

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

Case No. 1:23-cv-00089-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS CO., LTD.,

Defendant.

Case No. 1:23-cv-00094-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

FORMYCON AG,

Defendant.

Case No. 1:23-cv-00097-TSK

JURY TRIAL DEMANDED

PLAINTIFF'S MOTION FOR ALTERNATIVE SERVICE

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") hereby moves pursuant to Federal Rules of Procedures 4(h)(2) and 4(f)(3) for authorization to serve defendants Celltrion, Inc., LTD., Samsung Bioepis Co., Ltd., and Formycon AG via electronic mail to each

defendant's respective United States counsel. The grounds for relief are fully set forth in the accompanying briefing and supporting papers submitted herewith.

Dated: December 22, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on the 22nd day of December 2023, service of the foregoing “Plaintiff’s Memorandum in Support of its Motion for Alternative Service” was made by U.S. Mail to the following counsel:

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NATURE AND STATE OF PROCEEDINGS

On November 8, 2023 Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) filed an action against Celltrion, Inc. (“Celltrion”), a Korean company, under the Biologics Price Competition and Innovation Act (“BPCIA”), 42 U.S.C. § 262(k)-(l). Regeneron then filed suit against Samsung Bioepis, Co., Ltd. (“Bioepis”), a Korean company, on November 21, and against Formycon AG (“Formycon”), a German company, on November 29, also under the BPCIA. Regeneron filed its suit against Celltrion in response to its provision of a notice of commercial marketing by and through its counsel, pursuant to the BPCIA, notifying Regeneron that it may commercialize its proposed biosimilar product in no less than 180 days. The statute envisages that such notice may—as here—trigger a lawsuit and an ensuing motion for preliminary injunction to prevent commercialization of the biosimilar product, for which the parties must “reasonably cooperate” and conduct “expedite[d] . . . discovery.” 42 U.S.C. § 262(l)(8)(C).

Celltrion, Bioepis, and Formycon (collectively “Defendants”) had other plans. Rather than permit this Court to adjudicate the patent infringement on the merits, Defendants are erecting a series of wasteful and baseless procedural roadblocks in an effort to consume the limited 180-day time period that the statute allocates to preliminary injunction proceedings. Each of the Defendants has submitted a U.S. Food & Drug Administration (“FDA”) application seeking approval to market its biosimilar product nationwide—the very act that, the Federal Circuit has confirmed, confers personal jurisdiction in all fifty states. *See Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755 (Fed. Cir. 2016). Nevertheless, in a desperate effort to avoid this Court—in particular its knowledge of the asserted patents obtained during the course of Regeneron’s co-pending litigation against Mylan and Biocon—Defendants’ counsel indicated their intent to contest personal jurisdiction. But the procedural gambits have not stopped there.

After the filing of each complaint, Regeneron promptly provided via email a copy of the complaint to each Defendant's U.S. counsel—Gemini Law LLP (“Gemini”) for Celltrion,¹ Quinn Emanuel Urquhart & Sullivan, LLP (“Quinn Emanuel”) for Bioepis, and Jenner & Block LLP (“Jenner & Block”) for Formycon. Regeneron asked each counsel to accept service of its complaint on behalf of their client. Defendants' counsel were not strangers to these cases; each had repeatedly (and recently) conferred with Regeneron's counsel and served papers frequently on their respective Defendant's behalf.

Remarkably, each U.S. counsel has declined to accept service, often after weeks of silence. Bioepis's counsel Quinn Emanuel, for example, failed to respond to the simple request to accept service by email for more than two weeks before declining. Quinn Emanuel's stated basis for forgoing this formality—and it is just that, a formality, given that Bioepis and its counsel long had notice of the dispute—was that accepting service may waive Bioepis's ability to challenge personal jurisdiction. But Bioepis knows that position is baseless, because it previously agreed to a stipulation accepting service while preserving its defenses as to jurisdiction and venue in a prior BPCIA case. *See Genentech, Inc. v. Samsung Bioepis Co. Ltd.*, Case 1:20-cv-00859-CFC-JLH, Dkt. 5 (D. Del. July 6, 2020).

Nevertheless, in an attempt to avoid this motion, Regeneron agreed to meet and confer with Bioepis on December 13, 2023. But Bioepis's counsel remained unwilling to accept service. On December 15, Regeneron provided caselaw to confirm that Bioepis's concerns were unwarranted and proposed a stipulation nearly identical to the one Bioepis previously accepted in the *Genentech* matter.

¹ Celltrion is also represented by Wilkie Farr & Gallagher LLP, but Gemini has been responsible for all relevant communication with Regeneron.

Celltrion’s U.S. counsel, Gemini, proceeded in even more egregious fashion. After negotiating for weeks on a proposed preliminary injunction schedule and *agreeing to accept service* if Regeneron would extend the date for Celltrion to respond to the complaint (which Regeneron offered to do), *see* Ex. A (Nov. 13, 2023 Email from A. Zalcenstein to P. Patel), Celltrion stopped engaging in those discussions. When Celltrion’s counsel finally responded to Regeneron’s latest draft of the proposed schedule—weeks later—it became clear that Gemini had determined it would stand shoulder to shoulder with the other Defendants in refusing to accept service, thereby obstructing this litigation. Celltrion ultimately reneged on its month-old commitment to accept service in a December 21 email in which it permitted Formycon’s counsel to speak on its behalf.

Formycon’s U.S. counsel, Jenner & Block, ignored Regeneron’s request to accept service for weeks. After finally stating that they were “working through [the service] issue with our client,” Ex. B (Dec. 12, 2023 Email from S. Van Horn to A. Trask), Formycon continued to negotiate a potential preliminary injunction schedule, making no further mention of concerns about service. Indeed, during a meet and confer between Regeneron and all Defendants on December 19, Formycon’s counsel suggested it was still awaiting approval from its client on whether to accept service. Two days later, Formycon’s counsel, writing on behalf of all the Defendants, also refused.

Defendants’ deliberate, and now coordinated, delay tactics have already hindered progress in these litigations. Given the urgency of the 180-day time period set by statute to adjudicate the preliminary injunction, Regeneron thus moves for entry of an order authorizing alternative service on each of the Defendants. *See* Fed. R. Civ. P. 4(h)(2), 4(f)(3).

SUMMARY OF ARGUMENT

Alternative service on Defendants via email to their U.S. counsel is proper, because such service is reasonably calculated to apprise Defendants of the actions, is not barred by international agreement, and is necessary to ensure timely progression of this matter to litigation on the merits. Defendants are already aware of this litigation, and have each been communicating with their counsel and with Regeneron for months about the underlying subject matter of this litigation—Defendants’ EYLEA® biosimilar products and Regeneron’s infringement allegations. The Hague Convention does not address or prohibit service by email. Finally, the circumstances of these cases, in particular the congressionally acknowledged need for expedited discovery and a timely adjudication of Regeneron’s forthcoming motion for preliminary injunction, especially in light of the impending potential FDA approval and launch of Defendants’ biosimilar products, necessitate expeditious service. Numerous courts have authorized service on foreign defendants via email to U.S. counsel in analogous situations.

