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

meaningful differences' between the [biosimilar drug and innovator drug] in terms of 'safety, purity, and potency.'" *Id.* Thus, the BPCIA allows biosimilar manufacturers to take a cheaper and faster route to regulatory approval. On the other side of the scale, Congress granted innovator companies a period of exclusivity before biosimilar drugs could be marketed. FDA may not approve an application for a biosimilar product until 12 years after the innovator product was first approved. *Id.* (citing 42 U.S.C. §§ 262(k)(7)(A), (B)).

Of course, an innovator company "may hold multiple patents covering the biologic, its therapeutic uses, and the processes used to manufacture it. Those patents may constrain an applicant's ability to market its biosimilar even after the expiration of the 12–year exclusivity period contained in § 262(k)(7)(A)." *Id.* The BPCIA is designed to "facilitate[] litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Id.* To that end, the BPCIA prescribes a series of iterative disclosures from both the biosimilar applicant and the innovator company. *Id.* at 8-11. These exchanges have come to be known colloquially as the "Patent Dance."

One requirement of the Patent Dance is that "[t]he [biosimilar] applicant shall provide notice to the [innovator company] not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). The "Notice of commercial marketing" or "NCM" plays an important role in structuring biosimilar patent litigation. Once a biosimilar applicant enters the Patent Dance, the BPCIA limits the ability of the innovator company to sue before certain steps of the dance are complete. 42 U.S.C. § 262(*l*)(9). Those limitations are lifted when the biosimilar applicant serves its NCM. *Id.* §§ 262(*l*)(8),(9). In fact, the BPCIA expressly contemplates that service of an NCM may necessitate PI proceedings, because—depending on any remaining regulatory exclusivity for the

innovator and status of FDA review for the biosimilar applicant—the parties may have only 180 days left to adjudicate patent issues before the biosimilar applicant is entitled to launch. *Id.* § 262(*l*)(8)(B),(C). In view of that exigency, the BPCIA mandates that "[i]f the [innovator] has sought a preliminary injunction under subparagraph (B), the [innovator] and the [biosimilar] applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion." *Id.* § 262(*l*)(8)(C).

III. PROCEDURAL POSTURE

This Court is no stranger to Eylea®. In June 2023, this Court held trial in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.*, Case No. 1:22-cv-00061-TSK. That case arose from Mylan's application under the BPCIA to market a biosimilar copy of Eylea® before the expiration of several Regeneron patents. Regeneron and Mylan completed the full Patent Dance exchanges, Regeneron sued Mylan as contemplated in § 262(*l*)(6), and the parties proceeded quickly to a trial on the merits. On December 28, 2023, this Court issued a judgment finding that Mylan/Biocon's biosimilar aflibercept product would infringe Regeneron's '865 patent, and that the '865 patent is not invalid. D.I. 665 (1:22-cv-00061-TSK).

The above-captioned matters will involve the same '865 patent, but the timing is different. Like Mylan/Biocon, Defendants each have filed their own applications with FDA, seeking to market their own biosimilar copies of Eylea®. Like Mylan/Biocon, each Defendant will infringe the '865 patent if and when they market their biosimilar product. But *unlike* Mylan/Biocon, Defendants in the above-captioned matters filed their biosimilar applications with FDA late enough to ensure that there would not be enough time to go to trial before Regeneron's regulatory exclusivity expires.

Defendant Celltrion served its NCM during the Patent Dance. Receipt of Celltrion's

NCM allowed Regeneron to file a complaint against Celltrion without waiting for the rest of the Patent Dance to take place. Regeneron subsequently filed complaints against Samsung and Formycon as well. In view of the limited time before its regulatory exclusivity expires, Regeneron promptly filed the above-captioned cases in this Court and reached out to Defendants to discuss schedules for PI hearings, as described above.

IV. PROMPT ENTRY OF A SCHEDULE IS NECESSARY TO PERMIT RESOLUTION OF A PRELIMINARY INJUNCTION BEFORE EXPIRY OF REGULATORY EXCLUSIVITY

Regeneron has been in contact with each of Defendants regarding the need for a PI schedule for more than six weeks. As described above, Defendants do not disagree that PI proceedings should take place. Defendants just do not want to hold those proceedings in West Virginia. No Defendant has yet filed the promised motion to dismiss, likely in hopes this Court's decision in the Mylan/Biocon case would give them cause to reconsider. That is not what happened. This Court's decision upholding the '865 patent will have strengthened Defendants' desire to flee the Mountain State. *Nothing* has strengthened their legal basis to do so—Defendants' jurisdictional arguments remain as weak as ever. *Acorda, Inc.*, 817 F.3d 755. Unchecked, Defendants' procedural gamesmanship will consume Regeneron's BPCIA-guaranteed 180 days to seek a PI.

Regeneron's goal is simple: ensure an orderly process that will result in resolution of its forthcoming motion for PI before May 17, 2024. In order to achieve that goal, Regeneron needs to obtain modest but expedited discovery from each of Defendants. The BPCIA expressly requires "reasonab[e] cooperat[ion] to expedite such further discovery as is needed in connection with the preliminary injunction motion." 42 U.S.C. § 262(*l*)(8)(C). To that end, and as the attached schedule reflects, Regeneron has already served a short list of targeted requests for production on Defendants and has offered to produce a large tranche of Regeneron's documents

as soon as counsel confirm they will be maintained on an outside-counsel only basis pending entry of a protective order. Prompt access to the requested documents from Defendants will permit Regeneron to file a motion on a timeline that makes resolution before May 17, 2024 attainable. The remaining entries in Regeneron's proposed schedule reflect a straightforward effort to work backwards from the date by which a decision is needed and sensibly allocate the available time to Regeneron's motion, Defendants' opposition, and Regeneron's reply, along with accompanying declarations and depositions of those declarants.

V. CONCLUSION

Regeneron remains willing to work cooperatively with Defendants throughout the coming months, but the short time between now and May 2024 does not permit further delay. Regeneron therefore respectfully requests this Court enter the schedule attached hereto in the above-captioned matters, or in the alternative convene a status conference on an expedited basis following the New Year holiday.

Date: December 28, 2023

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on the 28th day of December 2023, service of the foregoing "PLAINTIFF REGENERON PHARMACEUTICALS, INC.'S EMERGENCY MOTION FOR ENTRY OF A SCHEDULE FOR PRELIMINARY INJUNCTION PROCEEDINGS OR IN THE ALTERNATIVE AN EMERGENCY STATUS CONFERENCE" was made by U.S. Mail to the following counsel:

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