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 DISCRETIONARY DENIAL REPLY

# TABLE OF CONTENTS

TABLE OF AUTHORITIES ..... ii

TABLE OF EXHIBITS ..... iii

I. Celltrion's Stipulation Does Not Outweigh the Substantial Investment. ..... 1

II. Celltrion's *Sotera* Stipulation Does Not Make This IPR a True Alternative. ..... 3

# TABLE OF AUTHORITIES

## CASES

*Apple Inc. v. Fintiv, Inc.*,
IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020).....3

*Duke Mfg. v. Low Temp Indus.*,
IPR2021-00415, Paper 13 (P.T.A.B. July 20, 2021).....2

*Hyatt v. Boone*,
146 F.3d 1348 (Fed. Cir. 1998).....4

*Lockwood v. Am. Airlines, Inc.*,
107 F.3d 1565 (Fed. Cir. 1997).....4

*Motorola Sols., Inc. v. Stellar, LLC*,
IPR2024-01205, Paper 19 (P.T.A.B. Mar. 28, 2025).....1, 2, 3, 4

*Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*,
714 F. Supp. 3d 652 (N.D.W. Va. 2024).....2

## OTHER AUTHORITIES

35 U.S.C. § 112.....4

35 U.S.C. § 119.....4

35 U.S.C. § 120.....4

MPEP § 2163.....4

## TABLE OF EXHIBITS

| Exhibit | Description |
|---|---|
| 2001-2021 | *Previously presented*. |

Celltrion's Petition should be denied because it seeks to relitigate for the seventh time the adequacy of the '865 patent's written description, under the guise of a priority-date challenge. Celltrion's belated *Sotera* stipulation, filed months after its Petition, does nothing to change that, as Celltrion's stipulation neither outweighs the substantial investment that has already occurred in the parallel proceedings nor prevents the wasteful duplication of effort that institution of Celltrion's Petition would create. The Board should deny institution.

## I. Celltrion's Stipulation Does Not Outweigh the Substantial Investment.

The Board has rejected the adequacy of a *Sotera* stipulation where a substantial investment has been made in a parallel proceeding. *Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 4 (P.T.A.B. Mar. 28, 2025) (concluding that "the stipulation does not outweigh the substantial investment in the district court proceeding"). Such is the case here, where four parallel proceedings yielded six decisions directly addressing and upholding written description of the '865 patent. Paper No. 7 ("Br.") 5-17.

Celltrion's fantastical assertion that "[t]he district court's investment in the parallel litigation involving Celltrion, as well as Samsung and Formycon has been minimal," Paper No. 9 ("Opp.") 32, defies the reality of three detailed preliminary-injunction decisions and three separate affirmances by two distinct panels of the Federal Circuit, in addition to the District Court's *Mylan* decision following a two-

week bench trial—totaling hundreds of pages of analysis directed to the '865 patent. Br. 17-18. Celltrion's sole authority is off base. Opp. 32-33 (citing *Duke Mfg. v. Low Temp Indus.*, IPR2021-00415, Paper 13 at 13 (P.T.A.B. July 20, 2021)). There, the petition was filed five months before—not seven months after—the preliminary injunction was granted, only one preliminary injunction was at issue, it had not yet been affirmed, and "[t]he determination underlying the grant of the preliminary injunction d[id] not go to" the patent for which IPR was sought "at all." *Duke*, IPR2021-00415, Paper 13 at 2, 13-14; *id.*, Ex.2019. Here, in contrast, six pertinent decisions addressed written description of the '865 patent.

Celltrion urges disregard of "the district court's investment in the *Mylan* trial" because it "involved different written description arguments." Opp. 33. Celltrion is mistaken; its arguments here squarely overlap with those addressed in *Mylan*. *Compare*, *e.g.*, Opp. 3 ("[T]he *US865* disclosure fails to support the broad scope of the formulations of the claims challenged here."), *and* Opp. 16 ("[T]he examples … do not support the broad challenged claims."), *with*, *e.g.*, *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652, 751 (N.D.W. Va. 2024) ("[T]he POSA … could recognize from the specification that the inventors invented the claimed formulations."), *and id.* at 751-53 ("[E]ach of the examples" "allowed the POSA to recognize [the claimed formulations]," "all of the ['865] Patent's examples have 'at least 98 percent native conformation,'" and "the examples in the specification were

predictive of the performance of formulations that were not exemplified in the patent.").