STATEMENT OF FACTS

Regeneron invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. *See* Celltrion Compl. ¶ 2. Defendants are each in the process of seeking approval to commercialize a biosimilar of EYLEA® in the United States. A brief recitation of Regeneron’s interactions with each, conducted entirely with or through Defendants’ U.S. counsel, follows.

Celltrion

On June 30, 2023, Celltrion—a company organized under the laws of the Republic of Korea—publicly announced that it had applied for approval from the FDA to commercialize “CT-P42,” a biosimilar of EYLEA®. *See id.* ¶ 3. In September 2023, Celltrion provided Regeneron with a copy of its abbreviated Biologics License Application or “aBLA” for CT-P42

and later provided its notice of commercial marketing, indicating its intent to begin marketing and selling the biosimilar immediately upon receiving approval from the FDA. *See id.* ¶¶ 23, 25. Because Celltrion’s submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e), Regeneron filed the above-captioned action for patent infringement to obtain relief before Celltrion launches CT-P42 in the United States.

Regeneron has been in communication with Celltrion’s U.S. counsel since September 2023 as the parties followed the “patent dance”² procedures of the BPCIA and prepared for this litigation. *See* Celltrion Compl. ¶ 2. All of Regeneron’s contact with Celltrion about its aBLA has occurred through its U.S. counsel, Gemini. In early November, prior to the filing of the complaint, counsel for Regeneron reached out to Celltrion’s U.S. counsel to discuss a proposed preliminary injunction schedule and confidentiality agreement to govern this infringement litigation. Counsel for Celltrion responded and acknowledged they were aware Regeneron planned to file an action. Shortly thereafter, on November 8, 2023, Regeneron filed its complaint, and the same day Regeneron’s counsel emailed Gemini a copy of the complaint and requested that they confirm whether they would accept service of process on behalf of Celltrion. When Celltrion’s counsel failed to respond, Regeneron followed up two days later, and on November 13, Gemini “agree[d] to accept service of the complaint on behalf of Celltrion” provided Regeneron agreed to an extension of Celltrion’s time to respond. Ex. A (Nov. 13, 2023 Email from A. Zalcenstein to P. Patel).

In the weeks that followed, Celltrion’s U.S. counsel continued to discuss the preliminary injunction schedule with Regeneron, and the parties traded drafts of a proposed stipulated

² The term “patent dance” refers to a set of pre-litigation steps outlined by the BPCIA, whereby the parties exchange infringement and validity contentions. *See* 42 U.S.C. § 262(l).

preliminary injunction schedule. In every iteration of the draft stipulation, counsel for Celltrion agreed to accept service of process.

With the parties close to a final stipulation as to service and schedule, counsel for Regeneron requested a December 1 meet and confer. Celltrion's counsel asserted they were unavailable, so Regeneron shared another set of proposed revisions via email and followed up on the meet-and-confer request. Counsel for Celltrion did not respond. A week later, counsel for Regeneron again requested a call to discuss the schedule and service issues, but counsel for Celltrion was again unavailable. Regeneron would not hear from Celltrion again until its December 19, 2023 meet and confer with all Defendants, during which Celltrion would no longer commit to accepting service. Prior to that meeting, Celltrion gave no indication that it might refuse service. Two days later, in a December 21 email from all Defendants (sent by Formycon's counsel), Celltrion finally and conclusively retracted its earlier commitment and refused to accept service.

Samsung Bioepis

Bioepis—a company organized under the laws of the Republic of Korea—applied for approval from FDA to commercialize “SB15,” a biosimilar of EYLEA®. Regeneron filed its action for patent infringement to obtain relief before Bioepis launches SB15 in the United States under 35 U.S.C. § 271(e).

Regeneron has been in communication with Bioepis's U.S. counsel as the parties prepared for this litigation. All of Regeneron's contact with Bioepis about its aBLA has occurred through Quinn Emanuel.

On November 21, 2023, Regeneron filed the above-captioned action. The following day, Regeneron emailed Bioepis's in-house legal counsel and Quinn Emanuel a copy of the complaint

and docket entry and requested that they confirm whether Bioepis would agree to accept service by email. Having received no response whatsoever from Bioepis for more than two weeks, Regeneron's counsel wrote to Quinn Emanuel again on December 8 in follow-up, again requesting confirmation that Quinn Emanuel would accept service on behalf of Bioepis. Nineteen days after Regeneron's initial email, on December 11, Quinn Emanuel replied that counsel was unable to accept service of the complaint via email, citing concerns about Bioepis's intended personal jurisdiction defense.

The parties met and conferred on December 13. During the meet and confer, Quinn Emanuel asserted that it was reluctant to accept service because of concern that doing so might waive Bioepis's ability to challenge the Court's personal jurisdiction. To alleviate those concerns, on December 15, Regeneron provided caselaw confirming that acceptance of service would not threaten Bioepis's right to contest personal jurisdiction and proposing a stipulation explicitly preserving Bioepis's personal jurisdiction defense. Bioepis's counsel nevertheless again refused to accept service.

Formycon

On June 29, 2023, Formycon—a company organized under German law—publicly announced that it had applied for approval from FDA to commercialize “FYB203,” a biosimilar of EYLEA®. *See* Formycon Compl. ¶¶ 3, 7. In August 2023, Formycon announced that FDA had accepted its aBLA for FYB203. *See id.* ¶ 4. Because Formycon's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e), Regeneron filed its action for patent infringement to obtain relief before Formycon launches FYB203 in the United States.

Regeneron has been in communication with Formycon's U.S. counsel, Jenner & Block, as the parties prepared for this litigation. All of Regeneron's contact with Formycon about its

aBLA has occurred through Jenner & Block. In early November, counsel for Regeneron reached out to Formycon's U.S. counsel to discuss a proposed preliminary injunction schedule in anticipation of this infringement action. Formycon's counsel responded that they had "discussed the issue with Formycon" and indicated they were aware Regeneron planned to file this action. Ex. C (Nov. 10, 2023 Email from S. Van Horn to T. Fletcher). In the ensuing days, the parties met and conferred via videoconference and communicated by email numerous times to discuss the preliminary injunction schedule.

On November 29, 2023, Regeneron filed its complaint, and shortly thereafter Regeneron's counsel emailed Jenner & Block a copy of the sealed complaint. Formycon's counsel acknowledged receipt and a few days later, Regeneron's counsel followed up, providing a further revision of the proposed preliminary injunction schedule and requesting confirmation that Jenner & Block would accept service on Formycon's behalf. When Jenner & Block failed to respond, counsel for Regeneron followed up again to request confirmation that Jenner & Block would accept service. Counsel for Formycon finally replied that they were "working through this issue with our client" and "[were] not in a position to accept service at this time." Ex. B (Dec. 12, 2023 Email from S. Van Horn to A. Trask).

In the days that followed, the parties continued to discuss the preliminary injunction schedule, but the service issue remained unresolved. As with Celltrion, Formycon's U.S. counsel ultimately confirmed that it would not accept service via Defendants' joint correspondence on December 21.

