

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. 1:23-cv-94-TSK

SAMSUNG BIOEPIS, CO., LTD.,

Defendant.

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 1:23-cv-106-TSK

SAMSUNG BIOEPIS, CO., LTD.,

Defendant.

ORDER GRANTING MOTION FOR
TEMPORARY RESTRAINING ORDER [ECF NO. 72]

Pending before the Court is Plaintiff's Motion for Temporary Restraining Order [ECF No. 72]. Defendant filed a Response in Opposition to that motion [ECF Nos. 102, 103] which the Court has considered. 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. Defendant Samsung Bioepis Co., Ltd. ("Bioepis") has sought FDA approval via its Biologics License Application No. 761350 to market a biosimilar version of Regeneron's drug EYLEA®. Bioepis's product that is the subject of this BLA is also known as "SB15."

2. The SB15 formulation described in BLA No. 761350 purportedly infringes claims 4, 7, 9, 11,14-17, and 55 of U.S. Patent No 11,084,865 (the '865 Patent) as further set forth in the Declaration of Dr. Bernhardt Trout.

3. Bioepis has not yet demonstrated that there is a substantial question about the validity of the infringed claims of the '865 Patent.

4. Regeneron has clearly shown through specific facts in an affidavit that any manufacture, importation, or commercialization of SB15 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 Bioepis.

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®.

7. Regeneron has demonstrated that there is a reasonable probability of ultimate success upon the question of personal jurisdiction when the action against Bioepis is tried on the merits.

IT IS FURTHER ORDERED THAT:

Defendant Bioepis, its 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, specifically including Bioepis's U.S. distributor Biogen MA Inc., 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. 761350, including SB15.


Defendant, its 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, specifically including Bioepis's U.S. distributor Biogen MA Inc., 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 Defendant consents.

Defendant shall provide copies of this order to its officers, Biogen MA Inc., and any employee with responsibility for Bioepis's development or commercialization of SB15 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. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA