

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 BRIEF

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2004	Celltrion Redacted PI Decision, 24-md-3103, Dkt. 248 (N.D.W. Va.)
2005	SB Appeal Decision, 24-1965, Dkt. 76 (Fed. Cir.)
2006	Formycon Appeal Decision, 24-2009, Dkt. 67 (Fed. Cir.)
2007	Celltrion Appeal Decision, 24-2058, Dkt. 62 (Fed. Cir.)
2008	Exhibit A, Samsung Bioepis's Proposed Schedule, 24-md-3103, Dkt. 478-1 (N.D.W. Va.)
2009	Regeneron Pharmaceuticals, Inc.'s Response to Defendant Samsung Bioepis Co., Ltd.'s Motion for Entry of Scheduling Order Pursuant to Rule 16 or, in the Alternative, a Status Conference, 24-md-3103, Dkt. 483 (N.D.W. Va.)
2010	Celltrion's Opening Appeal Brief, 24-2058, Dkt. 25 (Fed. Cir.)
2011	Celltrion's Reply in Support of Celltrion's Motion for Status Conference, 24-md-3103, Dkt. 504 (Fed. Cir.)
2012	Celltrion's Redacted Brief in Opposition to Regeneron's Preliminary Injunction Motion, 23-cv-89, Dkt. 142-3 (N.D.W. Va.)

Celltrion's Petition is a poster child for discretionary denial. *Four* decisions of the Northern District of West Virginia and *two* decisions of the Court of Appeals for the Federal Circuit already have rejected substantially similar validity challenges to Regeneron's U.S. Patent No. 11,084,865 ("865 patent")—on appeal, after trial, and at the preliminary-injunction stage. Celltrion offers no reason to believe that the *seventh* time will be the charm.

To the contrary, Celltrion itself already has tried and failed to establish a substantial question of invalidity as to the '865 patent, in an unsuccessful bid to avoid a preliminary injunction. The District Court rejected Celltrion's invalidity theories and issued the injunction, Celltrion appealed, and the Federal Circuit affirmed. Remarkably, despite appealing (unsuccessfully) numerous aspects of the District Court's judgment, Celltrion *did not even bother* to appeal that Court's rejection of its written-description theory—the same theory (reformulated as a priority-based challenge) on which its entire Petition now rests. The District Court litigation remains pending and Celltrion may renew its validity challenges at trial, before a Court that already has issued hundreds of pages of opinions regarding the validity of the '865 patent. Institution of yet *another* proceeding to adjudicate these issues would be wildly inefficient and wasteful of resources. The Board should exercise its discretion under 35 U.S.C. § 314(a) to deny institution of Celltrion's Petition.

I. Introduction

The '865 patent discloses and claims the formulation of Regeneron's biologic drug, Eylea®, a groundbreaking treatment for certain vision-threatening disorders of the eye. For the past two-and-a-half years, Regeneron has been engaged in parallel patent litigation before Chief Judge Thomas Kleeh in the Northern District of West Virginia ("District Court") against multiple entities seeking to market biosimilar versions of Eylea®, including Celltrion. The focal point of that litigation has been the '865 patent. In 2023, the District Court presided over a *Markman* hearing and a two-week bench trial against the first biosimilar applicant, Mylan. Celltrion and two other biosimilars—Samsung Bioepis ("SB") and Formycon—filed biosimilar applications after Mylan, and Regeneron sought preliminary injunctions against each. In all of these proceedings, Regeneron asserted the '865 patent, and across *four* decisions—one 313-page bench-trial decision, and three ~200-page decisions granting preliminary injunctions, Ex.2001-2004—the District Court upheld the '865 patent against every validity challenge the defendants could conjure, including written-description challenges redolent of Celltrion's priority-based argument here. In particular, four biosimilars—including Celltrion—argued that the '865 patent was invalid because its specification failed to provide adequate written-description support for the same limitations of the same claims of the same patent that Celltrion challenges here. Not one of them succeeded.

Each of the biosimilar applicants appealed the District Court’s adverse judgments. SB and Formycon each challenged the District Court’s written-description holdings. Celltrion challenged numerous aspects of the District Court’s judgment but elected *not* to appeal the District Court’s rejection of its written-description argument—*i.e.*, the very issue underlying the priority-based challenge in Celltrion’s Petition. The Federal Circuit affirmed the District Court’s judgments in the *Celltrion*, *SB*, and *Formycon* appeals. See *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 706079 (Fed. Cir. Mar. 5, 2025) (“*Celltrion*”); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 127 F.4th 896 (Fed. Cir. 2025) (“*SB*”); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 324288 (Fed. Cir. Jan. 29, 2025) (“*Formycon*”). In the *Mylan* appeal, following oral argument the parties filed a joint voluntary dismissal to resolve the appeal. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2002, Dkt. 58 (Fed. Cir. Apr. 14, 2025).

Thus, as it stands, the District Court and the Federal Circuit have considered hundreds of pages of briefing and thousands of pages of expert testimony addressing the ’865 patent. And in each case decided to date that addressed written description—one bench-trial decision, three preliminary-injunction decisions, and two appellate decisions—the District Court and the Federal Circuit have upheld the validity of the ’865 patent against written-description challenges. Those failed challenges argued that the ’865 patent lacked Section 112 support in the ’865

patent's specification, and thus were substantially similar to the argument Celltrion advances here, namely, that the challenged claims are unsupported by the specification of a priority application that is identical to the specification of the '865 patent.

Remarkably, Celltrion never acknowledges that its Petition effectively seeks reversal of at least six judicial decisions, including two by the very Court that would review this Board's adjudication of its Petition (if instituted). And Celltrion never justifies advancing a Petition based on a written-description theory that was not only rejected by the District Court, but that Celltrion itself did not even deem worthy of appealing. Instead, Celltrion simply ignores the mountains of work the District Court already has done to adjudicate this issue in the pending litigation, while demanding a do-over in the form of an entirely new proceeding on the same issue before this Board. Celltrion's self-granted mulligan is precisely the kind of inefficient and duplicative validity challenge that *Fintiv* forecloses.

Celltrion's Petition thus flouts the AIA's basic objective of "provid[ing] an effective and efficient alternative to the district court litigation." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, 2018 WL 4373643, at *7 (P.T.A.B. Sept. 12, 2018) (precedential) (citation omitted). It is difficult to imagine a less efficient use of the Board's resources than to adjudicate, for the seventh time, the same disputes the District Court and Federal Circuit already have resolved in Regeneron's

favor six times, across hundreds of pages of decisions. *Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 2-3 (P.T.A.B. Mar. 28, 2025) (denying institution based on substantial investment in singular parallel proceeding and incomplete overlap in issues and arguments). As explained below, the *Fintiv* factors all strongly favor non-institution or at most are neutral.

II. Background

A. Parallel Proceedings

Regeneron sued Mylan, SB, Formycon, Celltrion, and Amgen for infringement of the '865 patent. These suits have been consolidated for pre-trial purposes as a multidistrict litigation in the Northern District of West Virginia. *In re Aflibercept Pat. Litig.*, 730 F. Supp. 3d 1374, 1377 (J.P.M.L. 2024). That court has issued one bench-trial decision (*Mylan*) and four preliminary-injunction decisions (*SB*, *Formycon*, *Celltrion*, and *Amgen*); in each other than *Amgen* (which did not address invalidity), the District Court rejected written-description challenges to the '865 patent.