Because Celltrion and Bioepis are Korean companies, and Formycon a German company, effectuating service through Rule 4(f)(2) would require the Hague Convention process.³ This would take a significant amount of time. For Celltrion and Bioepis, the Convention would require Regeneron first to transmit a request for service and each complaint (in English and Korean translation) to the Republic of Korea’s Director of International Affairs within the National Court Administration, the country’s designated “Central Authority.”⁴ The Korean Director of International Affairs would then send the request to a “competent court,” which in turn would serve Celltrion and Bioepis, respectively.⁵ Once the Korean court had served Celltrion and Bioepis, Regeneron would need to wait for the Korean central authority to send a certificate of service back to Regeneron. *See* Theodore J. Folkman, International Judicial Assistance § 2.3.4(d) (2012). As to Formycon, the Convention would require that Regeneron first transmit a request for service and the complaint (in English and German translation) to the President of the appropriate Regional Court,⁶ which would in turn attempt to effectuate service via the postal service, after which time Regeneron would need to wait for the return of a certificate of service from that Regional Court.

³ Regeneron also is pursuing service via Rule 4(h)(1) and will file proofs of service if it succeeds. Such a proof of service would not moot this motion to the extent Defendants contend that service via Rule 4(h)(1) was improper.

⁴ Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, Nov. 15, 1965, art. 5, 20 U.S.T. 361, *available at* <https://assets.hcch.net/docs/f4520725-8cbd-4c71-b402-5aae1994d14c.pdf>.

⁵ *Republic of Korea – Central Authority and Practical Information*, Hague Conference on Private International Law, <https://www.hcch.net/en/states/authorities/details3/?aid=262> (last visited Dec. 21, 2023).

⁶ Germany’s “Central Authority” is decentralized such that the appropriate authority is located in the district where the party designated for service resides. *See Germany – Central Authority and Practical Information*, Hague Conference on Private International Law, <https://www.hcch.net/en/states/authorities/details3/?aid=257> (last visited Dec. 21, 2023).

In each case, the process is likely to take several months to complete, meaning that Defendants could potentially avoid service until mid-2024, when Regeneron's regulatory exclusivity expires (on May 18, 2024).

ARGUMENT

I. Legal Standard

The Federal Rules of Civil Procedure permit a Court to order service on a foreign corporation by any “means not prohibited by international agreement as may be directed by the court.” *See* Fed. R. Civ. P. 4(f)(3), (h)(2); *see also Enovative Techs., LLC v. Leor*, 622 F. App'x 212, 214 (4th Cir. 2015) (quoting Fed. R. Civ. P. 4(f)(3));⁷ *Williams v. Advert. Sex LLC*, 231 F.R.D. 483, 486-87 (N.D.W. Va. 2005) (same). This broad discretion is limited only by Due Process considerations, which require that the method of service be “reasonably calculated, under all the circumstances, to give notice to defendant.” *Enovative Techs.*, 622 F. App'x at 214 (internal quotations omitted). “Rule 4(f) does not denote any hierarchy or preference for one method of service over another,” *Id.*, citing *Rio Properties, Inc. v. Rio International Interlink*, 284 F.3d 1007, 1016 (9th Cir. 2002), and a plaintiff need not attempt to serve a foreign defendant abroad before seeking alternative service, *see, e.g., In re OnePlus Tech. (Shenzhen) Co., Ltd.*, 2021 WL 4130643, at *3 (Fed. Cir. Sept. 10, 2021) (declining to find abuse of discretion by District Court in ordering service via email to U.S. counsel, notwithstanding that plaintiff had “made no showing that service under the Hague Convention had been tried and failed, would

⁷ As this issue involves interpretation of the Federal Rules of Civil Procedure, Fourth Circuit law applies. *See Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306 (Fed. Cir. 2003) (“We generally apply the law of the pertinent regional circuit when the precise issue to be addressed involves an interpretation of the Federal Rules of Civil Procedure.”); *See also Xilinx, Inc. v. Godo Kaisha IP Bridge I*, 246 F. Supp. 3d 1260, 1263 (N.D. Cal. 2017) (ordering service on a foreign corporation's U.S. counsel pursuant to Rule 4(f)(3), and noting that “[w]hen, as here, the issue to be addressed involves an interpretation of the Federal Rules of Civil Procedure, the law of the regional circuit applies even if the subject of the lawsuit is patent-related.”)

have been unlikely to succeed, or was otherwise impracticable”); *see also Celgard, LLC. v. Shenzhen Senior Tech. Material Co.*, 2020 WL 2575561, at *2 (W.D.N.C. May 21, 2020) (permitting service on foreign corporation via email to U.S. counsel despite Plaintiff not attempting service via Hague Convention).

II. Regeneron Should Be Permitted to Serve Defendants by Email to their U.S. Counsel

A. Service on U.S. Counsel Is Reasonably Calculated to Apprise Each Defendant of This Action and Satisfies Due Process

The Court should permit service on Defendants through email service on their U.S. counsel, because doing so will ensure that each Defendant receives actual notice of the claims against it. Due Process requires that an ordered method of alternative service be “reasonably calculated, under all circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.” *Rio Properties, Inc.*, 284 F.3d at 1016. This is consistent with the accepted “goal of Rule 4”—to provide actual notice. *Hanna v. Plumer*, 380 U.S. 460, 463 (1965) (“Actual notice is of course also the goal of Rule 4(d)(1)”); *Moore v. K-Mart Corp.*, 1994 WL 824518, at n.2 (W.D. Va. Dec. 15, 1994) (“[T]he revised Federal Rules of Civil Procedure, Rule 4, indicates that actual notice is the goal of service of process.” (citing Fed. R. Civ. P. 4(d), (e), & (k))).

Service through Defendants’ counsel is reasonably calculated to apprise them of this litigation because *each Defendant already has actual notice of the litigation*. Regeneron provided a copy of the complaint to each Defendant’s U.S. counsel via email weeks ago. That message, and indeed the filing of the complaints, occurred after months of regular and substantive communication and negotiation with each Defendant through U.S. counsel. It strains credulity to suggest that any Defendant has not been made aware of the litigation by that same counsel; no Defendant has ever asserted otherwise. At a minimum, each Defendant has

necessarily been apprised of the suit by their U.S. counsel to the extent necessary to determine whether to accept service.

Serving foreign corporations through U.S. counsel is both common and accepted as comporting with Due Process. *See Celgard, LLC*, 2020 WL 2575561, at *2 (“[S]ervice of the [foreign] Defendants through their U.S. counsel would not be improper under Rule 4(f).”); *Affinity Tool Works, LLC v. Hangzhou Great Star Indus. Co.*, 603 F. Supp. 3d 274, 279 (W.D.N.C. 2022) (ordering service on foreign company’s U.S. counsel pursuant to Rule 4(f)(3)); *Divx, LLC v. LG Elecs. Inc.*, 2021 WL 411708, at *2 (D. Del. Feb. 5, 2021) (same); *In re TK Holdings, Inc.*, 2021 WL 954827, at *5 (Bankr. D. Del. Mar. 8, 2021) (same); *In Re TFT-LCD (Flat Panel) Antitrust Litig.*, 2010 WL 1337743, at *3 (N.D. Cal. Apr. 2, 2010) (same, highlighting that foreign defendant had “consulted its U.S. counsel regarding these lawsuits . . .”).

