

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI SWISSBIOSIM GMBH,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: IPR2025-01268
U.S. Patent No. 11,084,865

PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

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Exhibit	Description
2001	Mylan Redacted Trial Decision, 22-cv-61, Dkt. 692 (N.D.W. Va.)
2002	SB Redacted PI Decision, 24-md-3103, Dkt. 194 (N.D.W. Va.)
2003	Formycon Redacted PI Decision, 24-md-3103, Dkt. 247 (N.D.W. Va.)
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	Fresenius, Fresenius to Expand Biopharma Portfolio with a New Licensing Agreement to Commercialize a Proposed Aflibercept Biosimilar (Dec. 20, 2024), https://www.fresenius.com/node/6982
2009	Email from D. Berl to S. Gibson re Scheduling Conference (Sept. 12, 2025)

I. Introduction

One would be hard-pressed to identify a patent that has received more judicial scrutiny than—and been the subject of as much judicial investment as—Regeneron’s U.S. Patent 11,084,865 (“’865 patent”), which discloses and claims the formulation of Regeneron’s groundbreaking ophthalmic product, Eylea[®], used to treat eye disorders that may lead to blindness. For over three years, Regeneron has been engaged in multi-district patent litigation before Chief Judge Thomas Kleeh in the Northern District of West Virginia (“District Court”) against multiple entities—Mylan, Samsung Bioepis (“SB”), Formycon, Celltrion, Amgen, and Sandoz—seeking to market biosimilar versions of Eylea[®]. The focal point of that litigation has been the ’865 patent, and across *four* decisions—one 313-page bench-trial decision (*Mylan*), and three ~200-page decisions granting preliminary injunctions (*SB*, *Formycon*, and *Celltrion*), Ex.2001-2004—the District Court upheld the ’865 patent against every validity challenge the defendants could conjure. Critically, those challenges include the identical one raised by Fresenius’s Petition—anticipation by U.S. Patent 10,406,226 (“Dix ’226”). Pet. 11. Furthermore, the District Court repeatedly rejected Fresenius’s argument that the 98% native conformation limitation in the ’865 patent’s claims is an “inherent propert[y] of the claimed formulation.” Pet. 1; *e.g.*, *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652, 731-33 (N.D.W. Va. 2024) (“*Mylan*”); *In re Aflibercept Pat.*

Litig., 2024 WL 3422971, at *28-31 (N.D.W. Va. June 24, 2024) (“*SB PI Decision*”).

In addition to the District Court, the Federal Circuit also rejected numerous validity challenges to the ’865 patent in affirming the District Court’s three preliminary injunction decisions addressing validity. *See 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*”); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 706079 (Fed. Cir. Mar. 5, 2025) (“*Celltrion*”).¹ In the *Mylan* appeal, following oral argument, the parties filed a joint voluntary dismissal of the appeal pursuant to a broader settlement. No. 24-2002, ECF No. 58 (Fed. Cir. Apr. 14, 2025).

In parallel with the appeals, three biosimilars sought *inter partes* review (“IPR”) of the ’865 patent. The Board and the Director exercised their discretion to deny each petition, explaining that “other forums . . . have already adjudicated the validity of the challenged patent claims” and that “there has been substantial investment by the parties and the court in [the parallel] proceeding,” including “briefing and discovery relating to a preliminary injunction motion [that] has already resulted in the district court issuing an order granting a preliminary injunction.” *Celltrion Inc. v. Regeneron Pharm., Inc.*, IPR2025-00456, Paper 14, at 2 (P.T.A.B.

¹ The Federal Circuit affirmed the denial of a preliminary injunction against Amgen on the basis of noninfringement, without addressing validity.

June 25, 2025); *see also Formycon AG v. Regeneron Pharm., Inc.*, IPR2025-00233, Paper 15, at 12-23 (P.T.A.B. June 2, 2025); *Samsung Bioepis Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2025-00176, Paper 12, at 11-23 (P.T.A.B. June 2, 2025).

Accordingly, ten decisions from three adjudicative bodies have considered validity challenges to the '865 patent, and ten decisions have denied them. Fresenius's Petition offers no reason to believe that the *eleventh* try will be the charm. To the contrary, Fresenius asserts an invalidity theory that already has been fully litigated and rejected after a two-week bench trial in the *Mylan* litigation. Fresenius's sole justification for a do-over is its speculation based on a subset of the questions asked by the Federal Circuit panel regarding criticality. Pet. 1. However, as the District Court found, Dix '226 fails to anticipate regardless of criticality, including because it fails to teach the claim limitations "arranged as in the claim." *Mylan*, 714 F. Supp. 3d at 732-34. Fresenius simply ignores this dispositive finding, which is equally fatal to its Petition and wasteful to re-adjudicate. Furthermore, the District Court made a number of other findings addressing validity, both in *Mylan* and its other decisions, that each foreclose Fresenius's anticipation theory here. But Fresenius fails to discuss, let alone demonstrate error in, any of those findings.