On appeal, the Federal Circuit affirmed the three preliminary-injunction decisions addressing invalidity. These decisions repeatedly have confirmed that:

(1) there is adequate written description of aflibercept formulations that achieve “at least 98% native conformation,” including both the lower and upper ends of that range, *SB*, 127 F.4th at 915-17; *Formycon*, 2025 WL

324288, at *7; *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652, 751-54 (N.D.W. Va. 2024) (“*Mylan*”); *In re Aflibercept Pat. Litig.*, 2024 WL 3422971, at *34-35 (N.D.W. Va. June 24, 2024) (“*SB PI Decision*”); *In re Aflibercept Pat. Litig.*, 2024 WL 3423047, at *38-40 (N.D.W. Va. July 9, 2024) (“*Formycon PI Decision*”); Ex.2004 (*Celltrion PI Decision*) at 118-24;¹

(2) the “at least 98% native conformation” limitation does not require a comparison of the amount of intact aflibercept present at the time of measurement to the amount present at time zero, *Celltrion*, 2025 WL 706079, at *3; *Formycon*, 2025 WL 324288, at *5; and

(3) there is adequate written description of “glycosylated” aflibercept, *SB*, 127 F.4th at 914-15.

B. Celltrion’s Petition

Celltrion’s Petition repeats written-description and claim-construction arguments already considered and rejected multiple times by the District Court and Federal Circuit decisions that Celltrion’s Petition wholly ignores. For instance, Celltrion principally asserts that there is inadequate written-description support for

¹ The District Court’s validity analyses in the *SB PI Decision*, *Formycon PI Decision*, and *Celltrion PI Decision* are substantially similar, as the three defendants raised substantially similar validity challenges, including written-description defenses. For brevity, Regeneron generally cites the *Celltrion PI Decision*.

the native-conformation limitations, maintaining that the specification does not support the 98% and 99% lower limits, a purported 100% upper limit, or that “the broad range of formulations encompassed by the claims” can achieve the claimed stability. Pet. 2-3, 32-45. Celltrion also advances a twice-rejected claim construction of the native-conformation limitations that would require a “comparison” of the amount of intact VEGF antagonist present after storage versus at time zero. Pet. 24-26, 32, 37, 39, 43. Celltrion further asserts that there is no written-description support for the “glycosylated” limitation. Pet. 2-3, 45-46.

As the table below sets forth, each of those arguments has been repeatedly rejected by decisions of the District Court or Federal Circuit:

Celltrion’s Petition	District Court and Federal Circuit
“Despite the <i>broad genus of glycosylated VEGF antagonist proteins</i> covered by the challenged claims, US865 mentions glycosylation only once, and only in the context of describing one specific glycosylated VEGF antagonist, aflibercept, which has a specific glycan structure. Similarly, despite Regeneron’s <i>broad claims to a genus of VEGF antagonists containing a buffer, a sugar, and an</i>	“[Regeneron’s expert] Dr. Trout testified that each of the claim limitations in the [’865] Patent have <i>‘common structural features,’ including the ‘very specific’ VEGF antagonist</i> and the categories of organic co-solvent, buffer, and stabilizing agent. He further testified that these structures were well known in the art.... The Court credits Dr. Trout’s analysis and conclusion.”

<i>organic co-solvent covered by the challenged claims</i>, the specification discloses stability testing only for formulations containing a specific VEGF antagonist, aflibercept, and only for a handful of formulations containing the specific buffer phosphate, the specific sugar sucrose, and the specific organic co-solvents polysorbate 20 and polyethylene glycol 3350 for specified lots of aflibercept.” Pet. 2-3 (emphases added).	<i>Mylan</i>, 714 F. Supp. 3d at 751-52 (emphasis added) (citations omitted).
“Accordingly, this claim phrase should be construed such that the ‘at least 98% or 99%’ is in <i>comparison with the amount of VEGF antagonist that is in intact functional form at time zero.</i>” Pet. 25 (emphasis added).	<i>“According to Celltrion, the common knowledge of a person of ordinary skill in that art and the intrinsic evidence make clear that the at least 98% limitation in the ’865 patent defines a rate of aggregation over a particular time, under particular conditions. We disagree.</i> Celltrion’s argument contradicts the plain claim language, which states that ‘at least 98% of the VEGF antagonist is present in native conformation following ... storage for two months as measured by SEC.’

	<i>Nothing in the claims or specification suggests that a rate must be calculated. Rather, the claim states that after two months, the formulation is measured by SEC, and the result is either above 98%—within the scope of the claim—or below 98%—outside the scope of the claim.</i> On this record and even under de novo review of the claim construction issue, we discern no error in the district court’s analysis.” <i>Celltrion</i>, 2025 WL 706079, at *3 (emphasis added) (internal quotation marks omitted). “Formycon argues for inherency on the ground that the ‘native conformation’ limitation in the ’865 patent ... refer[s] not to the starting point but to the amount of change in the percentage of native conformation after the period of time specified in the claims.... [A] <i>substantial argument would be needed to overcome the apparent meaning of the claim language on its face, which requires that at least 98% of the VEGF</i>
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	<i>antagonist is present in native conformation following storage for two months—a reference simply to a property at that time—without calling for a comparison to an earlier time.”</i> <i>Formycon</i>, 2025 WL 324288 at *5 (cleaned up) (emphasis added).
“Notably, nothing in the general disclosure, or even in the text accompanying the examples, discloses these end points, much less these ranges.... <i>The disclosure as filed, however, does not disclose, discuss, or suggest the[] [98-100% or 99-100%] ranges or their end-points</i>, and thus again fails to provide support for the claim limitation in which at least 98% (or 99%) of a glycosylated VEGF antagonist comprising amino acids 27-457 is present in native conformation following storage at 5°C for two months (or twenty-four months) as measured by SEC for the broadly claimed formulations. Moreover, the examples do not provide data that allow the skilled	<i>“The [’865] Patent’s multiple disclosures of native conformations less than 1% shy of 100% (the absolute upper limit for the claim term, which in general is not met for proteins) meets the Federal Circuit’s [written description] standard.... [T]he [’865] Patent contained multiple disclosures of native conformations throughout the range of 98% to 100%,” such that “it is clear to a POSA reading the [’865] Patent that inventors possessed the entirety of the claimed subject matter”</i> Ex.2004 (<i>Celltrion PI Decision</i>) at 122, 124 (emphases added) (internal quotation marks and citations omitted).