Here, each Defendant’s communications with its U.S. counsel regarding the same biosimilar products and the same infringement allegations appearing in the above-captioned actions, as well as regarding the suit itself at least as to accepting service of the complaint,⁸ confirm that service via email to U.S. counsel is “reasonably calculated” to inform each Defendant about this action.

B. Service by Email Is Not Prohibited by International Law

Pursuant to Rule 4(f)(3), the Court may order service by any alternative means not “prohibited by international agreement.” Fed. R. Civ. P 4(f)(3). The Hague Convention, to

⁸ Correspondence from Celltrion and Formycon confirm this fact explicitly. *See* Ex. A (Nov. 13, 2023 Email from A. Zalcenstein to P. Patel) (conditionally agreeing to accept service and taking no issue with the statement from Regeneron’s counsel in the preceding email that “Celltrion Inc. has been aware of Regeneron’s plan to file a complaint, [and] is currently aware that a complaint has been filed.”); Ex. B (Dec. 12, 2023 Email from S. Van Horn to A. Trask) (confirming that Jenner & Block was “working through [the service] issue with our client”).

which the Republic of Korea and Germany are signatories,⁹ neither addresses nor prohibits service via email. *See Lexmark Int’l, Inc. v. Ink Techs. Printer Supplies, LLC*, 295 F.R.D. 259, 261 (S.D. Ohio 2013) (noting that “[v]arious courts have agreed that service by email is not prohibited by the Hague Convention,” and collecting cases); *Facebook, Inc. v. Banana Ads, LLC*, 2012 WL 1038752, at *2 (N.D. Cal. Mar. 27, 2012) (collecting cases confirming same).

Courts have reached the same conclusion with respect to service on Korean and German defendants in particular, permitting service via email on U.S. counsel. *See, e.g., Nexon Korea Corp. v. Ironmace Co.*, 2023 WL 3599548, at *2 (W.D. Wash. May 23, 2023) (concluding that “service by email to parties located in Korea is not prohibited by international agreement,” and authorizing alternative service via email to U.S. counsel); *In re One Apus Container Ship Incident on Nov. 30, 2022*, 2022 WL 17370122, at *3 (S.D.N.Y. Dec. 2, 2022) (same); *Sec. & Exch. Comm’n v. Richman*, 2021 WL 9816612, at *3 (N.D. Cal. July 19, 2021) (confirming that “international agreement does not preclude the SEC’s proposed means of services” and ordering alternative service via email and personal mail to defendants’ U.S. counsel). Rule 4(f)(3) thus permits service on Defendants via email to their U.S. counsel.

C. Requiring Service Only Via Hague Convention Procedures May Delay This Litigation, Prejudicing Regeneron

Alternative service is appropriate in these matters because time is of the essence. Avoiding “unnecessarily delaying the litigation” is a “primary concern” in assessing requests for alternative means of service. *Vanderhoef v. China Auto Logistics Inc.*, 2019 WL 6337908, at *3 (D.N.J. Nov. 26, 2019). Courts have “frequently cited delays in service under the Hague Convention as supporting an order of alternative service under Rule 4(f)(3).” *Affinity Labs of*

⁹ *HCCH Members*, Hague Conference on Private International Law, <https://www.hcch.net/en/states/hcch-members> (last visited Dec. 18, 2023)

Tex., LLC v. Nissan N. Am. Inc., 2014 WL 11342502, at *3 (W.D. Tex. July 2, 2014) (collecting cases); *In GLG Life Tech Corp. Sec. Litig.*, 287 F.R.D. 262, 266 (S.D.N.Y. 2012) (same); *see also Knit With v. Knitting Fever, Inc.*, 2010 WL 4977944, at *5 (E.D. Pa. Dec. 7, 2010) (granting plaintiff’s motion for alternative service on foreign defendant via email to U.S. counsel, noting that requiring plaintiff to pursue “further efforts through the Hague Convention will simply prove to be time-consuming, expensive, burdensome, and ultimately an obstacle to the forward progression of this litigation.”).

Avoiding unnecessary delay is particularly critical in these litigations. Regeneron’s statutory regulatory exclusivity over its patented drug EYLEA® expires on May 18, 2024. To preserve the status quo and prevent Defendants from bringing their infringing products to market, Regeneron intends to move for a preliminary injunction effective as of or before that date—now only five months away. Effectuating service through the Hague Convention process would needlessly delay the progress of this litigation on the merits by months. *See, e.g., Kaneka Corp. v. SKC Kolon PI, Inc.*, 2013 WL 11237203, at *4 (C.D. Cal. May 6, 2013) (denying motion to add an additional Korean defendant because doing so “would cause additional delay because service would have to be made through the Hague Convention process, which both parties recognize could take up to four months.”) By the time Regeneron effects service on Defendants through the Hague Convention, Regeneron may already face improper competition from the Defendants’ infringing biosimilars. As such, service through the Hague Convention could ultimately deprive Regeneron the opportunity to proactively vindicate its patent rights and avoid the irreparable harm attendant with an infringing competitor’s entry into the market. *See Lexmark*, 295 F.R.D. at 262 (ordering service on foreign defendants via email where service

“could be significantly delayed if formal service pursuant to the Hague Convention is required,” and “further delay may prejudice Plaintiff’s ability to obtain relief.”).

Permitting Defendants to delay this litigation by insisting upon service through the Hague Convention would also be inconsistent with the objectives of the BPCIA. The BPCIA requires that biosimilar applicants provide 180-day notice of commercial marketing, with the intention that such notice will provide “the parties and the district court the time for adjudicating [preliminary injunctions] without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury.” *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016). Service through the Hague Convention would squander all or substantially all of that statutorily prescribed 180-day notice period, depriving the parties and this Court of the “time for adjudicating” contemplated by Congress.

In short, Defendants are aware of this litigation. And, contrary to its assertions, Bioepis is aware that there is no risk to its personal jurisdiction argument from accepting service through counsel, because it has done so in the past. Defendants’ refusal to accept service now is a naked attempt to slow litigation and part and parcel of their broader, meritless gambit to avoid litigating before this Court. There is no cause to forestall this matter on avoidable technical grounds. Service on Defendants’ U.S. counsel is contemplated by Rule 4(f)(3), comports with due process, and is necessary to avoid unnecessary delay.

CONCLUSION

For the foregoing reasons, Regeneron respectfully requests that this Court enter an order pursuant to Federal Rules Civil Procedure 4(h)(2) and 4(f)(3), authorizing Regeneron to effect service on each of the Defendants via email to their U.S. counsel.

