

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: IPR2025-00456
U.S. Patent No. 11,084,865

PATENT OWNER'S SURREPLY
IN SUPPORT OF PRELIMINARY PATENT OWNER RESPONSE

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Exhibit	Description
2001-2021	<i>Previously presented.</i>
2022	Celltrion's Motion to Dismiss for Lack of Personal Jurisdiction, or Alternatively, to Transfer Venue, 23-cv-89, Dkt. 68 (N.D.W. Va. Jan. 17, 2024)

Celltrion filed its Petition more than one year after it waived service of Regeneron’s complaint—thus, its Petition is time-barred. Preliminary Patent Owner Response 15-20 (Paper No. 8, “POPR”). Celltrion’s Reply (Paper No. 11) offers no basis to conclude otherwise. Celltrion has no response to the basic legal proposition that the time bar of § 315(b) is triggered *either* by service or, as relevant here, by *waiver of service*. Reply 2-3; *see* POPR 15-16 (citing *Game & Tech. Co. v. Wargaming Grp. Ltd.*, 942 F.3d 1343, 1349 (Fed. Cir. 2019)). Moreover, Celltrion declares that its January 4, 2024 response to Regeneron’s motion did not waive service, Reply 3-5, but—remarkably—Celltrion says not one word about its repeated representations to the District Court that the issue of service “is moot” and “need not be addressed,” POPR 16-18 (citing Ex.2014, 1, 3). A claim of improper service cannot be simultaneously “moot” and a subject of live dispute—and Celltrion provides no justification for this nonsensical suggestion. Because Celltrion waived service on January 4, 2024, its Petition is time-barred under § 315(b).

I. Formal Service of a Complaint Is Unnecessary.

Celltrion does not contest that the time-bar clock under § 315(b) starts upon waiver of service, *see* Reply 3-5, yet its Reply focuses on the irrelevant question of whether formal service triggered the time bar—an argument Regeneron does not make. Reply 1-3. Precedent dictates that § 315(b) does not apply only when a defendant has been formally served. As the Federal Circuit has explained, “Section

315(b) does not itself define what it means to be ‘served with a complaint,’” so “the Board can look to multiple sources to discern the meaning of ‘served,’” including not only “Rule 4,” which “establishes the basic requirements for service in a federal court,” but also “the ordinary meaning of ‘served,’ *as well as common law interpreting Rule 4.*” *Game & Tech.*, 942 F.3d at 1349 (emphasis added) (summarizing cases). That common law dictates “that the service requirement is satisfied” not only “by proper service of process” but also by “consent, ***waiver***, or ***forfeiture*** by the defendant.” *Id.* (emphases added) (citing *King v. Taylor*, 694 F.3d 650, 655 (6th Cir. 2012)). Celltrion’s waiver of service on January 4, 2024, triggered the time bar, *see* POPR 15-16, and “subsequent events” after that waiver—including the Court’s grant of Regeneron’s alternative-service motion and the subsequent emailing of the Complaint—are “wholly irrelevant.” *Click-To-Call Techs., LP v. Ingenio, Inc.*, 899 F.3d 1321, 1330 (Fed. Cir. 2018), *vacated and remanded sub nom. on other grounds, Thryv, Inc v. Click-To-Call Techs., LP*, 590 U.S. 45 (2020), and *vacated sub nom.*, 810 F. App’x 881 (Fed. Cir. 2020).

II. Celltrion Waived Service as of January 4, 2024.

Celltrion waived service as of January 4, 2024, in its response to Regeneron’s alternative-service motion. In that filing, as Regeneron emphasized and Celltrion ignores entirely, POPR 16-20; Reply 1-5, Celltrion represented to the District Court that the issue of service “is moot” and “need not be addressed.” Ex.2014, 1, 3.

Celltrion’s declaration that service was “moot” meant that it “no longer involv[ed] a real, live controversy”—in other words, that Celltrion was not contesting service and had waived it. “Moot,” Black’s Law Dictionary (12th ed. 2024).

