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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. CELLTRION, INC., Defendant.	Civil Action No. 1:23-cv-89-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. SAMSUNG BIOEPIS, CO., LTD., Defendant.	Civil Action No. 1:23-cv-94-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. SAMSUNG BIOEPIS, CO., LTD., Defendant.	Civil Action No. 1:23-cv-106-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. FORMYCON AG,	Civil Action No. 1:23-cv-97-TSK

Defendant.

PLAINTIFF REGENERON PHARMACEUTICALS, INC.'S EMERGENCY MOTION FOR ENTRY OF A SCHEDULE FOR PRELIMINARY INJUNCTION PROCEEDINGS OR IN THE ALTERNATIVE AN EMERGENCY STATUS CONFERENCE

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") respectfully requests that the Court enter the attached schedule to ensure the orderly conduct of impending preliminary injunction proceedings in the above-captioned matters, precipitated by the impending expiration of regulatory exclusivity protecting Eylea on May 17, 2024. The facts necessitating this emergency motion and entry of the schedule attached hereto are set forth below. Should the Court prefer not to enter the requested schedule at this time, Regeneron respectfully requests an emergency status conference after the New Year holiday to discuss the impending preliminary injunction proceedings.

I. BACKGROUND

Regeneron markets the vision-saving product Eylea®, a medication injected into a patient's eyeball in order to treat angiogenic eye disorders like age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. Each of Defendants Samsung Bioepis Co., Ltd. ("Samsung"), Celltrion, Inc. ("Celltrion"), and Formycon AG ("Formycon") (collectively, "Defendants") has filed an application with FDA seeking to market a biosimilar copy of Eylea® pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"). In each of the above-captioned matters, Regeneron alleges that the respective Defendant would infringe Regeneron patents by engaging in the commercial manufacture or sale of its proposed biosimilar product before the relevant patents expire.

Non-patent, statutory protections currently prohibit any Defendant from obtaining FDA approval or launching its product, as explained further below. Those protections will begin to expire on May 17, 2024. Regeneron therefore intends to seek a preliminary injunction ("PI") prohibiting each of Defendants from marketing its biosimilar copy of Eylea® until this Court has decided issues of patent infringement and validity.

Regeneron accordingly reached out to each of Defendants to discuss potential PI

schedules, in some cases even before complaints were filed.[1] In particular, Regeneron sent each Defendant a proposed PI schedule designed to ensure orderly submissions culminating in a hearing sufficiently before May 17, 2024. No Defendant responded to suggest PI proceedings would be unnecessary. Instead, Regeneron engaged productively over the course of multiple calls and emails with Celltrion and Formycon, in an effort to arrive at a mutually agreeable schedule in this Court. Regeneron made every effort to engage equally with Samsung, but was repeatedly rebuffed.

Negotiations continued until mid-December, when Defendants asked that Regeneron convene a call with Defendants collectively, so that the parties could discuss scheduling concerns en masse. That call appeared to be a productive one. Defendants, however, now have announced—in concert by a single email—that they will each seek to flee the Northern District of West Virginia by filing spurious motions to dismiss for lack of personal jurisdiction. Indeed, counsel for each Defendant, with whom Regeneron had been communicating for months about this very litigation both before and after complaints were filed, announced they would not even accept service of the Complaints on behalf of their foreign clients. *See* D.I. 43 (*Celltrion*, 23-cv-89); D.I. 31 (*Formycon*, 23-cv-97); D.I. 38 (*Samsung*, 23-cv-94).

To be clear: this Court does not lack personal jurisdiction over any Defendant. Each Defendant has submitted an FDA application seeking approval to market its biosimilar product nationwide, an act that confers personal jurisdiction in all fifty states. *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc.*, 817 F.3d 755 (Fed. Cir. 2018). Defendants plan is nothing more than a transparent effort to escape this Court, and in particular, to escape this Court's knowledge of many of the asserted patents obtained during Regeneron's co-pending litigation against Mylan

[1] Regeneron's ability to file a complaint is limited by the BPCIA, as described below.

and Biocon. No Defendant has yet filed a motion to dismiss; presumably, Defendants were awaiting this Court's decision in the Mylan and Biocon case. In view of the Court's decision that Mylan/Biocon infringed Regeneron's U.S. Patent No. 11,084,865 (the "'865 patent") and that the '865 patent is not invalid, D.I. 665 (1:22-cv-00061-TSK), Regeneron expects those motions to be forthcoming.

The BPCIA—that is, the same act that allowed Defendants to submit applications to market a biosimilar product—expressly guarantees 180 days for PI proceedings before a biosimilar applicant may launch its product, and demands cooperation regarding expedited discovery. 42 U.S.C. § 262(*l*)(8)(C). Defendants' manufactured procedural roadblocks reflect a desperate attempt to dodge their obligations and run out the clock. Accordingly, Regeneron respectfully requests this Court convene a status conference after the New Year holiday to discuss a PI schedule, including document discovery, that can proceed while Defendants' motions to dismiss are litigated. In the absence of prompt discovery, adjudicating a PI before the expiration of regulatory exclusivity will become impossible.

II. STATUTORY AND REGULATORY BACKGROUND

Regeneron's Eylea® is an innovative biologic drug, and the ability of other pharmaceutical companies to market "biosimilar" copies of Eylea® is governed by the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21. The BPCIA created an abbreviated process by which follow-on drug manufacturers can seek to market copies of innovative drugs that have already been approved by FDA. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 7 (2017) (citing 42 U.S.C. § 262(k)). Instead of proving that its drug is "safe, pure, and potent"—like Regeneron had to do in order to obtain approval for Eylea®—a company seeking to market a biosimilar copy of an existing drug can "piggyback" on the innovator's data, and need only prove that there are no "'clinically

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