Dated: December 22, 2023

Respectfully submitted,

OF COUNSEL:

CAREY DOUGLAS KESSLER & RUBY, PLLC

Elizabeth S. Weiswasser (*pro hac vice*
forthcoming)
Anish R. Desai (*pro hac vice* forthcoming)
Natalie C. Kennedy (*pro hac vice*
forthcoming)
Tom Yu (*pro hac vice* forthcoming)
Yi Zhang (*pro hac vice* forthcoming)
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Kathryn S. Kayali (*pro hac vice* forthcoming)
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Adam Pan (*pro hac vice* forthcoming)
Rebecca A. Carter (*pro hac vice* forthcoming)
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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on the 22nd day of December 2023, service of the foregoing “Plaintiff’s Memorandum in Support of its Motion for Alternative Service” was made by U.S. Mail to the following counsel:

Robert Cerwinski, Esq.
Aviv Zalcenstein, Esq.
Gemini Law LLP
40 W. 24th Street, Suite 6N
New York, NY 10010

Counsel for Defendant Celltrion, Inc.

Laura Fairneny, Esq.
Matthew Traupman, Esq.
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Ave, 22nd floor
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Counsel for Defendant Samsung Bioepis, Co., Ltd.

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Washington, DC 20001

Counsel for Defendant Formycon AG

/s/ Steven R. Ruby
Steven R. Ruby (WVSB No. 10752)

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

Case No. 1:23-cv-00089-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS CO., LTD.,

Defendant.

Case No. 1:23-cv-00094-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

FORMYCON AG,

Defendant.

Case No. 1:23-cv-00097-TSK

JURY TRIAL DEMANDED

**DECLARATION OF ANDREW E. GOLDSMITH IN SUPPORT OF
PLAINTIFF'S MOTION FOR ALTERNATIVE SERVICE**

I, Andrew E. Goldsmith, hereby declare as follows:

1. I am a partner at the law firm of Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., counsel for Regeneron Pharmaceuticals, Inc. ("Regeneron") in the above-captioned

cases. I have appeared *pro hac vice* in these matters and am a member in good standing of the Bar of the State of New York and the Bar of the District of Columbia. I submit this Declaration in support of Regeneron's Motion for Alternative Service filed contemporaneously herewith. I have personal knowledge of the facts stated in this Declaration and am competent to testify to the same.

2. Attached hereto as Exhibit A is a true and correct copy of an email from Aviv Zalcenstein of Gemini Law, LLP ("Gemini"), counsel for Celltrion, Inc. ("Celltrion"), to Priyata Patel of Weil, Gotshal & Manges LLP ("Weil"), counsel for Regeneron, dated November 13, 2023.

3. Attached hereto as Exhibit B is a true and correct copy of an email sent by Shaun Van Horn of Jenner & Block LLP ("Jenner & Block"), counsel for Formycon AG, to Andrew Trask of Williams & Connolly LLP ("Williams & Connolly"), counsel for Regeneron, dated December 12, 2023.

4. Attached hereto as Exhibit C is a true and correct copy of an email sent by Shaun Van Horn of Jenner & Block to Tom Fletcher of Williams & Connolly, dated November 10, 2023.

I, Andrew E. Goldsmith, declare under penalty of perjury that the foregoing is true and correct.

Dated: December 22, 2023

/s/ Andrew E. Goldsmith
Andrew E. Goldsmith

Exhibit A

From: [Aviv Zalcenstein](#)
To: [Patel, Priyata](#); [Robert Cerwinski](#); [DG-Aflibercept](#); [WFG-aflibercept@willkie.com](#)
Cc: [Eylea Biosimilars](#); [Eylea@wc.com](#); [Goldsmith, Andrew E.](#); [Hartman, Jacob E.](#)
Subject: RE: Complaint - C.A. 1:23-CV-89 - Regeneron v. Celltrion
Date: Monday, November 13, 2023 9:46:31 AM

Priya,

We can agree to accept service of the complaint on behalf of Celltrion provided that Regeneron agrees to a 30-day extension on the due date to respond (i.e., 21 days from service + 30 additional days). Please let us know if this is acceptable to Regeneron. We are conferring with our client regarding your other inquiry below and will revert as soon as possible.

Regards,
Aviv

From: Patel, Priyata <Priyata.Patel@weil.com>
Sent: Friday, November 10, 2023 1:02 PM
To: Aviv Zalcenstein <azalcenstein@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; DG-Aflibercept <DG-Aflibercept@NETORG8512690.onmicrosoft.com>; WFG-aflibercept@willkie.com
Cc: Eylea Biosimilars <Eylea.Biosimilars@weil.com>; Eylea@wc.com; agoldsmith@kellogghansen.com; jhartman@kellogghansen.com
Subject: RE: Complaint - C.A. 1:23-CV-89 - Regeneron v. Celltrion

Hi Aviv,

Following up on the below, please let us know if you will accept service on behalf of Celltrion, Inc. Our understanding based on our previous meet and confers is that Celltrion Inc. has been aware of Regeneron's plan to file a complaint, is currently aware that a complaint has been filed, and wishes to expedite proceedings in district court. Failing to accept service will only needlessly delay the litigation, which is in neither party's interests.

Sincerely,
Priya

From: Patel, Priyata <Priyata.Patel@weil.com>
Sent: Wednesday, November 8, 2023 5:08 PM
To: Aviv Zalcenstein <azalcenstein@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; DG-Aflibercept <DG-Aflibercept@NETORG8512690.onmicrosoft.com>; WFG-aflibercept@willkie.com
Cc: Eylea Biosimilars <Eylea.Biosimilars@weil.com>; Eylea@wc.com; agoldsmith@kellogghansen.com
Subject: Complaint - C.A. 1:23-CV-89 - Regeneron v. Celltrion

Aviv,

Following up on the below, please find attached the complaint that Regeneron filed against Celltrion today in the Northern District of West Virginia.

Thanks,
Priya

From: Patel, Priyata <Priyata.Patel@weil.com>
Sent: Wednesday, November 8, 2023 2:03 PM
To: Aviv Zalcenstein <azalcenstein@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; DG-Aflibercept <DG-Aflibercept@NETORG8512690.onmicrosoft.com>; WFG-aflibercept@willkie.com
Cc: Eylea Biosimilars <Eylea.Biosimilars@weil.com>; Eylea@wc.com; agoldsmith@kelloggghansen.com
Subject: FW: Activity in Case 5:23-cv-11111 Plaintiff v. Defendant COMPLAINT - Electronic Intake

Aviv,

Regeneron filed a complaint against Celltrion, Inc. in the Northern District of West Virginia—see below. We will send you a copy of the complaint as soon as we have the file-stamped copy. Please let us know if you will accept service of process on behalf of Celltrion, Inc.

On the schedule, Regeneron has considered Celltrion's proposed preliminary injunction schedule, which provides the parties and Court with approximately one additional month to present and adjudicate a motion for preliminary injunction. Subject to the Court's review and approval of this schedule, Regeneron is willing to proceed on Celltrion's proposed schedule, provided that Celltrion will be subject to a Court Order not to commercialize its aflibercept biosimilar product prior to the Court's ruling on Regeneron's preliminary injunction motion. Please let us know if Celltrion accepts that condition.

