

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CIVIL NO. 1:23-CV-89

CELLTRION, INC.,

Defendant.

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CIVIL NO. 1:23-CV-94

SAMSUNG BIOEPIS, CO., LTD.,

Defendant.

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CIVIL NO. 1:23-CV-97

FORMYCON AG,

Defendant.

ORDER GRANTING MOTIONS FOR ALTERNATIVE SERVICE

Pending before the Court in each of the above-styled cases are Plaintiff's Motions for Alternative Service [ECF Nos. 43, 38 and 31, respectively]. Each of the motions is sufficiently briefed

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to consider the issue ripe for decision. For the reasons set forth herein, each of Plaintiff's motions are **GRANTED**.

I. FACTUAL BACKGROUND

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 envisions that such notice may – as it has here – prompt 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).

Regeneron invented, developed, and sells EYLEA®, a medication alternative for several serious eye diseases. See Celltrion Compl. at ¶ 2. Defendants are each in the process of seeking approval to commercialize a biosimilar of EYLEA® in the United States.

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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 alleged 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.

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).

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. at ¶¶ 3, 7. In August 2023, Formycon announced that FDA had accepted its aBLA for FYB203. See id. ¶ 4. Because Formycon’s

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submission of its aBLA constitutes an alleged 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.

Plaintiff's counsel and U.S. counsel for each Defendant were in contact before each Complaint was filed as part of the required "patent dance" under 42 U.S.C. § 262(l). The parties spend significant time recounting counsels' specific communications - and lack thereof at peculiar intervals - in their papers. However, none of that is relevant to the Court's decision here.

II. APPLICABLE LAW AND ANALYSIS

Federal Rule of Civil Procedure 4(f)(3) provides for service upon parties in a foreign country by other means not prohibited by international agreement as may be directed by the court. See Fed. R. Civ. P. 4(f)(3). "Rule 4(f) does not denote any hierarchy or preference for one method of service over another." Enovative Techs., LLC v. Leor, 622 F. App'x 212, 214 (4th Cir. 2015) (citing Rio Props., Inc. v. Rio Int'l Interlink, 284 F.3d 1007, 1015 (9th Cir. 2002)). "The only limitations on Rule 4(f)(3) are that the means of service must be directed by the court and must not be prohibited by international agreement." Id. (citation omitted). "Service of process under Rule 4(f)(3) is neither a 'last resort'

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nor 'extraordinary relief.' It is merely one means among several which enables service of process on an international defendant." Id. (internal citation omitted).

District courts are invested with wide discretion in permitting service of process under Rule 4(f)(3), which "provides the Court with . . . flexibility and discretion . . . empowering courts to fit the manner of service utilized to the facts and circumstances of the particular case." See id. (quoting In re Int'l Telemedia Assocs., Inc., 245 B.R. 713, 719 (Bankr. N. D. Ga. 2000) (granting Rule 4(f)(3) motion approving service to defendant's last-known email address)). Service under Rule 4(f)(3) must also comply with Constitutional notions of due process. Specifically, any method of service ordered by the Court must be "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford then an opportunity to present their objections." Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950).

As Regeneron notes, service upon United States counsel has become common and in compliance with Due Process. See Celgard LLC v. Shenzhen Senior Tech. Material Co., LLC, 2020 WL 2575561, at *2 (W.D.N.C. May 21, 2020) ("[S]ervice of the[foreign] Defendants through their U.S. counsel would not be improper under Rule

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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"). Moreover, service via email has now been long recognized in this Court. In addressing a then-matter of first impression, Judge Keeley undertook an extensive analysis of Rule 4(f)(3), ultimately concluding that service via email was appropriate. See Williams v. Advertising Sex LLC, 231 F.R.D. 483, 488 (N.D.W. Va. 2005).

"Service of process refers to a formal delivery of documents that is legally sufficient to charge the defendant with notice of a pending action." Volkswagenwerk Aktiengesellschaft v. Schlunk, 486 U.S. 694, 700 (1988); see also § 1063 Subject Matter Jurisdiction, Venue, Personal Jurisdiction, and Service of Process Distinguished, 4 Fed. Prac. & Proc. Civ. § 1063 (4th ed.) ("The primary function of Rule 4 is to provide the mechanism for bringing notice of the commencement of an action to the defendant's

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attention and to provide a ritual that marks the court's assertion of jurisdiction over the lawsuit.").

Both the Republic of Korea and Germany are signatories to The Hague Convention. See HCCH Members, Hague Conference on Private International Law, <https://www.hcch.net/en/states/hcchmembers> (last visited Sept. 30, 2024). That convention does not address and, therefore, does not prohibit 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). Rule 4(f)(3) permits service on Defendants by email to their U.S. counsel.

Moreover, there is no basis in fact or reality to suggest any Defendant is unaware of this litigation. Each Defendant has made a special appearance via U.S. counsel to contest jurisdiction. Each Defendant has vigorously litigated issues implicated in Plaintiff's motions for preliminary injunction and each Defendant has now appealed the Court's ruling on those motions. Notice of this case, at this point, is but a formality. Therefore, nothing - the rules or the facts - should preclude Plaintiff from being permitted to serve each Defendant via email to U.S. counsel.

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III. CONCLUSION

"A suit at law is not a children's game, but a serious effort on the part of adult human beings to administer justice; and the purpose of process is to bring parties into court." United States v. A.H. Fischer Lumber Co., 162 F.2d 872, 873 (4th Cir. 1947). This case has and will continue to be litigated among sophisticated parties represented by capable and sophisticated counsel. Each of those groups knew this case was coming and has been involved from the outset. Bluntly, service via email among those "adult human beings" is appropriate. Id.

The following motions are **GRANTED**:

1. Civil Action No. 1:23-CV-89, ECF No. 43;
2. Civil Action No. 1:23-CV-94, ECF No. 38; and,
3. Civil Action No. 1:23-CV-97, ECF No. 31.

It is so **ORDERED**.

The Clerk is directed to forward a copy of this Order to all counsel of record.

DATED: September 30, 2024



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