artisan to derive the lower 98% and 99% end points of the claimed ranges. <i>Nothing in the general disclosure, the text accompanying the examples, the data, or anything else in the specification provide blaze marks to the % claimed stability limitations including the 98 and 99% lower end or 100% upper end of the claimed range.</i>” Pet. 3, 34 (emphases added) (citation omitted).	“Here, the district court appropriately credited expert testimony that most proteins are not purified to 100% to conclude that the maximum percent native conformation would be limited by what a relevant artisan would understand to be workable.... <i>The district court relied appropriately on expert testimony—this time from Dr. Trout—to find that the results in the patent show between 98.5 and 99.2% native conformation for the liquid formulations tested after storage for 2–3 months’ and that those multiple disclosures of native conformations less than 1% shy of 100% (the absolute upper limit for the claim term, which in general is not met for proteins) showed possession of the claimed range....</i> SB contends[] a relevant artisan cannot reasonably discern the 98% lower bound.... Here, no cobbling together of numbers is necessary—the ’865 patent contains multiple disclosures of native conformations throughout the range of 98% to 100%. <i>Thus, the district court</i>
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	<i>could properly find that it is clear to a relevant artisan reading the '865 patent that inventors possessed the entirety of the claimed subject matter.”</i> <i>SB, 127 F.4th at 916-17 (cleaned up) (emphases added).</i>
<i>“And a POSA reading the narrow examples would not understand that the inventors possessed the broadly claimed formulations having the claimed stability range after storage for a defined amount of time given only the specifically reported data points of the examples having very similar formulations.... There are no blaze marks pointing the skilled artisan to the claimed stability ranges or indicating that the data points would also apply to the broad range of formulations encompassed by the claims.... Regeneron also never explained how the very similar formulations of the Examples provide written description support for these limitations given the</i>	<i>“Dr. Trout also testified that the POSA could recognize the formulations that were claimed in the [’865] Patent, could visualize the formulations within the claims, and could recognize from the specification that the inventors invented the claimed formulations. As for the specific disclosures in the [’865] Patent that allowed the POSA to recognize these features, Dr. Trout pointed to the disclosure of column 2, lines 39 to 57, as well as each of the examples. Those disclosures conveyed what structures would fall within the scope of the claim, permitting the POSA to visualize the claimed formulations and to recognize that the inventors invented and possessed what the [’865] Patent claims. He noted that</i>

<i>broad range of formulations encompassed by the claims.”</i> Pet. 35, 37, 39 (emphases added).	<i>all of the [’865] Patent’s examples have at least 98 percent native conformation</i> as measured by SEC after two months.... Following this analysis, Dr. Trout testified that the [’865] Patent provided species or examples representative of the genus, claimed structures rather than function, and thus provided adequate written description for the asserted claims. The Court credits Dr. Trout’s analysis and conclusion.... <i>Here, in contrast, the evidence demonstrated that the examples in the specification were predictive of the performance of formulations that were not exemplified in the patent.</i> Regeneron pointed to several working examples of embodiments that were outside the disclosed examples (and the prior art) but nonetheless met the 98% native conformation [limitation].... The Defendants did not dispute these results, nor did the Defendants point to any formulation within the claims that did not achieve the claimed functional
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	properties.... [T]he evidence showed that the POSA would have pursued a more linear process that, the Defendants’ expert agreed, would not require making and testing each permutation of the structural elements of the claim, and that the POSA could use formulation design systems.... Thus, the Court concludes that the Defendants have failed to demonstrate by clear and convincing evidence that the asserted claims of the Product Patent are invalid for lack of written description.” <i>Mylan</i>, 714 F. Supp. 3d at 751-54 (emphases added) (internal quotation marks and citations omitted).
“A sufficient written description requires a statement of an invention, not an invitation to go on a hunting expedition to <i>cobble together</i>, after the fact, a synthetic definition of an invention. <i>Indivior UK Ltd. v. Dr. Reddy’s Labs. S.A.</i>, 18 F.4th 1323, 1329 (Fed. Cir. 2021) (<i>finding that PO’s</i>	“In reaching its conclusion, <i>the district court correctly distinguished the present cases from the case SB relied on: Indivior UK Ltd. v. Dr. Reddy’s Laboratories S.A.</i>, 18 F.4th 1323 (Fed. Cir. 2021).... <i>Here, no cobbling together of numbers is necessary</i>—the ’865 patent contains multiple

<i>range was not described but was merely ‘cobbling together numbers after the fact’).</i>” Pet. 36 (emphases added).	disclosures of native conformations throughout the range of 98% to 100%. Thus, the district court could properly find that it is clear to a relevant artisan reading the ’865 patent that inventors <i>possessed the entirety of the claimed subject matter.</i>” <i>SB</i>, 127 F.4th at 917 (cleaned up) (emphases added).
“The disclosure mentions glycosylation only once, and only mentions one glycosylated VEGF antagonist variant. That one variant is glycosylated at each of Asn residues 62, 94, 149, 222, and 308.... <i>Thus, to the extent that glycosylation in claim 1 is construed to mean anything other than glycosylation at each of Asn residues 62, 94, 149, 222, and 308, ... the term ‘glycosylated’ lacks written description support</i>” Pet. 46 (emphasis added) (citations omitted).	“<i>SB</i> argues that there is no support in the ’865 patent’s specification for glycosylated aflibercept formulations with the claimed level of stability. <i>SB</i> states that the specification has only one generic disclosure of glycosylation that precedes the examples and is not connected in any way to them.... We disagree.... The ’865 specification, in discussing the preparation of the VEGF trap, states that the VEGF trap in a specific embodiment comprises amino acids 27-457 of SEQ ID NO:4, <i>i.e.</i>, aflibercept, and is glycosylated at Asn residues 62, 94, 149, 222 and 308. The specification then provides several

	embodiments along with their stability data, including Examples 3 and 4, which comprise the same amino-acid sequence (SEQ ID NO:4) and have stability measurements that fall within the claimed range. Regeneron presented expert testimony that a relevant artisan reading those examples would look to the rest of the specification to see how the VEGF trap was made, would note the specification's disclosure that glycosylation results from a particular method of manufacture, and would understand the VEGF trap to be glycosylated at those specific residues. SB has not cited any evidence in rebuttal. <i>The district court did not clearly err in finding, on this record, that a relevant artisan, reading the specification as a whole, would understand the specification to disclose glycosylation as claimed.</i>" SB, 127 F.4th at 914-15 (cleaned up) (emphasis added).
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Celltrion relies on the Declaration of Dr. Tessier (Ex.1002), the same expert

Celltrion relied on in the District Court and whose testimony the District Court previously considered in resolving the preliminary-injunction proceedings.

III. The Board Should Deny Institution Under *Fintiv*

Regeneron will detail in its Preliminary Response why Celltrion's Petition is fatally deficient on the merits. But the Board need not reach the merits, as Celltrion's Petition is exceptionally well-suited for discretionary denial under 35 U.S.C. § 314(a). Celltrion's Petition, filed fourteen months after it was sued,² implicates the same or substantially similar written-description issues that have been decided repeatedly by the District Court and the Federal Circuit. Given the considerable investment by the parties and the courts in these proceedings, institution would be highly inefficient. Accordingly, the Board should exercise its discretion and deny institution.

A. Investments in Overlapping Parallel Litigation (*Fintiv* Factors 3 and 4)

The parties, the District Court, and the Federal Circuit all have invested enormously in the *Mylan*, *SB*, *Formycon*, and *Celltrion* litigations—each of which implicates substantially similar written-description issues as Celltrion's Petition.