Best,
Priya

From: wvndcmecf@wvnd.uscourts.gov <wvndcmecf@wvnd.uscourts.gov>
Date: Wednesday, November 8, 2023 at 9:23 AM
To: wvndcmecf@wvnd.uscourts.gov <wvndcmecf@wvnd.uscourts.gov>
Subject: Activity in Case 5:23-cv-11111 Plaintiff v. Defendant COMPLAINT - Electronic Intake

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.

*****NOTE TO PUBLIC ACCESS USERS***** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.

U.S. District Court

Northern District of West Virginia

Notice of Electronic Filing

The following transaction was entered by Ruby, Steven on 11/8/2023 at 9:21 AM EST and filed on 11/8/2023

Case Name: Plaintiff v. Defendant

Case Number: [5:23-cv-11111](#)

Filer: Plaintiff

Document Number: [204](#)

Docket Text:

COMPLAINT WITH FEE PAID. Regeneron v. Celltrion. Filing Fee \$402. Receipt #AWVNDC-3822353., filed by Plaintiff. (Attachments: # (1) Civil Cover Sheet, # (2) Attachment AO-120 Form, # (3) Attachment Proposed Summons, # (4) Exhibit 1, # (5) Exhibit 2, # (6) Exhibit 3, # (7) Exhibit 4, # (8) Exhibit 5, # (9) Exhibit 6, # (10) Exhibit 7, # (11) Exhibit 8, # (12) Exhibit 9, # (13) Exhibit 10, # (14) Exhibit 11, # (15) Exhibit 12, # (16) Exhibit 13, # (17) Exhibit 14, # (18) Exhibit 15, # (19) Exhibit 16, # (20) Exhibit 17, # (21) Exhibit 18, # (22) Exhibit 19, # (23) Exhibit 20, # (24) Exhibit 21, # (25) Exhibit 22, # (26) Exhibit 23, # (27) Exhibit 24, # (28) Exhibit 25, # (29) Exhibit 26, # (30) Exhibit 27, # (31) Exhibit 28, # (32) Exhibit 29, # (33) Exhibit 30, # (34) Exhibit 31, # (35) Exhibit 32, # (36) Exhibit 33, # (37) Exhibit 34, # (38) Exhibit 35, # (39) Exhibit 36, # (40) Exhibit 37, # (41) Exhibit 38, # (42) Exhibit 39, # (43) Exhibit 40)(Ruby, Steven)

5:23-cv-11111 Notice has been electronically mailed to:

Steven Robert Ruby sruby@cdkrlaw.com, nsmith@cdkrlaw.com, sjohnson@cdkrlaw.com

5:23-cv-11111 Notice must be delivered by other means to:

Defendant

The following document(s) are associated with this transaction:

Document description:Main Document

Original filename:n/a

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Original filename:n/a

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Document description:Attachment Proposed Summons

Original filename:n/a

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Original filename:n/a

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[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-1
3] [530d8e17efc72e697ac5c5d9ab66aed2781efeeb1a7318f87681253408a01aa64c
c8dbd3b19e85759c1b2710ae40a786367be10904ec7a7132180339c343a503]]

Document description:Exhibit 11

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-1
4] [5687c287217b4131bf52d09bf962d1b307c5352184e2d12bc8f5eb5031ac2a5369
21b765f42ef0131da268e98c0bf2471b3feb746ea79256b54ef2aa4e8a2cb6]]

Document description:Exhibit 12

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-1
5] [a8dc304121139452ba03ad1d84c8cd5e396f27dd76ab0c0bae2aced16a99ad5345
24f1c90703a2287bbec2b95c0eb8912b425572dbeb1a8c199afa2f4665c19c]]

Document description:Exhibit 13

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-16] [6fdc2386926822593b437d3933fb2da34150762b0cf14084cfd43f8bee5b9677661baa107d0dc4be1897bd2eef21e92dfed5f06897753945237f52eedddab69e]]

Document description:Exhibit 14

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-17] [a95ea5ba933d478b9ffcd23e2c8bc2e38628c41bdeb5ba5d51c24776567f99f3754a491f67cdb33d8cdd55b3376c7babacc267655bc6481065502b257d98405]]

Document description:Exhibit 15

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-18] [9ff6e4d4c5adac16b4ea08bfa5adf35419a3b32e44e666bf112cdcc49fad0519faf782a6b2c6019eebd10e677c9fe6fe5eeb4d6c1c8723713e7249fd0a9f657e]]

Document description:Exhibit 16

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-19] [35dca6001492282568b614b8668e923c7f9a5e8b2e5eba9ad6859387c95a868bde e3e4cea7f2a32b5dcc249fdc625d9eaa254a7f3c66d3808359e1006b2b8e2d]]

Document description:Exhibit 17

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-20] [27a401af57cc796e572c82f1461dbed3503b3101fc996c89c9201617c8e5a77ce6 ee62b1cc1233c9f57f897ae163c6a353bc8bdb1e0aa7178899ddece6be8ab1]]

Document description:Exhibit 18

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-21] [3992d80c83dd4b703a1ab793712b70f362424991aab12617e865480eebd0244fb1 f9607dcbe9c31b5fac57f1889a54248c0f6e6c4da98a82ea319fa0734e3a09]]

Document description:Exhibit 19

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-22] [35dd6aebc657cbad30ae280b9da43e034e741f923624fb6cc9b2d4d5f56c88b461 f111c7d0433756cb88154fb01070243121ad66de06a23a78377890ab90c0dd]]

Document description:Exhibit 20

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-23] [142f842e5fd7ed8d1c67a6c6ea3e67006a2fc8c0624ceab1dbc65625b0a5ee2b6d

6fc5a3b095b4c85a38c4450bf849be7e37a103eb559697837b6c9d6722ab11]]

Document description:Exhibit 21

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-24] [6d77b5b66bab3a5ab6921e9ebaa46e9fec66ee55025208cb04d2cf058bf74d6a9bbbfb8e08eff5c6a8d548f84ff81548b7433f22b35dc5d9851a61bf48620c9]]

Document description:Exhibit 22

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-25] [598bbf343322e81eeef15e7f4ce106a7e04c848c1a79b2de10a1d00ad50bc6b68511aa36957d1e496171b04dd70dd143e1f5101e052e2f56ed8517754bb58801]]

Document description:Exhibit 23

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-26] [94be895d75738a1d8594dafb8eba7d0da4c35994bfc31c1f0c543faf4ac80f5ed3c3ad13eca2052c7c60a4471db0f292e9c58b034c006d38e9c4a45970900e95]]

Document description:Exhibit 24

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-27] [a53b023de33a6541132b304c0c80ce0a628b3e030c224c62ade3af7a86aa09bb552be42282a0f826c9a9633526204d4b96fde7bcfeab6db89236eb001ade9978]]

Document description:Exhibit 25

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-28] [0b3e1703f64281c4991d9cee61a7349e561aad2427975a39b16331fd036caa2b82030a4a1a41a325a8d25f639e117a115ab798ecb667bdbdb0688b9eebafbe46]]