Fresenius's Petition completely overlaps in issues and arguments with the parallel litigation. The parties, District Court, and Federal Circuit have invested enormously in those litigations. Institution of *another* proceeding to adjudicate the

validity of the '865 patent would epitomize wasteful inefficiency. And more fundamentally, institution would upset the settled expectations regarding the '865 patent's validity, earned over ten adjudications across the District Court, the Federal Circuit, and the Board in the four years since the patent issued. The Director should deny institution of the Petition under 35 U.S.C. § 314(a).

II. The Director Should Deny Institution Under *Fintiv*

Regeneron will detail in its Preliminary Response why Fresenius's Petition is fatally deficient on the merits. But the Board need not reach the merits, as Fresenius's Petition is exceptionally well-suited for discretionary denial under 35 U.S.C. § 314(a). At bottom, Fresenius's Petition raises the same anticipation theory the District Court rejected squarely in *Mylan* and other arguments that have been decided repeatedly by the District Court and the Federal Circuit in Regeneron's favor. Fresenius asserts that the '865 patent's claimed formulations are anticipated by Dix '226, and in support it argues that: (1) disclosure of 10-50 mg/ml of a generic VEGF antagonist fusion protein anticipates the 40 mg/ml aflibercept formulations claimed by the '865 patent, Pet. 17-18, 29-33; (2) disclosure of a 40 mg/ml pre-lyophilized solution anticipates the claimed formulations, Pet. 18-19, 32-33; and (3) the native-conformation limitations are inherent, Pet. 1, 4-5, 28-29, 33, 39-40.

The problem for Fresenius, though, is that each of its arguments was rejected in the parallel litigation. First, the District Court determined that Dix '226's

disclosures of formulations containing 10-50 mg/ml of “a generic ‘VEGF-specific fusion protein antagonist’” and of a “40 mg/ml pre-lyophilized solution” are not anticipatory, because separate and apart from any deficiencies in those prior-art disclosures, Dix ’226 does not teach all the elements as arranged in the ’865 claims, *i.e.*, an ophthalmic formulation comprising 40 mg/ml aflibercept with at least 98% native conformation after two months’ storage. *Mylan*, 714 F. Supp. 3d at 730-34. In its decisions in the *SB*, *Formycon*, and *Celltrion* litigations, the Court further found that ophthalmic formulations with 40 mg/ml aflibercept do not necessarily achieve 98% native conformation after two months’ storage—meaning that, even if Dix ’226 had disclosed those formulations as arranged in the claims, it still would not anticipate. *SB PI Decision*, 2024 WL 3422971, at *28-31; *In re Aflibercept Pat. Litig.*, 2024 WL 3423047, at *32-35 (N.D.W. Va. July 9, 2024) (“*Formycon PI Decision*”); Ex.2004 (*Celltrion PI Decision*) at 97-109.² Multiple panels of the Federal Circuit, in turn, affirmed those decisions. *SB*, 127 F.4th at 913; *Formycon*, 2025 WL 324288, at *5-6; *Celltrion*, 2025 WL 706079, at *3. Second, the District Court found that Dix ’226 disclosed a range that is too broad to invoke a presumption of anticipation, rendering criticality irrelevant. *Mylan*, 714 F. Supp. 3d at 730-33.

² The District Court’s validity analyses in the *SB PI Decision*, *Formycon PI Decision*, and *Celltrion PI Decision* are substantially similar. For brevity, Regeneron generally cites the *SB PI Decision*.

And third, even were criticality relevant, the District Court found that the 40 mg/ml concentration is critical. *Id.* at 731, 734.

Fresenius’s Petition therefore effectively seeks to reverse seven judicial decisions, including three by the Court that would review this Board’s adjudication of Fresenius’s Petition (if instituted). Fresenius’s Petition flouts the AIA’s basic objective of “provid[ing] an effective and efficient alternative to district court litigation.” *NHK Spring Co., Ltd. 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 the same disputes the District Court and Federal Circuit already have resolved in Regeneron’s favor numerous times, over 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). All the *Fintiv* factors strongly favor non-institution; viewed most generously for Fresenius, a few are neutral. The Director should exercise his discretion to deny institution.