² Celltrion's delay of more than one year in filing this IPR also renders it statutorily time-barred under 35 U.S.C. § 315(b), as Regeneron will explain in its Patent Owner Preliminary Response.

The six court decisions addressing written description and the *Celltrion* decision addressing related claim-construction issues—totaling nearly 1,000 pages, *see* Ex.2001-2007, with dozens of pages on written description alone—are the culmination of years of litigation between Regeneron and biosimilar manufacturers, including a two-week trial and a lengthy *Markman* hearing in the *Mylan* litigation, four injunction proceedings involving voluminous expert declarations and numerous expert depositions, and three arguments concerning validity before two distinct Federal Circuit panels. The third and fourth *Fintiv* factors thus decisively favor discretionary denial.

1. There Have Been Significant Investments in the Related District Court Litigations and Appeals (*Fintiv* Factor 3)

a. Investment in the District Court Litigations

The District Court’s preliminary injunction against Celltrion—in which the Court directly addressed the validity of the ’865 patent, including the adequacy of its written description—alone constitutes a substantial investment. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *4 & n.16 (P.T.A.B. Mar. 20, 2020) (precedential) (identifying a “preliminary injunction order after finding petitioner’s invalidity contentions unlikely to succeed on the merits” as a “substantive order[] related to the patent at issue in the petition” that “favors denial” (citing *E-One, Inc. v. Oskhosh Corp.*, IPR2019-00162, 2019 WL 2396798 (P.T.A.B. June 5, 2019))); *Int’l Bus. Machs. Corp. v. Trusted Knight Corp.*, IPR2020-00323,

2020 WL 3892131, at *5 (P.T.A.B. July 10, 2020) (same). As the Federal Circuit has explained, the IPR institution “procedure is directly analogous to a district court determining whether there is ‘a likelihood of success on the merits’ and then later deciding the merits of a case.” *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1030 (Fed. Cir. 2016); *Monosol Rx, LLC v. Arius Two, Inc.*, IPR2014-00376, 2016 WL 7985428, at *2 (P.T.A.B. Dec. 19, 2016). Accordingly, the District Court’s grant of a preliminary injunction—especially because its decision addressed the ’865 patent’s validity—weighs heavily in favor of discretionary denial of institution. *See, e.g., E-One*, IPR2019-00162, 2019 WL 2396798, at *4-9 (denying institution under § 314(a) in light of preliminary injunction); *Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01479, 2020 WL 927867, at *4-5 (P.T.A.B. Feb. 26, 2020) (similar).

That is not where the District Court’s investment ends. It conducted a two-week trial in the *Mylan* case and two other preliminary-injunction proceedings (in addition to *Celltrion*) focused on the validity of the ’865 patent. As described below (*infra* III.A.2), Celltrion’s Petition substantially overlaps with the *Mylan*, *SB*, *Formycon*, and *Celltrion* litigations, so all four parallel proceedings are relevant to the Board’s *Fintiv* analysis. *See generally Edwards Lifesciences Corp. v. Colibri Heart Valve LLC*, IPR2020-01649, 2021 WL 1158197, at *5-6 (P.T.A.B. Mar. 26, 2021); *Dolby Labs., Inc. v. Intertrust Techs. Corp.*, IPR2020-00661, 2020 WL

6084148, at *5-7 (P.T.A.B. Oct. 15, 2020); *TCO AS v. NCS Multistage Inc.*, PGR2020-00077, 2021 WL 662165, at *5-6 (P.T.A.B. Feb. 18, 2021). In these four litigations, the District Court has conducted the *Mylan* bench trial and *Markman* hearing; considered testimony from seven experts addressing the '865 patent; resolved three preliminary-injunction motions, one permanent-injunction motion, two motions for temporary restraining orders, and three motions to strike validity-related fact declarations, among others; and issued dozens of pages of analysis on written description alone. The District Court also resolved a fourth preliminary-injunction motion based on the '865 patent in the *Amgen* case. It would be hard to overstate the District Court's investment in these cases generally and in the '865 patent in particular.

Nor is that investment at a standstill. The MDL litigation is ongoing, and one of Celltrion's MDL co-defendants has proposed a schedule with trial occurring in March 2026. Ex.2008. If that schedule is adopted, the District Court and parties in the *Celltrion* litigation will further invest in claim construction, fact discovery, expert discovery, summary judgment, *Daubert*, motions-in-limine, and a bench trial—all before the Board would issue its Final Written Decision here. *Id.* The coordinated cases against the other biosimilars likewise will resume, further compounding these parallel proceedings.

b. Investment in the Appeals

The substantial investment in the appeals from the District Court's decisions likewise supports discretionary denial. The Federal Circuit has held argument on multiple appeals involving the '865 patent, including four appeals from preliminary-injunction decisions. These appeals were argued in December (*SB* and *Formycon*), January (*Amgen*), and February (*Celltrion*). The Federal Circuit issued decisions in the *SB*, *Formycon*, and *Celltrion* appeals that addressed (and rejected) many of the written-description and claim-construction assertions in Celltrion's Petition. *See infra* III.A.2.b-c. Institution of IPR after such investments by the parties, District Court, and Federal Circuit would be manifestly inefficient. *Cf. Snap Inc. v. Blackberry Ltd.*, IPR2020-00392, Paper 8 at 10-16 (P.T.A.B. July 13, 2020) (finding *Fintiv* factors favored discretionary denial where appeal of final district-court determination of patent invalidity was pending before Federal Circuit).

c. Celltrion's Unexplained Delay

Celltrion's undue delay in filing its Petition further favors discretionary denial. Celltrion did not file its Petition until late January 2025, more than fourteen months after Regeneron filed suit, eleven months after Regeneron filed its preliminary-injunction motion, and seven months after Celltrion was preliminarily enjoined by the District Court. Celltrion's delay in challenging the '865 patent was, in short, a tactical choice.

Celltrion has offered no excuse for its delay, which substantially increased the costs incurred by the parties and the courts. Pet. 14-16. Celltrion forced Regeneron to litigate, and the District Court to adjudicate, written-description issues that it lost at the District Court and then abandoned on appeal, only to turn around and demand this Board review them afresh in a belated Petition. Celltrion's unexplained delay weighs in favor of discretionary denial. *Fintiv*, 2020 WL 2126495, at *5; *Ericsson Inc. v. Godo Kaisha IP Bridge 1*, IPR2022-00725, 2022 WL 16704704, at *4 (P.T.A.B. Nov. 2, 2022).

2. The Related Litigation Overlaps with Celltrion's Petition (*Fintiv* Factor 4)

The fourth *Fintiv* factor weighs heavily in favor of discretionary denial. The claims Celltrion challenges in its Petition substantially overlap with the claims challenged at the District Court, and Celltrion itself acknowledges that the additional claims in its Petition are unlikely ever to be at issue before the District Court. Pet. 16. The written-description issues implicated by Celltrion's Petition also substantially overlap with those raised before and decided by the District Court and Federal Circuit. Accordingly, this factor strongly favors discretionary denial.

a. The Challenged Claims Substantially Overlap

Celltrion's Petition challenges claims 1-50. Pet. 21. Claims 4, 7, 9, 11, and 14-17 were at issue in the *Mylan* litigation, and those claims plus claims 29, 32, 34, 36, and 39-42 were asserted in preliminary-injunction proceedings against Celltrion.

