

Filed on behalf of: Celltrion, Inc.
By: Lora M. Green (lgreen@geminilaw.com)

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 SURREPLY TO
PATENT OWNER'S DISCRETIONARY DENIAL REPLY**

TABLE OF CONTENTS

	<u>Page</u>
I. Introduction and Background	1
II. Celltrion’s <i>Sotera</i> Stipulation Outweighs the Investment in Prior Proceedings Because Its IPR Arguments Are Different.	2
A. Celltrion’s IPR Arguments Have Not Been Raised Before.	2
B. The <i>Mylan</i> Decision Is Not the Same Scope as Celltrion’s Petition.....	4
III. Celltrion’s <i>Sotera</i> Stipulation Makes This a True Alternative.....	4
IV. Conclusion	5

I. INTRODUCTION AND BACKGROUND¹

Regeneron's reply brief simply repeats the arguments in its original brief without refuting the key points regarding Celltrion's *Sotera* stipulation: (1) that Celltrion's arguments in this IPR are different than those before the district court; and (2) that Celltrion *still does not have a trial date* in the district court and has no reason to expect trial before this IPR is decided. In addition, the record below has been limited. Despite "hundreds of pages" of decisions, three decisions are preliminary and not based on full fact or expert discovery, and one is from a Mylan trial that occurred before Celltrion was even sued and was vacated by a settlement before Federal Circuit review.

Celltrion's situation is thus readily distinguishable from *Motorola*, where the parties "had served extensive infringement and invalidity contentions, served opening and rebuttal expert reports, filed claim construction briefs, and conducted several depositions," construed claims, and had a scheduled trial date "*eleven months before* the Board's projected final written decision date." *Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19, 4 (emphasis added). Regeneron also tries to distinguish from *Duke Mfg. v. Low Temp Indus.*, IPR2021-00415, Paper 13, 14, but, like in *Duke*, "much work remains to be done in the district court" in this case. Thus, discretionary denial is not warranted.

¹ This Surreply was authorized in an email dated May 22, 2025.

II. CELLTRION'S *SOTERA* STIPULATION OUTWEIGHS THE INVESTMENT IN PRIOR PROCEEDINGS BECAUSE ITS IPR ARGUMENTS ARE DIFFERENT.

Regeneron argues that Celltrion's *Sotera* stipulation does not outweigh the "substantial investment" in prior district court proceedings because Celltrion's arguments have already been made by itself or others in those proceedings, such as the *Mylan* proceeding. Regeneron is wrong.²

A. Celltrion's IPR Arguments Have Not Been Raised Before.

Celltrion's arguments in the district court related to the lack of written description supporting the ***claimed range*** of 98-100% native conformation. Celltrion's arguments in this IPR relate to Regeneron's lack of written description in its priority documents for its claimed ***stability limitations*** and ***glycosylation limitation***. These are different arguments based on very different evidence.

Celltrion's argument in the district court was that U.S. Patent No. 11,084,865 ("*US865*") lacked written description because its claimed range of 98-100% native conformation was not described in the specification. Opposition to Discretionary Denial Brief, 15 ("Opp."). Because the % native conformation data in the *US865* examples only went up to 99.2%, and a POSA would have known it is difficult to approach 100% stability, a POSA would not have recognized that Regeneron possessed the claimed range. *Id.* ***In contrast***, Celltrion's argument in

² The timing of Celltrion's petition was addressed in Celltrion's May 27, 2025, reply to the patent owner's preliminary response.

this IPR is that *US865* lacks an effective filing date earlier than U.S. Patent Publication No. 2007/0293432 (“*US432*”) because Regeneron’s priority applications do not provide written description support for the claimed stability limitations or broad glycosylation limitation. Celltrion’s IPR petition has at least three significant differences from the arguments made in the district court.