The parties' and courts' investment in the parallel proceedings here dwarfs anything in *Motorola* and vastly outweighs Celltrion's *Sotera* stipulation. For nearly three years, Regeneron and multiple biosimilars (including Celltrion) have litigated the adequacy of the '865 patent's written description, resulting in one bench-trial decision, three preliminary-injunction decisions, and two Federal Circuit decisions. Br. 17-21. Those six decisions—totaling hundreds of pages, with dozens on written description alone—were the product of thousands of pages of briefing, a two-week trial, a lengthy *Markman* hearing, three oral arguments before two Federal Circuit panels, many hours of expert depositions, and thousands of pages of expert opinions. *Id.* Celltrion's stipulation simply cannot "outweigh the substantial investment in the district court proceeding[s]" and appeals here. *Motorola*, IPR2024-01205, Paper 19 at 4; *see also Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *6 (P.T.A.B. Mar. 20, 2020) (precedential) (denial appropriate where "issues are the same as, or substantially similar to, those already … litigated").

## II. Celltrion's *Sotera* Stipulation Does Not Make This IPR a True Alternative.

Celltrion's *Sotera* stipulation also fails to "ensure that these IPR proceedings would be a 'true alternative' to the district court proceeding[s]." *Motorola*, IPR2024-01205, Paper 19 at 3-4. According to Celltrion, "the challenges in this IPR

concern the effective filing date of *US865*, an issue not raised by Celltrion (or any other defendant) in the district court, or at the Federal Circuit." Opp. 16. But this assertion is premised on a false distinction between the priority and written-description inquiries. The Federal Circuit has repeatedly held that a priority claim under §§ 119 & 120 requires "compl[iance] with the written description requirement of 35 U.S.C. § 112," *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997)—which is why Celltrion's Petition focuses predominantly on written description. *See also Hyatt v. Boone*, 146 F.3d 1348, 1354 (Fed. Cir. 1998); MPEP § 2163. There is no meaningful distinction between the priority-date challenge in Celltrion's Petition and the written-description challenges Celltrion and the other biosimilars have already raised before the District Court and Federal Circuit.

What is more, Celltrion appears to argue that its stipulation would not prevent it from simultaneously making the same written-description arguments before both the District Court and the Board. Celltrion asserts that "[t]he preliminary written description argument made to the district court was also very different than the priority challenge in the Petition." Opp. 16. According to Celltrion, then, its stipulation allows simultaneously raising identical written-description arguments before both the Board to challenge priority and the District Court to challenge validity under § 112. In Celltrion's view, therefore, its stipulation does not "mitigate … concern of duplication." *Motorola*, IPR2024-01205, Paper 19 at 4.

Over years of patent litigation against Regeneron, Celltrion made the tactical choice not to seek IPR of the '865 patent even as it contemporaneously challenged other Regeneron patents (Opp. 9), instead electing to contest validity of the '865 patent before the District Court. There, Celltrion, along with Samsung and Formycon, developed written-description defenses through their shared expert Dr. Tessier; but when those proved unsuccessful, Celltrion abandoned them on appeal. Opp. 1, 13-14, 18. Having lost in court, Celltrion sought a do-over from the Board in January 2025—fourteen months after it was sued, twelve months after it learned that Regeneron had successfully asserted the '865 patent against Mylan's biosimilar, eleven months after Regeneron filed its preliminary-injunction motion asserting the '865 patent, seven months after Celltrion was enjoined, and two months after Celltrion's appeal had been fully briefed. But a *Sotera* stipulation is not a magic eraser that can undo the consequences of Celltrion's strategic choices or render irrelevant the extensive investment in the parallel proceedings upholding the adequacy of the '865 patent's written description. And were Celltrion's baseless distinction between priority and written description to be adopted, its *Sotera* stipulation would not meaningfully narrow its subsequent defenses in the District Court. The Board should therefore deny institution.

Date: May 27, 2025

/David I. Berl/
David I. Berl
Reg. No. 72,751

Williams & Connolly LLP
680 Maine Street SW
Washington, D.C. 20024
Lead Counsel for Patent Owner

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

The undersigned hereby certifies that on May 27, 2025, I caused true and correct copies of the following materials:

- Patent Owner's Discretionary Denial Reply
- Patent Owner's Exhibit List

to be served via e-mail on the following:

| Name | E-Mail Address |
|---|---|
| Lora M. Green | lgreen@geminilaw.com |
| Robert Cerwinski | rcerwinski@geminilaw.com |
| Michael Johnson | mjohnson1@willkie.com |
| Keith A. Zullow | kzullow@geminilaw.com |
| Michael Cottler | mcottler@geminilaw.com |
| Yahn-Lin (Franklin) Chu | fchu@geminilaw.com |
| Aviv Zalcenstein | azalcenstein@geminilaw.com |

Date: May 27, 2025

/David I. Berl/
David I. Berl
Reg. No. 72,751
Lead Counsel for Patent Owner