Mylan, 714 F. Supp. 3d at 677; Ex.2004 (*Celltrion PI Decision*) at 10. Celltrion’s Petition thus challenges all the claims asserted in the *Mylan* and *Celltrion* proceedings.

Celltrion cannot avoid discretionary denial merely by challenging additional claims that have not been asserted or otherwise disputed in the parallel proceedings. Pet. 16. The Board has repeatedly affirmed that “the mere existence of non-overlapping claims does not ... favor[] institution”; rather, the Board considers “the similarity of the claims challenged in the petition to those at issue in the district court” as well as the other claims’ significance. *E.g.*, *Samsung Elecs. Co. v. Clear Imaging Rsch., LLC*, IPR2020-01551, 2021 WL 628829, at *7-9 (P.T.A.B. Feb. 17, 2021); *Amazon.com, Inc. v. Vocalife LLC*, IPR2020-00864, 2020 WL 6323540, at *5 (P.T.A.B. Oct. 28, 2020).

Celltrion does not argue that the additional claims implicate limitations that materially differ from those in the parallel proceedings. Rather, Celltrion repeatedly asserts the opposite. *E.g.*, Pet. 52-57 (generally citing Examples 3 and 4 to assert that dependent claims are anticipated as “explained above” for independent claims); Pet. 60-64 (similar, for obviousness).

Furthermore, Celltrion has not explained how it would be prejudiced by non-institution. Indeed, Celltrion contends that “it is unlikely that Regeneron will assert all 50 claims Celltrion is challenging here.” Pet. 16. Celltrion would suffer no

prejudice from non-adjudication of similar claims that were not asserted in the preliminary-injunction proceedings and, as Celltrion itself acknowledges, are unlikely to be relevant to the parties' dispute. *Amazon.com*, 2020 WL 6323540, at *5.

b. The Issues Substantially Overlap

There is a substantial overlap in issues and arguments between Celltrion's Petition and the four parallel litigations. Indeed, Celltrion's written-description arguments are foreclosed by numerous District Court and Federal Circuit decisions.

The Native-Conformation Limitations. Celltrion maintains that the native-conformation limitations lack adequate written description. For instance, Celltrion asserts that "Regeneron's broad claims [encompass] a genus of VEGF antagonists containing a buffer, a sugar, and an organic co-solvent." Pet. 2. The claims, however, recite a specific VEGF antagonist by its amino-acid sequence, *i.e.*, aflibercept, '865 patent, claim 1, and the District Court specifically found that "the claim limitations in the ['865] Patent have 'common structural features,' including the 'very specific' VEGF antagonist [aflibercept] and the categories of organic co-solvent, buffer, and stabilizing agent," *Mylan*, 714 F. Supp. 3d at 751.

Celltrion further argues that "the specification['s] disclos[ure] [of] stability testing ... only for a handful of formulations ... for specified lots of aflibercept," Pet. 2-3, is insufficient to demonstrate the inventors' possession of "the broad range

of formulations encompassed by the claims,” Pet. 37-41. But in the *Mylan* litigation, which featured live trial testimony from multiple inventors and experts on both sides, the District Court rejected a substantially similar argument, “credit[ed] [Regeneron’s expert] Dr. Trout’s analysis and conclusion,” and found that the disclosure in the specification, including the examples, sufficiently described the full scope of formulations encompassed by the ’865 patent’s claims. *Mylan*, 714 F. Supp. 3d at 752; *see id.* at 751-54 (finding that: (1) “the POSA could recognize the formulations that were claimed in the [’865] Patent, could visualize the formulations within the claims, and could recognize from the specification that the inventors invented the claimed formulations”; (2) “the disclosure of column 2, lines 39 to 57, as well as each of the examples ... conveyed what structures would fall within the scope of the claim, permitting the POSA to visualize the claimed formulations and to recognize that the inventors invented and possessed what the [’865] Patent claims”; (3) “all of the [’865] Patent’s examples have ‘at least 98 percent native conformation as measured by SEC after two months’”; (4) “the patent did not need to provide an exhaustive description to the POSA” of “buffers and stabilizing agents[,] [which] were ‘structures well known in the art’”; and (5) “the examples in the specification were predictive of the performance of formulations that were not exemplified in the patent,” with “Regeneron [having] pointed to several working examples of embodiments that were outside the disclosed examples (and the prior art) but

nonetheless met the 98% native conformation ... limitation[]” and “the Defendants [having failed to] point to any formulation within the claims that did not achieve the claimed functional properties” (citations omitted)).

Celltrion’s Petition also asserts that the specification does not adequately demonstrate the inventors’ possession of formulations achieving 98-100% native conformation, including formulations with native conformations at the lower and upper ends of that range. Pet. 32-35, 40. In enjoining Celltrion, SB, and Formycon, however, the District Court found that the specification adequately describes formulations achieving native conformations of 98-100%. Ex.2004 (*Celltrion PI Decision*) at 122, 124 (“The [’865] Patent’s multiple disclosures of native conformations less than 1% shy of 100% (the absolute upper limit for the claim term, which ‘in general’ is not met for proteins) meets the Federal Circuit’s standard.... [T]he [’865] Patent contained multiple disclosures of native conformations throughout the range of 98% to 100%,” such that “it is clear to a POSA reading the [’865] Patent that inventors possessed the entirety of the claimed subject matter” (citations omitted)). And the Federal Circuit affirmed those findings, including specifically for the lower and upper limits of the 98-100% range. *SB*, 127 F.4th at 916-17 (“Here, the district court appropriately credited expert testimony that most proteins are not purified to 100% to conclude that the maximum percent native conformation would be limited by what a relevant artisan would understand to be

workable.... The district court relied appropriately on expert testimony—this time from Dr. Trout—to find that the results in the patent show between 98.5 and 99.2% native conformation for the liquid formulations tested after storage for 2–3 months and that those multiple disclosures of native conformations less than 1% shy of 100% (the absolute upper limit for the claim term, which in general is not met for proteins) showed possession of the claimed range.... SB contends[] a relevant artisan cannot reasonably discern the 98% lower bound.... Here, no cobbling together of numbers is necessary—the ’865 patent contains multiple disclosures of native conformations throughout the range of 98% to 100%. Thus, the district court could properly find that it is clear to a relevant artisan reading the ’865 patent that inventors possessed the entirety of the claimed subject matter.” (cleaned up)).

In its decisions, the Federal Circuit directly addressed and rejected many of the same arguments Celltrion raises here. *First*, the Federal Circuit held that case law upon which Celltrion’s Petition relies is inapplicable. *Compare id.* at 917 (“[T]he district court correctly distinguished the present cases from the case SB relied on: *Indivior UK Ltd. v. Dr. Reddy’s Laboratories S.A.*, 18 F.4th 1323 (Fed. Cir. 2021).”), *with* Pet. 36, 40 (relying on *Indivior* to argue that the POSA would not recognize the inventors’ possession of the 98-100% range).

