

**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 MEMORANDUM IN SUPPORT OF ITS
MOTION FOR ALTERNATIVE SERVICE**

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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 1*, 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,

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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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