A. Investments in Parallel Litigation (*Fintiv* Factors 3-5)

The parties, District Court, and Federal Circuit all have invested enormously in the *Mylan*, *SB*, *Formycon*, and *Celltrion* litigations—each of which implicates substantially similar invalidity theories and arguments as Fresenius’s Petition. The

seven court decisions addressing the '865 patent—totaling nearly 1,000 pages, *see* Ex.2001-2007, with hundreds of pages on validity alone (including non-anticipation by Dix '226 and non-inherency of the native-conformation limitations)—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. *See Samsung*, IPR2025-00176, Paper 12, at 3-4. The third, fourth, and fifth *Fintiv* factors thus decisively favor discretionary denial.

1. The Related Litigation Overlaps with Fresenius's Petition (*Fintiv* Factor 4)

The fourth *Fintiv* factor weighs heavily in favor of discretionary denial, as the claims Fresenius challenges and the anticipation theory and arguments it raises in its Petition substantially overlap with those at issue in the parallel litigation.

a. The Challenged Claims Substantially Overlap

Fresenius's Petition challenges claims 1-5, 7-30, and 32-50. Claims 4, 7, 9, 11, and 14-17 were at issue in the *Mylan* litigation, while those claims plus claims 29, 32, 34, 36, 39-42, and 55 were collectively asserted in the *SB*, *Formycon*, and *Celltrion* litigations. *Mylan*, 714 F. Supp. 3d at 677; *SB PI Decision*, 2024 WL 3422971, at *3; *Formycon PI Decision*, 2024 WL 3423047, at *3; Ex.2004 (*Celltrion PI Decision*) at 10. Fresenius's Petition thus challenges all the claims that

were asserted—and challenged as anticipated by Dix ’226—in the *Mylan* proceeding and all but one of the claims at issue in the preliminary-injunction proceedings. The additional claims that Fresenius challenges in its Petition are substantially similar to the claims at issue in the parallel litigation, as Fresenius itself acknowledges. *See* Pet. 33-41 (generally arguing for invalidity of overlapping and non-overlapping claims together). Because Fresenius challenges only claims that were asserted in parallel proceedings or are substantially similar to such claims, “the mere existence of non-overlapping claims does not . . . favor[] institution.” *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). Instead, the extensive overlap favors denial of institution. *E.g., Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *6 (P.T.A.B. Mar. 20, 2020) (precedential).

b. The Issues Substantially Overlap

Fresenius asserts precisely the same anticipation defense rejected in *Mylan*: anticipation by Dix ’226. Fresenius’s Petition is therefore completely duplicative of the *Mylan* litigation, and institution here would be wastefully inefficient.

Dix ’226’s “10-50 mg/ml” Disclosure. Like *Mylan*, Fresenius asserts that Dix ’226 anticipates the ’865 patent’s claims because it discloses a concentration range that overlaps with the 40 mg/ml concentration required by all but two of the

challenged claims. Pet. 1-4, 6, 29-32. But the District Court already resolved anticipation in Regeneron's favor. *See Mylan*, 714 F. Supp. 3d at 730-34.

Fresenius suggests, focusing singularly on the issue of "criticality," that its Petition should be instituted, so that this proceeding can serve as a mulligan for the District Court's thorough analysis following a lengthy trial. Pet. 2. Fresenius cites not to any new evidence or argument, but rather to questions regarding criticality raised by a subset of judges on the Federal Circuit panel during oral argument. Pet. 32 (arguing that panel's questions "call into question and render irrelevant the district court's finding that Dix '226 did not anticipate the Challenged Claims."); Pet. 1-4, 6, 30-31 (similar). But no authority supports Fresenius's outlandish proposition that reading the tea leaves from an oral argument provides a valid basis for disregarding a District Court decision after a two-week trial, either substantively or for purposes of assessing whether there would be inefficient duplication under *Fintiv*. Additionally, Fresenius's one-sided characterization of the oral argument ignores the panel's questions critical of Mylan's position acknowledging that reversal on criticality would be insufficient to vacate the District Court's finding that Dix '226 did not anticipate. *E.g.*, Ex.1008 at 17:6-20:22 (Judge Chen: "What about the 98 percent stability limitation? I think there was a finding that . . . even if Dix discloses the 40 mg [concentration] . . . there is nothing in Dix that necessarily leads to that particular formulation that would get you this . . . particularized stability.")).