Second, the Federal Circuit rejected Celltrion’s construction of the native-conformation limitations. *Compare Celltrion*, 2025 WL 706079, at *3 (“According

to Celltrion, the common knowledge of a person of ordinary skill in that art and the intrinsic evidence make clear that the at least 98% limitation in the '865 patent defines a rate of aggregation over a particular time, under particular conditions. We disagree. *Celltrion's argument contradicts the plain claim language*, which states that at least 98% of the VEGF antagonist *is present* in native conformation following storage for two months as measured by SEC. Nothing in the claims or specification suggests that a rate must be calculated. Rather, the claim states that after two months, the formulation is measured by SEC, and the result is either above 98%—within the scope of the claim—or below 98%—outside the scope of the claim. On this record and even under de novo review of the claim construction issue, we discern no error in the district court's analysis.” (first emphasis added)), *and Formycon*, 2025 WL 324288, at *5 (“Formycon argues for inherency on the ground that the ‘native conformation’ limitation in the '865 patent ... refer[s] not to the starting point but to the amount of change in the percentage of native conformation after the period of time specified in the claims.... [A] substantial argument would be needed to overcome the apparent meaning of the claim language on its face, which requires that at least 98% of the VEGF antagonist *is present* in native conformation following storage for two months—a reference simply to a property at that time—without calling for a comparison to an earlier time.” (cleaned up)), *with* Pet. 24 (“[T]he claim permits a maximum of 1% or 2% of the VEGF antagonist initially present in intact

functional form at time zero to have aggregated (or otherwise degraded) during the specified storage period.”).

Third, the Federal Circuit found that the testimony of Dr. Tessier, Celltrion’s expert both here and before the District Court, *see* Ex.2004 (*Celltrion PI Decision*) at 119-22, supported a finding that the specification adequately described the 98-100% range. *SB*, 127 F.4th at 915-16 (“SB faults the district court for crediting the testimony of its own expert, Dr. Tessier, who stated that most proteins are not purified to 100% but who did not state the same about aflibercept in particular.... Here, the district court appropriately credited expert testimony that most proteins are not purified to 100% to conclude that the maximum percent native conformation would be limited by what a relevant artisan would understand to be workable. SB has not pointed to any evidence that aflibercept differs from most proteins in this regard, nor has SB shown that even a small change in native conformation above 99.2% would be both possible and so difficult to achieve that formulations with stability percentages within the 99.3–100% are significantly different inventions, making it improper to view the inventors as having invented them based on the 99.2% figure in the specification.” (cleaned up)).

In sum, the issue of whether the specification adequately describes the native-conformation limitations has repeatedly been addressed by numerous District Court and Federal Circuit decisions, each of which supports the ’865 patent’s validity. In

its Petition, Celltrion cites the same cases, advances the same claim-construction arguments, and relies upon the same expert that the District Court and Federal Circuit already considered. There is thus almost complete overlap between Celltrion's Petition and the parallel proceedings.

The Glycosylation Limitation. Celltrion further asserts that there is inadequate written description of “glycosylated” aflibercept. Specifically, it argues that the claims encompass a “broad genus of glycosylated VEGF antagonist proteins” but that the specification “mentions glycosylation only once, and only in the context of describing one specific glycosylated VEGF antagonist, aflibercept, which has a specific glycan structure.” Pet. 2; *see* Pet. 45-46 (arguing that “the term ‘glycosylated’ lacks written description support” because “[t]he disclosure mentions glycosylation only once, and only mentions one glycosylated VEGF antagonist variant”).

But this argument too has already been addressed and resolved by the Federal Circuit. The Court stated:

SB argues that there is no support in the '865 patent's specification for glycosylated aflibercept formulations with the claimed level of stability. SB states that the specification has only one generic disclosure of glycosylation that precedes the examples and is not connected in any way to them.... We disagree.... The '865 specification, in discussing the preparation of the

VEGF trap, states that the VEGF trap in a specific embodiment comprises amino acids 27-457 of SEQ ID NO:4, *i.e.*, aflibercept, and is glycosylated at Asn residues 62, 94, 149, 222 and 308. The specification then provides several embodiments along with their stability data, including Examples 3 and 4, which comprise the same amino-acid sequence (SEQ ID NO:4) and have stability measurements that fall within the claimed range. Regeneron presented expert testimony that a relevant artisan reading those examples would look to the rest of the specification to see how the VEGF trap was made, would note the specification's disclosure that glycosylation results from a particular method of manufacture, and would understand the VEGF trap to be glycosylated at those specific residues. SB has not cited any evidence in rebuttal. ***The district court did not clearly err in finding, on this record, that a relevant artisan, reading the specification as a whole, would understand the specification to disclose glycosylation as claimed.***

SB, 127 F.4th at 914-15 (cleaned up) (emphases added). As a result, Celltrion's argument that there is inadequate written description of "glycosylated" aflibercept is foreclosed by the Federal Circuit's precedential decision in *SB*, reflecting the near-complete overlap in issues between Celltrion's Petition and the parallel litigations.

To prevail, Celltrion would have to revisit and reverse all of those court findings regarding the native-conformation and glycosylation limitations of the '865 patent. Instead, Celltrion conspicuously overlooks each of them, and makes no effort to show error. This overlap in issues and arguments thus strongly favors discretionary denial of institution.

c. Celltrion's Stipulation

Celltrion's narrow stipulation does not outweigh the considerable overlap in claims and issues. Celltrion "stipulates that if the IPR is instituted, Petitioner will not pursue the same grounds in the district court litigation." Pet. 16. That is an empty promise where, as here, Celltrion *already* has pursued that ground in the District Court. And Celltrion does not stipulate to not pursue any grounds that could have reasonably been raised in the present proceeding. Indeed, even had Celltrion so stipulated, discretionary denial would still be appropriate. *Cf. Motorola*, IPR2024-01205, Paper 19 at 2-3. Furthermore, Celltrion has already asserted substantially similar written-description arguments before the District Court, as explained above. Celltrion's offer to not litigate the very same issues and arguments it has already litigated, lost, and abandoned on appeal can hardly support institution. Ex.2010 (only arguing invalidity for obviousness-type double patenting). As a result, Celltrion's narrow stipulation notwithstanding, the fourth *Fintiv* factor heavily favors discretionary denial, and the Board should deny institution. *E.g.*,

Zhuhai Cosmox Battery Co. v. Ningde Ampere Tech. Ltd., No. IPR2023-00587, 2023 WL 6514282, at *4 (P.T.A.B. Sept. 22, 2023) (denying institution despite narrow stipulation).

B. There Is No Possibility of a Stay (*Fintiv* Factor 1)

Celltrion has not sought to stay the District Court litigation, and Celltrion's MDL co-defendant SB has sought an accelerated schedule in which trial would be held in March 2026. Ex.2008. Regeneron does not intend to seek a stay either. Accordingly, the first *Fintiv* factor favors discretionary denial.