First, Celltrion presents evidence that Regeneron’s *own expert*, Dr. Klibanov, testified that stability is unpredictable, based on differences in glycosylation, excipients, and other factors. Opp., 16-17, 20, 24-25. This proves that the narrow range of formulations in the *US865* examples do not support the broad claims. *Id.*, 16, 21. This testimony was not presented or argued by *any* party in the district court, and Regeneron does not address this in its reply. **Second**, Celltrion points out the inconsistencies in Regeneron’s measurement errors using SEC as evidenced by the “% VEGF Trap Recovered” data. *Id.*, 17. Despite being measured in the same way as the “% VEGF Trap Native Configuration,” the “% VEGF Trap Recovered” measurement errors may be as high as **13%**, which far exceeds the claimed 1-2% stability range. *Id.*, 25. This argument was neither made to the district court nor addressed in Regeneron’s reply. **Third**, Celltrion argues that *US865* lacks priority for its broad glycosylation claims because the shared specification only discloses a single glycosylation variant. *Id.*, 27. This argument **was not made** in the district court (*id.*, 27) or addressed in Regeneron’s reply.

B. The *Mylan* Decision Is Not the Same Scope as Celltrion’s Petition.

Rather than focus on Celltrion’s prior arguments, Regeneron argues that Celltrion is repeating others’ arguments, particularly *Mylan*. The *Mylan* trial ended before Celltrion was *even sued*. Celltrion did not participate in the trial, it involved different evidence than Celltrion presents in its petition, and Regeneron settled with *Mylan* rather than let the Federal Circuit review the decision. Opp., 18-22.

Moreover, the *Mylan* decision proves Celltrion’s point, as many of the claims challenged in this petition (claims 1-50) are far broader than in *Mylan*. The district court explained its rationale as follows: “Because the claims are drawn to a specific protein *at a specific concentration* with *specific concentration ranges of polysorbate 20*, the Court holds that the specification allows the POSA ‘to visualize or recognize the identity of the subject matter purportedly described’ and thus meets the written description requirement.” *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 714 F. Supp. 3d 652, 751 (N.D.W. Va. 2024) (emphasis added). The claims challenged in this petition are different. In *Mylan*, Regeneron asserted only claims 4, 7, 8, 11, 14, 15, 16, and 17. *Id.*, 676. Moreover, even claim 4 is not as limited in scope as the examples. *Id.*, 20-21, 24. For all these reasons the *Mylan* decision provides no ground for discretionary denial.

III. CELLTRION’S *SOTERA* STIPULATION MAKES THIS A TRUE ALTERNATIVE.

Celltrion has provided as many assurances as possible to show that this IPR

proceeding will not waste judicial resources or overlap with the district court.

Celltrion has not only stipulated that it will not raise any argument before the district court that it raised or reasonably could have raised in its petition (including the same priority and written description arguments) but also agreed not to seek a trial on *US865* before any final written decision by the Board. Opp., 2.

Moreover, despite Regeneron's assurances in its opening brief that a trial date was forthcoming, the parties ***still do not have a trial date*** in the district court. In fact, they do not even have a scheduling conference set to ***discuss*** a trial date. And the statistics from Northern District of West Virginia show that a trial is not likely anytime soon. As noted in Formycon's Reply, the median time-to-trial in the district is 676 days. *Formycon AG v. Regeneron Pharms., Inc.*, IPR2025-00233, Paper 12, 4.³ Thus, like the acting Director's recent decisions in *Twitch Interactive, Inc. v. Razdog Holdings LLC*, IPR2025-00307, Paper 18, 2 and *Amazon.com v. NLGiken, Inc.*, IPR2025-00250, Paper 14, 2, discretionary denial is not warranted.

IV. CONCLUSION

For the reasons set forth above, Celltrion respectfully requests that the Board find that discretionary denial is not appropriate and institute trial.

³ Indeed, looking specifically at patent cases on Docket Navigator, the median time to trial in the district is 30 months (over 900 days).

Respectfully submitted,

Dated: May 30, 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 30, 2025, true and correct copies of Petitioner's Surreply to Patent Owner's Discretionary Denial Reply were served via electronic mail to Patent Owner at the following email addresses of record:

David Berl
Andrew Trask
Arthur Argall
WILLIAMS & CONNOLLY LLP
dberl@wc.com
atrask@wc.com
aargall@wc.com

Elizabeth Weiswasser
Priyata Patel
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
eweiswasser@paulweiss.com
ppatel@paulweiss.com

Respectfully submitted,

Dated: May 30, 2025

/ Lora M. Green /
Lora M. Green, Lead Counsel
Reg. No. 43,541