Document description:Exhibit 26

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-29] [74b497f64f291f79e99ea4e2d6359c0e27bc719f06bdc99c3ab56721e5d398d1ee5ba09c2a10ccc3bc7c120edef72e00d6bce0cb018d816ce4e4f2279ab1fd72]]

Document description:Exhibit 27

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-30] [853cea40227d9960128b2de16dc7d233892f40921ea80f2489a6b0e6eba2844dafca56b953b0682051cca406a22a7d666bae1db0c2a45cff7096f248f8a5391c]]

Document description:Exhibit 28

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
1] [0266a3c434e5f033d2205cc18a2b1c97f117e7db488562078412a1c0df46625c43
e3f68e51d3f8c70217755711e755112476c87ebf534139fea5d17785fbc5dc]]

Document description:Exhibit 29

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
2] [7d1df12ba16101cd96f92827ebab17c46a283fda6a3eccf1d17dcbbedb6aef93a8
bc67879e436c460acfe42d6cf144e8d1e623481c0f02d2b9a7c40cdb7c0103]]

Document description:Exhibit 30

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
3] [3da83b6f0c29e668dbca363bde677cfc67df68c4d1eecd3b15a9c914bf462cf328
48ea26735b85ae970356fbcce397c38e5ad2a48424c97f8721a74e8d7088f4]]

Document description:Exhibit 31

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
4] [212c5c0d41cb2f6c0a466eefac02b82adf986f0724bebd9947f5c47d9e09e60866
7eb143320fd575a382270c159ebcbab3eb83a3c68ca21f3a21a2d4eeba760e]]

Document description:Exhibit 32

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
5] [7313a1b9fd33c60ea24bc622846a89efea977c04f508cd3910b18331f9ba63f2da
dda4ceb1e1949f6c9bee6eb436570efd95b1181279d06e7fce4a20d72228f2]]

Document description:Exhibit 33

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
6] [05d544b779b50289e8430009b1ecc0f09b7a845037d9588b684d8d05627758c964
3245123dc493ba7e4cd01f8477cc2df05d3cccefa459c4ff10a195cbc23c46]]

Document description:Exhibit 34

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
7] [8434888ff26a18baf73a05a4557aad9070ae20de07b1674a2d4ae981b2eaa283a8
d43b09f139834e8d2c487a649d52e11af2f8db4a5366290ed14fff4e873a7c]]

Document description:Exhibit 35

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
8] [78077bcef7e4e8bb4331b54b79eea105ced4e70ac8ff54fc38994915ff0a7f872f

89d03c2ff2e03ff1daea1cd48c69bf83d0c88beacebb50f8a285e6f254ce3d]]

Document description:Exhibit 36

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-3
9] [891c5cc93b719f81d13b1957a849ef3bfa3e068b06c33f2b298073eab5b01849e6
83c3e7e74e0f1400b6f46e48803cb4b1fe3eb4480e962abd9cd7f831dfb66a]]

Document description:Exhibit 37

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-4
0] [53a41c2f25d775b2252462051240b355ecc8e1106e3771c75ed8c61b23a7f1ecbe
fbc67f11e48e495d3ba75451ebac61f8da7a7883d6fd81184417859126dd0e]]

Document description:Exhibit 38

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-4
1] [990586c39fc3b6a1884ce3126682b28214dfefb115519fd088025c8d055dbd4a05e
0070a830c953e7f6382d277b9965369d7b17c4e57e54e91796196f67df8494]]

Document description:Exhibit 39

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-4
2] [45d7007588628ca0f0ec179b504e6bcfd8b50c787e16ad9a9bf9530bc104a5caeb
a08909765c26d0599dbbadbab32527c591a7d5fe75caface34a00650c423c7]]

Document description:Exhibit 40

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1079362125 [Date=11/8/2023] [FileNumber=3172274-4
3] [a261e3c052624aa0e21d54435b301e0a96ec1782976bc3635a98a47f3586dc821c
d15f512b0cc83c2e45482f3c6627c4889ff47e0af399c5fe0a772019cff30b]]

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Exhibit B

From: [Van Horn, Shaun M.](#)
To: [Trask, Andrew](#); [DL_FYB203Internal](#)
Cc: [Eylea](#); [Fletcher, Thomas](#)
Subject: RE: Eylea: Complaint & Schedule Update
Date: Tuesday, December 12, 2023 2:20:03 PM

Andrew,

Thanks for reaching out. We are working through this issue with our client. We are not in a position to accept service at this time.

Shaun

From: Trask, Andrew <atrask@wc.com>
Sent: Tuesday, December 12, 2023 12:23 PM
To: Van Horn, Shaun M. <SVanHorn@jenner.com>; [DL_FYB203Internal](#) <DL_FYB203Internal@jenner.com>
Cc: Eylea <Eylea@wc.com>; Fletcher, Thomas <TFletcher@wc.com>
Subject: RE: Eylea: Complaint & Schedule Update

External Email - Do Not Click Links or Attachments Unless You Know They Are Safe

Shaun,

I am following up on my request below that you accept service of the summons and complaint on behalf of Formycon, AG. Please confirm whether you agree to do so.

Thanks,

Andrew

Andrew Trask | Williams & Connolly LLP | 202-434-5023 | atrask@wc.com <<mailto:atrask@wc.com>>

From: Trask, Andrew
Sent: Wednesday, December 6, 2023 19:35
To: 'Van Horn, Shaun M.' <SVanHorn@jenner.com<<mailto:SVanHorn@jenner.com>>>; [DL_FYB203Internal](#) <DL_FYB203Internal@jenner.com<mailto:DL_FYB203Internal@jenner.com>>
Cc: Eylea <Eylea@wc.com<<mailto:Eylea@wc.com>>>; Fletcher, Thomas <TFletcher@wc.com<<mailto:TFletcher@wc.com>>>
Subject: RE: Eylea: Complaint & Schedule Update

Shaun,

Attached is a revised proposed schedule for Formycon's review.

Also, please let us know if you agree to accept service of process on behalf of Formycon, AG.

Thanks,

Andrew

Andrew Trask | Williams & Connolly LLP | 202-434-5023 | atrask@wc.com<<mailto:atrask@wc.com>>

From: Van Horn, Shaun M. <SVanHorn@jenner.com<<mailto:SVanHorn@jenner.com>>>
Sent: Sunday, December 3, 2023 09:41
To: Fletcher, Thomas <TFletcher@wc.com<<mailto:TFletcher@wc.com>>>; DL_FYB203Internal <DL_FYB203Internal@jenner.com<mailto:DL_FYB203Internal@jenner.com>>
Cc: Eylea <Eylea@wc.com<<mailto:Eylea@wc.com>>>
Subject: RE: Eylea: Complaint & Schedule Update

Tom, Thanks for sending. We look forward to the new proposal re schedule. Shaun

From: Fletcher, Thomas <TFletcher@wc.com<<mailto:TFletcher@wc.com>>>
Sent: Saturday, December 2, 2023 7:09 PM
To: DL_FYB203Internal <DL_FYB203Internal@jenner.com<mailto:DL_FYB203Internal@jenner.com>>
Cc: Eylea <Eylea@wc.com<<mailto:Eylea@wc.com>>>
Subject: Eylea: Complaint & Schedule Update

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Dear Louis and Shaun,

1. Please find attached the sealed version of the Complaint. It was filed under seal prophylactically in the event that you contend that it discloses Formycon confidential information. It does not disclose Regeneron confidential information.