C. Trial May Be Scheduled as Early as March 2026 (*Fintiv* Factor 2)

The second *Fintiv* factor also favors discretionary denial, or is at least neutral. The Board's statutory deadline for a final written decision would be approximately August 14, 2026. Celltrion's MDL co-defendant SB has proposed a trial date five months earlier, in March 2026. Ex.2008. Regeneron proposed that the District Court convene a status conference upon resolution of the remaining pending appeals and then determine an appropriate schedule for the various parties in the MDL. Ex.2009 at 6. In light of the significant investments in the various parallel proceedings that have already occurred, compounded by Celltrion's delay in filing its Petition, *see supra* III.A.1.c, the second *Fintiv* factor favors discretionary denial, and certainly does not support institution. *See Glob. Tel*link Corp. v. HLFIP Holding, Inc.*, IPR2021-00444, 2021 WL 3117130, at *7-14 (P.T.A.B. July 22,

2021) (denying institution, notwithstanding district court having not yet set trial date, based on substantial investments in and significant overlap between petition and parallel proceedings); *Mylan Labs. Ltd. v. Janssen Pharmaceutica NV*, IPR2020-00440, 2020 WL 5580472, at *6-11 (P.T.A.B. Sept. 16, 2020) (denying institution despite “[a] trial date ha[ving] not been set for the *Mylan* litigation”).

D. The Parties Are the Same as in the Parallel Litigation (*Fintiv* Factor 5)

The fifth *Fintiv* factor also favors denial. Celltrion is the “same party” as the party participating in the parallel *Celltrion* litigation. *Fintiv*, 2020 WL 2126495, at *2. The *Celltrion* case is part of an MDL also including the *Mylan*, *SB*, and *Formycon* cases. Given the overlap among these proceedings discussed above, the fifth *Fintiv* factor heavily favors denial. *See, e.g., id.* at *6 (“An unrelated petitioner should, therefore, address any other district court or Federal Circuit proceedings involving the challenged patent to discuss why addressing the same or substantially the same issues would not be duplicative of the prior case even if the petition is brought by a different party.”); *Mylan*, 2020 WL 5580472, at *7, *10 (“[B]ecause the Petitioner is the same as the defendant in the *Mylan* litigation, and because the issues in both the *Teva* and *Mylan* litigations are substantially the same as those raised in the Petition, *Fintiv* factor #5 favors denial.” (citations omitted)).

E. Other Considerations (*Fintiv* Factor 6)**1. Celltrion's Written-Description Challenge Is Foreclosed by Numerous District Court and Federal Circuit Decisions**

Finally, the sixth *Fintiv* factor strongly favors discretionary denial. As will be discussed in more detail in Regeneron's Preliminary Patent Owner Response, Celltrion cannot demonstrate a reasonable likelihood that the claims are unpatentable, especially in light of its failure to show error in (or even mention) the numerous District Court and Federal Circuit outcome-determinative findings. Specifically, the District Court has already determined that the specification adequately describes the full scope of formulations encompassed by the '865 patent's claims, *Mylan*, 714 F. Supp. 3d at 751-55; the District Court and Federal Circuit repeatedly have held that the specification adequately describes the full scope of the 98-100% native-conformation range, e.g., Ex.2004 (*Celltrion PI Decision*) at 118-24; *SB*, 127 F.4th at 916; the Federal Circuit has foreclosed Celltrion's reliance on *Indivior*, *SB*, 127 F.4th at 917; the Federal Circuit has rejected Celltrion's claim construction, *Celltrion*, 2025 WL 706079, at *3; *Formycon*, 2025 WL 324288, at *5; the Federal Circuit has found that Celltrion's own expert's testimony supports the adequacy of the patent's written description with respect to the native-conformation limitations, *SB*, 127 F.4th at 915-16; and the Federal Circuit has found that there is adequate written-description support for the glycosylation limitation, *id.* at 914-15. Given these findings and decisions supporting the '865 patent's validity,

as well as Celltrion’s failure to discuss or show error in any of them, Celltrion’s unpatentability challenge is feeble at best. *See* Interim Processes for PTAB Workload Management at 2 (Mar. 26, 2025) (“Memo”) (relevant considerations include “[w]hether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims” and “[t]he strength of the unpatentability challenge”).

2. Celltrion’s Petition Advances a Construction Inconsistent with its Arguments in the District Court

In its Petition, Celltrion and its expert Dr. Tessier advance a construction of the native-conformation limitations that, in addition to having been twice rejected by the Federal Circuit, *Celltrion*, 2025 WL 706079, at *3; *Formycon*, 2025 WL 324288, at *5, is also diametrically opposed to the construction that Celltrion and the same expert urged to the District Court (and which the Federal Circuit has subsequently endorsed). Whereas Celltrion and Dr. Tessier now interpret the claims’ “% native conformation” requirement as the amount at the specified time point *relative to* the initial amount at time zero, Pet. 24, Celltrion’s and Dr. Tessier’s earlier interpretation of the same “% native conformation” requirement at the District Court involved not a relative amount but the actual measured % native-conformation value at the specified time point. These inconsistent positions are irreconcilable and support denial of Celltrion’s Petition.

In its preliminary-injunction opposition at the District Court, Celltrion and Dr. Tessier understood the claimed “% native conformation” to be the % native conformation recorded at the specified time point (*e.g.*, at “two months” for claim 1); they did not understand the claimed “% native conformation” to refer to the result of a calculation involving a time-zero measurement as its present construction requires. Specifically, at the District Court, Celltrion and Dr. Tessier, consistent with Regeneron, argued that the “% native conformation data in the [patent’s liquid formulation] examples ends at 99.2%”—*i.e.*, the specific two-month measured value reported in Example 3, not a number reflecting the difference between time zero and two months. Ex.2012, 20 (citing testimony of Dr. Tessier); Ex.1001, 9:19-42.

On appeal from the District Court’s judgment, however, Celltrion jettisoned that claim interpretation. Celltrion no longer maintained that the examples’ data “end[] at 99.2%” as a maximum value; instead, Celltrion posited on appeal (as it does here in its Petition) that the examples’ data *begins* at 99.6% as a result of a comparison with the amount of the VEGF antagonist in native conformation reported at time zero. *Compare* Ex.2010, 76, *with* Pet. 24, Ex.1002 ¶¶ 74, 115. In other words, the 99.2% maximum native conformation value at two months (under Celltrion’s and Dr. Tessier’s original understanding of the term (Ex.2012, 20-21)) is not even within the range of disclosed values (from 99.6% to 99.9%) under Celltrion’s new interpretation:

'865 Patent Example	Patent's Reported %N.C. (0 mo.)	Patent's Reported %N.C. (2-3 mo.)	Difference	%N.C. at 2-3 mo. under Celltrion's Original Construction	%N.C. at 2-3 mo. under Construction in Celltrion's Petition
1	98.8	98.7	0.1	98.7	99.9
2	98.9	98.5	0.4	98.5	99.6
3	99.5	99.2	0.3	99.2	99.7
4	99.4	99.1	0.3	99.1	99.7
5	99.3	99.2	0.1	99.2	99.9
6	99.2	99.1	0.1	99.1	99.9

Thus, Celltrion's present construction is irreconcilable with what Celltrion originally argued in the District Court. Moreover, as explained above, Celltrion's new construction is manifestly wrong; as the Federal Circuit held unambiguously, Celltrion's construction "contradicts the plain claim language" of the '865 patent's claims. *Celltrion*, 2025 WL 706079, at *3; *see supra* 8-10.