Celltrion’s response repeatedly confirmed its waiver of the service issue. Celltrion informed the Court that Regeneron’s alternative-service motion “is moot given that Celltrion intends to file a special appearance and motion to challenge venue in mid-January.” Ex.2014, 1. Celltrion confirmed that the Court “need not address Regeneron’s Motion.” *Id.* Celltrion explained that “Regeneron’s Motion is moot, and the Court need not address it,” because “[i]n order to efficiently move this matter along, Celltrion intends to file its motion to dismiss for lack of personal jurisdiction and improper venue by January 17, even though Celltrion has not been served (and no answer will be due on that date).” Ex.2014, 3. Finally, Celltrion reiterated that “[t]he issue of service ... need not be addressed by this Court.” *Id.* Thus, although Celltrion indicated that it would contest jurisdiction and venue, it repeatedly represented that it would not contest service.

These representations clearly effected a waiver of the issue of service. There can be no dispute that service is a waivable issue. *E.g., King*, 694 F.3d at 656 (explaining that a Rule 12 motion that fails to raise the defense of improper service “forever ‘waives’ that defense”). There likewise can be no dispute that waiver results from an “intentional relinquishment ... of a known right.” *United States v.*

Olano, 507 U.S. 725, 733 (1993). Here, Celltrion’s response unambiguously and repeatedly declared that Celltrion would *not* contest service—instead promising to file a Rule 12 motion based only on challenges to jurisdiction and venue. Ex.2014, 3 (“Celltrion intends to file its motion to dismiss ***for lack of personal jurisdiction and improper venue*** by January 17, even though Celltrion has not been served.” (emphases added)); *id.*, 1 (“[T]he Motion ***is moot*** given that Celltrion intends to file a special appearance and ***motion to challenge venue***.” (emphases added)). By representing to the Court and to Regeneron on January 4, 2024, that the service issue was “moot” and “need not be addressed” because Celltrion was seeking dismissal on bases *other than* service,¹ Celltrion waived the defense of improper service.

Celltrion cites a boilerplate footnote in its response to argue that it preserved all defenses merely by declaring that it “does not waive any objections or defenses.” Reply 4 (citing Ex.2014, 1 n.1). This vague reservation can hardly overcome Celltrion’s express representations that it would not contest the “moot” issue of service. *See, e.g., Bobo v. Umoh*, 2008 WL 4911222, at *1 (W.D. Ark. Nov. 13, 2008) (“generic assertion of the defenses available under Rule 12(b) was insufficient

¹ Consistent with those representations, Celltrion moved to dismiss solely “for lack of personal jurisdiction” (or alternatively to transfer); it never moved under Rule 12(b)(5) to dismiss for insufficient service of process. Ex.2022.

to preserve [the] objection to plaintiffs’ failure to perfect service of process”); *Tamarkin v. Valu Mgmt. Co.*, 2014 WL 4354388, at *3 (N.D. Ohio Sept. 2, 2014) (rejecting attempt to “raise[] and preserve[] each and every defense set forth in [Rule 12]” as “insufficient to preserve specific defenses”). Regeneron’s POPR (at 18) addressed this footnote, yet Celltrion ignores Regeneron’s position and sweeps its own “is moot” and “need not be addressed” statements under the rug. Reply 1-5. The notion that this generic footnote preserved the issue of service is irreconcilable with Celltrion’s specific and express statements that service was no longer a contested issue. Had Celltrion intended to contest service, it could not have been the case that service was “moot” and “need not be addressed.” Ex.2014, 3.

The circumstances here underscore why waiver of service triggers the time bar. By October 2024—the date Celltrion focuses on, Reply 2—it had been eleven months since Regeneron had sued Celltrion, eight months since Regeneron had filed its preliminary-injunction motion, and four months since that motion had been granted. That same month, briefing in Celltrion’s appeal would conclude. Celltrion’s post-hoc claim of having preserved a service defense contradicts its statements to the District Court and the reality of the parties’ extensive litigation, in which an entire preliminary-injunction proceeding was held.

Because Celltrion waived service—and thus triggered the § 315(b) time bar—on January 4, 2024, Celltrion’s Petition is untimely and institution should be denied.

Date: June 3, 2025

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CERTIFICATE OF SERVICE
(37 C.F.R. § 42.6(e))

The undersigned hereby certifies that on June 3, 2025, I caused true and correct copies of the following materials:

- Patent Owner's Surreply in Support of Preliminary Patent Owner Response
- Patent Owner's Exhibit List
- Exhibit 2022

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