2. Given the passing of time, we are working on a revised schedule proposal. We have given further thought to your request to have less restriction on early invalidity arguments, and our revised proposal will reflect that.

Thanks,

Tom

Thomas S. Fletcher
Williams & Connolly LLP
680 Maine Ave. SW
Washington, DC 20024
(202) 434-5497

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Shaun M. Van Horn

Jenner & Block London LLP
10 Exchange Square, London, EC2A 2BR | [jenner.com<http://www.jenner.com>](http://www.jenner.com)
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Biography<<http://www.jenner.com/people/ShawnVan%20Horn>>

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Exhibit C

From: [Van Horn, Shaun M.](#)
To: [Fletcher, Thomas](#); [Tuchman, Haley B.](#)
Cc: [Fogel, Louis E.](#); [DL_FYB203Internal](#); [Eylea](#); [Eylea Biosimilars](#)
Subject: RE: FYB 203: Regeneron's (l)(3)(A) List
Date: Friday, November 10, 2023 12:41:31 PM

Tom,

Thanks for the proposal below. We have discussed it with Formycon and are hoping you might have time this afternoon or Monday to discuss how this would work in a bit more detail, e.g., which court we'd file in, how it would relate to any parallel biosimilar proceedings, how we'd deal with the court's schedule/input, and what we'd do about the remainder of the case schedule. Let us know what works for you.

Best,
Shaun

From: Fletcher, Thomas <TFletcher@wc.com>
Sent: Thursday, November 9, 2023 8:49 AM
To: Tuchman, Haley B. <HTuchman@jenner.com>
Cc: Fogel, Louis E. <LFogel@jenner.com>; Van Horn, Shaun M. <SVanHorn@jenner.com>; DL_FYB203Internal <DL_FYB203Internal@jenner.com>; Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>
Subject: RE: FYB 203: Regeneron's (l)(3)(A) List

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Counsel,

With the end of regulatory exclusivity approximately 6 months away, please let us know if Formycon would be willing to proceed on the below schedule for preliminary injunction proceedings once an infringement action has been filed.

Note that we have included a date to suggest to the Court when a ruling is necessary based on our estimate of when FDA might approve your BLA—if you believe that date is inaccurate, please let us know. In any event, to give the Court the opportunity to evaluate the parties' position, this proposal assumes that you will promise to the Court that you will not commercialize your aflibercept biosimilar product prior to the Court's decision on the preliminary injunction motion.

Best,

Tom

Date

Event

November 16, 2023

Regeneron to identify list of no more than 4 patents to include in motion for preliminary injunction

November 22, 2023

Parties exchange targeted requests for production

December 22, 2023

Formycon to identify no more than 3 invalidity arguments per patent for purpose of the PI hearing only—for clarity, each prior art combination or anticipatory reference is one argument

January 19, 2024

Document production complete

February 23, 2024

Regeneron to file motion for preliminary injunction

March 8, 2024

Depositions of Regeneron declarants complete

March 22, 2024

Formycon to file opposition

April 5, 2024

Deposition of Formycon declarants complete

April 19, 2024

Regeneron Reply ISO preliminary injunction

Week of May 13, 2024

Proposed hearing

June 25, 2024

Estimated date of decision on preliminary injunction

Thomas S. Fletcher
Williams & Connolly LLP
680 Maine Ave. SW
Washington, DC 20024
(202) 434-5497

From: Fletcher, Thomas <TFletcher@wc.com<<mailto:TFletcher@wc.com>>>
Sent: Tuesday, November 7, 2023 4:40 PM
To: 'Tuchman, Haley B.' <HTuchman@jenner.com<<mailto:HTuchman@jenner.com>>>
Cc: Fogel, Louis E. <LFogel@jenner.com<<mailto:LFogel@jenner.com>>>; Van Horn, Shaun M.
<SVanHorn@jenner.com<<mailto:SVanHorn@jenner.com>>>; DL_FYB203Internal
<DL_FYB203Internal@jenner.com<mailto:DL_FYB203Internal@jenner.com>>; Eylea
<Eylea@wc.com<<mailto:Eylea@wc.com>>>; Eylea Biosimilars
<Eylea.Biosimilars@weil.com<<mailto:Eylea.Biosimilars@weil.com>>>
Subject: FYB 203: Regeneron's (l)(3)(A) List

Counsel,

Please see the attached letter with Regeneron's list of patents pursuant to 42 U.S.C. § 262(l)(3)(A), and if you have any trouble with the attached, please let me know.

Regards,

Tom

Thomas S. Fletcher
Williams & Connolly LLP
680 Maine Ave. SW
Washington, DC 20024
(202) 434-5497

From: Tuchman, Haley B. <HTuchman@jenner.com<<mailto:HTuchman@jenner.com>>>
Sent: Friday, September 8, 2023 12:37 PM
To: Fletcher, Thomas <TFletcher@wc.com<<mailto:TFletcher@wc.com>>>
Cc: Fogel, Louis E. <LFogel@jenner.com<<mailto:LFogel@jenner.com>>>; Van Horn, Shaun M.
<SVanHorn@jenner.com<<mailto:SVanHorn@jenner.com>>>
Subject: FYB 203 Production

Tom,

Please see the attached correspondence regarding Formycon AG's production of BLA No. 761378.

Regards,

Haley

Haley B. Tuchman

Jenner & Block LLP
1099 New York Avenue, NW
Suite 900, Washington, DC 20001-4412 | jenner.com<<http://www.jenner.com>>
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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

Case No. 1:23-cv-00089-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS CO., LTD.,

Defendant.

Case No. 1:23-cv-00094-TSK

JURY TRIAL DEMANDED

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

FORMYCON AG,

Defendant.

Case No. 1:23-cv-00097-TSK

JURY TRIAL DEMANDED

ORDER

For good cause shown, the Court **GRANTS** Plaintiff Regeneron Pharmaceuticals, Inc.’s (“Regeneron”) Motion for Alternative Service and **ORDERS:**

- 1). Regeneron to effect service on Celltrion, Inc. via electronic mail to Celltrion Inc.’s United States counsel at Gemini Law LLP;

2). Regeneron to effect service on Samsung Bioepis Co., Ltd. via electronic mail to Samsung Bioepis Co., Ltd.'s United States counsel at Quinn Emanuel Urquhart & Sullivan, LLP;

3). Regeneron to effect service on Formycon AG via electronic mail to Formycon AG's United States counsel at Jenner & Block LLP;

It is so **ORDERED**.

The Court **DIRECTS** the Clerk to transmit copies of this Order to all counsel of record.

Dated: _____, 2023

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