Regardless of the impropriety of its tea-leaf-reading approach, Fresenius ignores the District Court's findings that foreclose anticipation separately from criticality. First, the Court found that Dix '226 does not disclose all the elements of the claimed formulations as arranged in the '865 patent's claims. For instance, the Court recognized that "the disclosure in Dix '226 of '10-50 mg/ml' is not linked to aflibercept specifically, but instead refers to a generic 'VEGF-specific fusion protein antagonist,'" and that "multiple fusion proteins would fall within that genus" or "'class' of proteins," with "Dix '226 identify[ing] at least two such fusion proteins by sequence." *Mylan*, 714 F. Supp. 3d at 730-31. Furthermore, the District Court found that "Dix '226 [does not] disclose any formulation with 40 mg/ml aflibercept that meets the 98% native conformation limitation, or any ophthalmic formulation, also required by each claim, which separately is fatal to the Defendants' anticipation argument." *Id.* at 732. "Because Dix '226 does not disclose what the claims require specifically—40 mg/ml of aflibercept, with 98% native conformation after two months storage at 5°C—it cannot anticipate the claims." *Id.* at 732-33. Contrary to the requirement that "the prior-art reference must disclose each element 'arranged as in the claim,'" "the Defendants' anticipation theory involves the POSA arbitrarily and improperly selecting 40 mg/ml from the range of 10-50 mg/ml and cobbling together other, disparate disclosures from Dix '226." *Id.* at 733 (quoting *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370-71 (Fed. Cir. 2008)).

Fresenius's Petition simply ignores this finding that forecloses anticipation irrespective of criticality.

Second, the District Court found that criticality was not relevant because the range disclosed in Dix '226 was too broad. Criticality must be evaluated only "[o]nce the patent challenger has established, through overlapping ranges, its prima facie case of anticipation," and the Court found that Dix '226 failed to meet that threshold. *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 687 (Fed. Cir. 2023); *see Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) (holding no anticipation without addressing criticality). In particular, the Court found that Dix '226's "range of 10-50 mg/ml is not a small range," because "[Mylan's expert's] testimony made clear that '10-50 mg/ml' includes not just every whole-number value from 10 to 50, but also includes more precise values to the tenths and hundredths decimal places—like '37.2' and '49.35' mg/ml—resulting in thousands of discrete values within the disclosed range." *Mylan*, 714 F. Supp. 3d at 730. In addition, the Court found that this was not "a case of 'overlapping ranges'" because "[e]ach asserted claim recites the specific concentration of 40 mg/ml aflibercept, not a range of concentrations," and "the Federal Circuit has held that criticality is a factor only where a disclosed range 'overlaps' with a 'claimed range,' not a specific point." *Id.* at 731, 733 (quoting *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1338 (Fed. Cir. 2020)). Based on these findings, the District Court found that there were no

“‘overlapping ranges’ giving rise to a ‘prima facie case of anticipation.’” *Id.* at 731.

These findings, distinct from the finding of criticality that Fresenius singularly attacks, foreclose Fresenius’s anticipation theory. Though Fresenius at length discusses the Federal Circuit panel’s purported skepticism with respect to the District Court’s criticality analysis, its speculation from the oral argument transcript lacks any indication that the District Court’s non-criticality findings were erroneous. To the contrary, the panel’s questions at oral argument, largely ignored by Fresenius, implied that the District Court’s decision may be affirmed regardless of criticality. *See, e.g.*, Ex.1008 at 17:6-20:22 (pressing for evidence of inherency of 98% native conformation); *id.* at 7:11-13 (“I haven’t found a case, which is our case, which is the prior art has the range [of values] and the patent has just one [value].”); *id.* at 35:4-9 (“[A]s I understand your argument, you’ve got roadblocks that’s setting up before we have to worry about criticality. One is we’re dealing with, as you would call it, a class of VEGF antagonists and two, the size of the prior art . . . range is just too big.”). Because Fresenius does not demonstrate any error in the District Court’s findings, the Director should decline Fresenius’s request to relitigate these issues.

Dix ’226’s 40 mg/ml Pre-lyophilized Solution. Fresenius also argues that Dix ’226 anticipates the claimed formulations because it discloses a “pre-lyophilized solution” of aflibercept at a concentration of 40 mg/ml. Pet. 18-19. Again, the District Court considered and rejected this argument, which Fresenius ignores.

