14-17 of the '865 Patent are anticipated or obvious in light of the prior art or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness.

4. Regeneron has clearly shown through specific facts in an affidavit that any manufacture, importation, or commercialization of YESAFILI prior to the expiry of the '865 Patent will cause it

immediate and irreparable injury, including to Regeneron's market share, pricing, goodwill with patients and clinicians, and/or research and development funding as a result of facing improper competition from an infringing product. Such injury would not be fully redressable by monetary damages.

5. Regeneron has demonstrated that the balance of hardships favors Regeneron, not Defendants.

6. Regeneron has demonstrated that the public interest favors granting the temporary restraining order to protect intellectual property rights and because the public is already able to receive aflibercept therapy in the form of EYELA®.

IT IS FURTHER ORDERED THAT:

Defendants, their officers, agents, servants, representatives and employees, and any and all persons or entities acting by, through, under, or in active concert with any or all of them, are hereby enjoined and restrained from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States without a license from Regeneron any product that is the subject of BLA No. 761274, including YESAFILI.

Defendants, their officers, agents, servants, representatives and employees, and any and all persons or entities acting by, through, under, or in active concert or participation with any or all of them shall be so enjoined until the expiration of this Order, which shall occur fourteen (14) days from the date of this

Order's entry unless, before that time, the Court for good cause extends the duration of the Order or Defendants consent.

Defendant shall provide copies of this order to their officers and any employee with responsibility for Defendants' development or commercialization of YESAFILI as soon as possible and no later than three (3) business days after the issuance of this order.

The Court will set an appropriate bond in a separate order which Plaintiff shall post within five (5) days of that order.

DATED: May 17, 2024



THOMAS S. KLEE H, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA