

Filed on behalf of: Celltrion, Inc.
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2025-00456
Patent No. 11,084,865

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

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I. INTRODUCTION AND BACKGROUND¹

Regeneron's assertion in its Preliminary Response ("Response" or "POPR") that Celltrion's Petition challenging U.S. Patent 11,084,865 ("*US865*") is time-barred under 35 U.S.C. § 315(b) is meritless. The facts regarding Regeneron's service of its complaint are undisputed. On November 8, 2023, Regeneron filed a complaint alleging infringement of *US865*. EX2017, 1. The parties then negotiated over service, during which Celltrion's counsel repeatedly stated that it would waive service if Regeneron would comply with Rule 4(d). Regeneron refused. EX2014, 1-2. Regeneron filed a motion for alternative service on December 22, 2023. EX2013, 15.

On January 4, 2024, Celltrion made a special appearance to respond to Regeneron's motion. EX2014, 1 n.1. Celltrion not only disputed that it had been served but also specified that its appearance was for the limited purpose of opposing the motion, expressly stating that Celltrion "does not waive any objections or defenses, including those identified in Rule 12 ..., and specifically objections and defenses based on the lack of personal jurisdiction" *Id.* Celltrion further stated that it would file a motion to dismiss contesting personal jurisdiction and venue. *Id.*, 3. Celltrion again made a special appearance on January 17, 2024,

¹ This Reply was authorized in an email dated May 20, 2025.

filing its motion to dismiss. On September 30, 2024, the court granted Regeneron's motion for alternative service. EX2016, 8. On October 16, 2024, Regeneron finally served Celltrion by emailing the complaint to Celltrion's counsel "in accordance with the Court's Order Granting Motions for Alternative Service." EX2017, 2. Celltrion filed the instant IPR on January 15, 2025, less than three months after Regeneron admits that it served its complaint. *Id.*

II. CELLTRION'S PETITION IS NOT TIME-BARRED BECAUSE IT WAS FILED WITHIN THREE MONTHS OF SERVICE

The Board should reject Regeneron's time-bar argument for one simple reason—Celltrion was served the district court complaint on October 16, 2024, and filed its petition within three months of service. Regeneron's theory that Celltrion somehow waived service by making a special appearance for the specific purpose of contesting personal jurisdiction is demonstrably false.

A. Under the Facts Admitted by Regeneron, Celltrion Was Served and Filed its Petition Within the One-Year Limitations Period.

Regeneron cannot contest that Celltrion filed the Petition less than three months after being served with the complaint. Based on Regeneron's own admissions in its Response, that fact is sufficient to dispose of this issue.

Regeneron admits that the time-bar deadline under § 315(b) is based on service of the complaint. POPR, 15. Regeneron also admits that it filed a motion for alternate service, which was granted, and that it served the complaint on Celltrion

pursuant to the district court's order. *Id.*, 19 n.2. Although Regeneron self-servingly characterizes this service as “prophylactic,” *id.*, this admission only underscores that the complaint was not properly served before that date.

The cases Regeneron cites show that service matters, and “confirm that the plain meaning of the phrase ‘served with a complaint’ is ‘presented with a complaint’ or ‘delivered a complaint’ in a manner prescribed by law.” *Click-To-Call Techs., LP v. Ingenio, Inc., YellowPages.com, LLC*, 899 F.3d 1321, 1330 (Fed. Cir. 2018) (emphasis added). The Board decisions Regeneron relies on confirm this point, finding that neither attaching a proposed amended complaint to a motion for leave to amend nor defective service followed by subsequent effective service triggered § 315(b) until actual service was completed “in a manner prescribed by law.” *Amneal Pharms., LLC v. Endo Pharms. Inc.*, IPR2014-00360, Paper 15, 8-10; *Gordon * Howard Assocs., Inc. v. Lunareye, Inc.*, IPR2014-01213, Paper 11, 18. Notably, the Board held in *GoPro, Inc. v. 360Heros, Inc.*, IPR2018-01754, Paper 38, 14 (Precedential) that “*Click-to-Call* is unequivocal that ‘the text of § 315(b) *clearly and unmistakably* considers *only the date* on which the petitioner ... was properly served with a complaint.’” There is simply no argument that Regeneron served Celltrion prior to October 16, 2024.

B. Regeneron’s Argument that Celltrion Waived Service of the Complaint Is Demonstrably False.

Regeneron argues that Celltrion “waived service” on January 4, 2024, when

Celltrion told the district court that it “intends to file a special appearance and file a motion to challenge venue in mid-January.” POPR, 16. This misstates the proceedings in the district court. Celltrion made quite clear to the district court that Celltrion had **not** been served, and that it intended to contest personal jurisdiction.

Regeneron filed a Motion for Alternative Service on December 22, 2023, EX2013, and Celltrion responded to that motion, specifically stating that it makes only a “**special appearance**” and “**does not waive** any objections or defenses.” EX2014, 1 n.1 (emphasis added). Most importantly, Celltrion explained that it had “invited Regeneron on numerous occasions ... to provide it with an appropriate **notice and waiver request** under Rule 4(d),” which Regeneron refused. *Id.*, 1-2 (emphasis added). Celltrion pointed out that the Court need not address service at that time because Celltrion was going to file a motion to dismiss on January 17, 2024, “even though Celltrion **has not been served** (and no answer will be due on that date).” *Id.*, 3 (emphasis added). There is simply no way that Celltrion’s January 4, 2024, response brief could constitute a waiver of service, when the entire content of the brief **advised the district court that Celltrion had not been served**. Regeneron further argues that Celltrion’s actions “led both Regeneron and the District Court to believe that Celltrion would not contest the adequacy of service.” POPR, 18. However, this is belied by the court’s subsequent grant of Regeneron’s motion for alternative service, EX2016, and Regeneron’s decision to

serve its complaint “in accordance with the Court’s Order....” EX2017, 2.

The cases Regeneron cites in support of this waiver-by-conduct argument are clearly distinguishable from the facts here. In *Game & Tech. Co., Ltd. v. Wargaming Grp. Ltd.*, 942 F.3d 1343, 1349-51 (Fed. Cir. 2019), the Federal Circuit affirmed the Board’s ruling that neither two defective service attempts nor a purported waiver by petitioner’s attorneys triggered § 315(b). Neither of the two cases Regeneron cites in which waiver of service by conduct was found involved an IPR. More importantly, in both *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 1718826, at *2-3 (S.D. W. Va. Apr. 27, 2016) and *Trs. of Cent. Laborers’ Welfare Fund v. Lowery*, 924 F.2d 731, 733-34 (7th Cir. 1991), the defendants undertook multiple actions that invoked the court’s authority prior to contesting either sufficiency of service or personal jurisdiction. Those cases are in clear contrast to this case, where the first filings Celltrion made were special appearances for the express purpose of contesting the court’s authority over it, and where the district court later granted a motion for alternative service. There is simply no way that such conduct could possibly constitute a waiver.

III. CONCLUSION

For the reasons set forth above, Celltrion respectfully requests that the Board find that Celltrion’s Petition is not time-barred and institute trial.

Respectfully submitted,

Dated: May 27, 2025

/ Lora M. Green /

Lora M. Green, Lead Counsel

Reg. No. 43,541

CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. § 42.6(e), I hereby certify that on May 27, 2025, true and correct copies of Petitioner's Reply to Patent Owner's Preliminary Response were served via electronic mail to Patent Owner at the following email addresses of record:

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