

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

IN RE: AFLIBERCEPT PATENT LITIGATION

MDL No.: 1:24-md-3103-TSK

**THIS DOCUMENT RELATES TO  
CASE NO. 1:22-cv-00061-TSK**

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**REGENERON’S MOTION FOR EXTENSION OF TEMPORARY RESTRAINING  
ORDER**

Pursuant to Federal Rule of Civil Procedure 65(b)(2), Regeneron Pharmaceuticals, Inc. (“Regeneron”) moves the Court to extend its Temporary Restraining Order, issued on May 17, 2024, Case No. 1:22-cv-61-TSK Dkt. No. 776, for an additional fourteen days beyond its original expiration on May 31, 2024, for good cause shown, particularly in view of the lengthy submissions submitted by the parties on May 24. Fed. R. Civ. P. 65(b)(2); *Granny Goose Foods, Inc. v. Brotherhood of Teamsters*, 415 U.S. 423, 440 n.15 (1974).

As detailed in Regeneron’s Brief in Support of its Motion for a Temporary Restraining Order, Dkt. No. 771-1, Regeneron has filed for permanent injunctive relief in this case against the launch of Defendants’ infringing biosimilar product. Given the pendency of that motion, the Court previously granted Regeneron’s Motion for a Temporary Restraining Order, temporarily restraining Defendants’ launch until the end of the month. Dkt. No. 776 at 3. *See also, e.g., ClearOne Advantage, LLC v. Kersen*, -- F. Supp. 3d --, 2024 WL 69918, at \*2 (D. Md. Jan. 5, 2024) (“The purpose of a TRO is to ‘preserve the status quo only until a[n] injunction hearing can be held.’” (quoting *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 422 (4th Cir. 1999))).

At the Court’s direction, *see* Dkt. No. 780, Regeneron has since submitted a proposed order to accompany its permanent injunction motion. Cognizant of the length of that submission—and that of Defendants’ simultaneous submission, and those filed in the other cases in this multi-district litigation—Regeneron seeks to extend the TRO an additional fourteen days, in the event that it is not feasible for the Court to adjudicate the permanent injunction motion before May 31, 2024.

There is “good cause” to extend such an order under Federal Rule of Civil Procedure 65(b)(2) where “the grounds for originally granting the temporary restraining order continue to exist.” 11A WRIGHT & MILLER, FED. PRACT. & PROC. § 2953 (3d ed.). The grounds for Regeneron’s original Motion still exist: Defendants—which have now received FDA approval for their biosimilar<sup>1</sup>—may choose to launch their infringing product before the Court is able to adjudicate Regeneron’s permanent injunction motion, which would cause Regeneron irreparable harm. Just as courts commonly issue a temporary restraining order to preserve the status quo pending the adjudication of lasting injunctive relief, so too do they find good cause to extend such an order if the injunction motion cannot be decided within fourteen days. *See, e.g., Costa v. Bazron*, 2020 WL 2410502, at \*2 (D.D.C. May 11, 2020) (“[C]ourts have . . . found ‘good cause’ where more time is needed fully to consider the parties’ arguments and motions[.]”); *Versaterm Inc. v. City of Seattle*, 2016 WL 4399634, at \*1 (W.D. Wash. Aug. 18, 2016) (extending a TRO “until such time as the court resolves [plaintiff]’s pending motion for a preliminary injunction”).

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<sup>1</sup> *See FDA Approves First Interchangeable Biosimilars to Eylea to Treat Macular Degeneration and Other Eye Conditions*, U.S. Food & Drug Admin. (May 20, 2024), <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye>.

Regeneron therefore incorporates by reference the arguments made in its Brief in Support of its Motion for a Temporary Restraining Order, Dkt. No. 771-1, in support of this Motion.

Date: May 29, 2024

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 29, 2024, I electronically transmitted the foregoing to the Court. Counsel of record for all parties will be served by electronic mail.

*/s/ Steven R. Ruby* \_\_\_\_\_  
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**ORDER EXTENDING TEMPORARY RESTRAINING ORDER**

On May 17, 2024, the Court granted Plaintiff’s Motion for Temporary Restraining Order, which Order will expire on May 31, 2024, “unless, before that time, the Court for good cause extends the duration of the Order or Defendants consent.” Dkt. No. 776 at 4.

Pursuant to Rule 65(b)(2) of the Federal Rules of Civil Procedure, this Court may extend a temporary restraining order (“TRO”) for up to 14 additional days from the date of its expiration, upon a finding of good cause. Fed. R. Civ. P. 65(b)(2); *Granny Goose Foods, Inc. v. Brotherhood of Teamsters*, 415 U.S. 423, 440 n.15 (1974).

“The purpose of a TRO is to ‘preserve the status quo only until a[n] injunction hearing can be held.’” *ClearOne Advantage, LLC v. Kersen*, -- F. Supp. 3d --, 2024 WL 69918, at \*2 (D. Md. Jan. 5, 2024) (quoting *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 422 (4th Cir. 1999)). As such, good cause to extend the TRO exists where additional time is needed for the adjudication of lasting injunctive relief, such as a permanent injunction motion. *See, e.g., Costa v. Bazron*, 2020 WL 2410502, at \*2 (D.D.C. May 11, 2020) (“[C]ourts have . . . found ‘good cause’ where more time is needed fully to consider the parties’ arguments and motions[.]”); *Versaterm Inc. v. City of Seattle*, 2016 WL 4399634, at \*1 (W.D. Wash. Aug. 18,

2016) (extending a TRO “until such time as the court resolves [plaintiff]’s pending motion for a preliminary injunction”).

The Court makes the following findings of fact and conclusions of law:

1. On May 17, 2024, the Court issued a Temporary Restraining Order enjoining Defendants 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. Dkt. No. 776 at 3.
2. The Temporary Restraining Order will expire on May 31, 2024 if not extended. Dkt. No. 776 at 3-4.
3. Plaintiff’s Motion for a Permanent Injunction has been fully briefed and is pending before the Court. Dkt. Nos. 708-3; 722-1; 747-2.
4. Under the circumstances, there is good cause to extend the Temporary Restraining Order for an additional fourteen days. The myriad issues presented by the permanent injunction motion, coupled with the Court’s schedule, may prevent its adjudication before the expiration of the Temporary Restraining Order by the end of the month.
5. For the reasons detailed in the Court’s initial grant of the Temporary Restraining Order, (1) Plaintiff has previously succeeded on the merits of its infringement claims; (2) Plaintiff is likely to suffer irreparable harm if Defendants were to launch their product in the absence of temporary injunctive relief, only to be later permanently enjoined; (3) the balance of hardships imposed by the temporary restraining order favors Plaintiff, not Defendants; and (4) the public interest favors temporarily restraining Defendants until the permanent injunction motion is decided. Dkt. No. 776 at 2-3. The Court therefore finds good cause to extend the Temporary



Restraining Order, so that the status quo is preserved until the adjudication of the permanent injunction motion.

It is therefore **ORDERED THAT:**

Pursuant to Federal Rule of Civil Procedure 65(b)(2), for good cause, the Temporary Restraining Order, Dkt. No. 776, is extended for fourteen days beyond its original expiration. Defendants and others encompassed by the Temporary Restraining Order shall continue to be temporarily restrained and enjoined according to the terms of the Temporary Restraining Order, Dkt. No. 776.

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Hon. Thomas S. Kleeh, Chief Judge