In sum, not only has the Federal Circuit twice directly refuted the claim construction Celltrion and Dr. Tessier presently advance, so too have the prior positions of Celltrion and Dr. Tessier himself. The Petition's reliance on this discredited and inconsistent construction further supports discretionary denial. *See Kiosoft Techs., LLC v. Payrange, Inc.*, IPR2021-00086, Paper 12 at 15-17 (P.T.A.B. Mar. 22, 2021) (denying institution under *Fintiv* where Petitioner and its expert advanced inconsistent claim constructions between the district court and the Board).

3. The Parties Expect That Celltrion Will Remain Enjoined

The parties' settled expectations further support discretionary denial under *Fintiv*. The claims of the '865 patent have been in force since August 2021, nearly four years. Celltrion has been enjoined from infringing that patent since June 2024, nearly ten months. Since December 2023, four District Court and three Federal Circuit decisions have upheld the validity of the '865 patent. In light of this history and those decisions, even Celltrion expects to remain preliminarily enjoined until the District Court conducts a trial on its invalidity defenses. Ex.2011, 2 ("In its decision in the *Celltrion* case, the Federal Circuit expressly acknowledged that its decision upholding the preliminary injunction was not an adjudication of the merits of Celltrion's defense, and that Celltrion should have the 'opportunity to fully develop' the record and present that defense at trial." (citation omitted)). To allow Celltrion to resurrect written-description arguments that the District Court repeatedly rejected, that Celltrion abandoned on appeal, and that, in any event, the Federal Circuit rejected in *SB* would upset the parties' settled expectations. As a result, discretionary denial is appropriate. *See* Memo at 2 (relevant considerations include "[s]ettled expectations of the parties, such as the length of time the claims have been in force").

4. Celltrion's Petition Is an Inefficient Follow-on Petition

Before the District Court, Celltrion, SB, and Formycon were co-defendants. They coordinated their invalidity theories, raising substantially similar obviousness-type double patenting (ODP) and written-description arguments and relying on the same expert, Dr. Tessier. *SB PI Decision*, 2024 WL 3422971, at *7; *Formycon PI Decision*, 2024 WL 3423047, at *7; Ex.2004 (*Celltrion PI Decision*) at 22. Both the District Court and the Federal Circuit have rejected those ODP and written-description challenges. *SB PI Decision*, 2024 WL 3422971, at *17-35; *Formycon PI Decision*, 2024 WL 3423047, at *21-40; Ex.2004 (*Celltrion PI Decision*) at 61-124; *SB*, 127 F.4th at 911-17; *Formycon*, 2025 WL 324288, at *5-7; *Celltrion*, 2025 WL 706079, at *2-3.

SB and Formycon have since filed Petitions challenging the '865 patent as obvious over the Fraser and Wulff references. As Regeneron's Preliminary Patent Owner Responses explain, *see* IPR2025-00176, Paper 8; IPR2025-00233, Paper 10, those Petitions are a transparent attempt to collaterally attack numerous outcome-determinative factual findings from the District Court's *Mylan* bench-trial decision (addressing obviousness) and its *SB*, *Formycon*, and *Celltrion* preliminary-injunction decisions (addressing ODP), with many of those findings having already (and repeatedly) been affirmed by the Federal Circuit.

Now Celltrion has filed a *third* Petition attacking nearly all the same claims of the same patent. *Compare* Pet. 1 (claims 1-50), *with* IPR2025-00176, Paper 2 at 1 (claims 1-12, 14-17, 19-20, 22-36, 39-42, 44-45, and 47-55); IPR2025-00233, Paper 2 at 1 (same). But instead of joining efforts with SB and Formycon, it seeks to relitigate a different set of issues altogether: the adequacy of the '865 patent's written description, by way of a priority-date challenge. Just as with ODP and obviousness, the District Court and Federal Circuit repeatedly have upheld the '865 patent against written-description challenges substantially similar to the ones Celltrion presses here.

As the Board has explained:

Based on the Board's prior experience, one petition should be sufficient to challenge the claims of a patent in most situations. Two or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns. *See* 35 U.S.C. § 316(b). In addition, multiple petitions by a petitioner are not necessary in the vast majority of cases. To date, a substantial majority of patents have been challenged with a single petition.

Ericsson Inc. v. Uniloc 2017, LLC, IPR2019-01550, Paper 8 at 15 (P.T.A.B. Mar. 17, 2020) (quoting Trial Practice Guide Update, 26 (July 2019); Consolidated Trial

Practice Guide (November 2019), 59). It is hard to imagine anything less efficient for the Board—or more unfair for patent owners like Regeneron—than for co-defendants to split up amongst themselves the various invalidity theories they already litigated and lost both before the District Court and the Federal Circuit and to separately file serial petitions relitigating each of those invalidity theories.

Furthermore, Celltrion first challenged the adequacy of the '865 patent's written description in March 2024. Ex.2012, 20-21 (Dkt. 142-3). Nothing prevented Celltrion from filing its Petition then, or in the following months. Instead, however, Celltrion waited ten months, during which time the District Court issued numerous decisions rejecting Celltrion's arguments, and the Federal Circuit heard oral argument on three related appeals challenging the '865 patent's written description. Because of Celltrion's delay, this proceeding, if instituted, would result in the *seventh* decision addressing the adequacy of the '865 patent's written description. And had Celltrion not abandoned on appeal the written-description arguments it now seeks to relitigate before the Board, the Board would instead be responsible for the *eighth* decision addressing the exact same issues. Institution in these circumstances would be exceedingly inefficient. *Cf. General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 9-10 (P.T.A.B. Sept. 6, 2017) (precedential) (considering Board's limited resources and ability to issue final written decisions within statutory deadline in exercising discretion under § 314(a)).

The Board should thus exercise its discretion to deny institution of Celltrion's inefficient, unfair follow-on Petition.

IV. Conclusion

Celltrion's Petition transparently seeks to relitigate—for the *seventh* time—written-description arguments and theories that were extensively considered and rejected in four related District Court decisions and two related Federal Circuit decisions. Institution in these circumstances would be manifestly inefficient and unfair. The Board should therefore exercise its discretion under 35 U.S.C. § 314(a) to deny institution.

Date: April 14, 2025

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

In accordance with 37 C.F.R. § 42.24, as amended, and Director's Interim Processes for PTAB Workload Management, the undersigned certifies that this Discretionary Denial Brief complies with the applicable type volume limitations of 37 C.F.R. §§ 42.24(a)(i) and 42.24(b)(1). Exclusive of the portions exempted by 37 C.F.R. § 42.24(a), this Discretionary Denial Brief contains 9,169 words as counted by the word processing program used for its preparation (Microsoft Word 2019).

Date: April 14, 2025

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

The undersigned hereby certifies that on April 14, 2025, I caused true and correct copies of the following materials:

- Patent Owner's Discretionary Denial Brief
- Patent Owner's Exhibit List
- Exhibits 2001-2012

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