Fresenius asserts that “Dix ’226 even identified specifically a 40 mg/ml pre-lyophilized formulation that was lyophilized and reconstituted to an 80 mg/ml solution” and “thus demonstrated that 40 mg/ml would have been an easily achievable concentration.” Pet. 18. But the District Court in *Mylan* found expressly to the contrary, and Fresenius’s “pre-lyophilized solution” argument thus would require negating the District Court’s findings after a two-week bench trial. First, the Court found that Dix ’226 does not disclose “a pre-lyophilized *aflibercept* formulation,” Pet. 32 (emphasis added), and instead found “that Dix did not teach that the ‘pre-lyophilized solution’ included aflibercept” and “does not indicate whether the pre-lyophilized solution contains aflibercept or any other limitation of the claims,” *Mylan*, 714 F. Supp. 3d at 731, 733. Second, the Court specifically found that the pre-lyophilized solution is outside the scope of the claims, because: (1) it “is only ‘a manufacturing intermediate’ not intended for any kind of injection,” nor “a formulation for administration”; (2) Dix ’226 “states that the pre-lyophilized solution ‘is lyophilized and reconstituted’ to a different concentration” and “does not disclose the pre-lyophilized solution as being stored or injected”; and (3) “the POSA would not expect this manufacturing intermediate to meet the 98% native conformation limitation over two months, as a formulator would not ‘store it for nearly that long.’” *Id.* at 731-33. Accordingly, “Dix’s ‘40 mg/ml pre-lyophilized solution’ does not refer to any kind of formulation to be administered, much less an

ophthalmic formulation or, as the claim requires, an ophthalmic formulation of aflibercept,” and “th[is] isolated disclosure of 40 mg/ml pre-lyophilized solution, unconnected to any of the other claim elements, is not a disclosure of each element ‘arranged as in the claim.’” *Id.* Fresenius does not even acknowledge these findings, much less demonstrate any error in them. The Board previously denied institution on the ’865 patent where the petitioner simply ignored contrary decisions dooming its arguments, and the Director should do the same here. *Samsung*, IPR2025-00176, Paper 12, at 22-23 (“The fact that Petitioner elected not to mention, much less attempt to address the substance of the district court’s findings that such a motivation [to use glycosylated aflibercept] was lacking, suggests a weakness in this aspect of its asserted grounds.”).

98% Native Conformation. Despite six decisions holding to the contrary, Fresenius maintains that the native-conformation limitations are inherent. Particularly, Fresenius argues that Dix ’226 discloses formulations with ingredients (and amounts or concentrations thereof) falling within the scope of the claims of the ’865 patent, and it argues that all such formulations inevitably have the claimed stability levels. *See, e.g.*, Pet. 33 (“[T]he formulations with 40 mg/ml and polysorbate 20 in the claimed amounts would inherently meet the stability limitations of claim 1[.]”); Pet. 39 (similar).

But the District Court already rejected that very same argument, repeatedly.

The Court found that SS195, “a formulation [that comprises] . . . 40 mg/mL of aflibercept, 10 mM phosphate, 0.03% polysorbate 20, 5% sucrose, and 40 mM NaCl at pH 6.25”—*i.e.*, a formulation that “falls within the scope of” nearly all challenged claims—“possessed less than 98% native conformation by SEC even at time zero, before any storage.” *SB PI Decision*, 2024 WL 3422971, at *29. As a result, “not every formulation falling within the scope of [the challenged claims] ‘necessarily’ achieves 98% native conformation, as required for a finding of inherency.” *Id.* The Federal Circuit affirmed the non-inherency finding in a precedential opinion. *SB*, 127 F.4th at 913. That SS195 did not satisfy any of the native-conformation limitations—despite being “[a] 40 mg/ml aflibercept formulation with the claimed amounts of polysorbate 20 and sucrose,” Pet. 39—forecloses Fresenius’s theory that any formulations that Dix ’226 purportedly discloses that fall within the scope of the ’865 patent’s claims necessarily would achieve the claimed levels of native conformation. And this non-inherency finding only underscores that Dix ’226—which, as the District Court found, never “disclose[s] any formulation with 40 mg/ml aflibercept that meets the 98% native conformation limitation, or any ophthalmic formulation,” *Mylan*, 714 F. Supp. 3d at 732—cannot anticipate the claimed formulations. Once more, Fresenius points to no error in this determination.

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

As described above, Fresenius’s Petition substantially overlaps with the

Mylan, *SB*, *Formycon*, and *Celltrion* litigations, so all four parallel proceedings are relevant to the Director'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). The investment of the parties, District Court, and Federal Circuit over three years of complex litigation has been enormous. *Supra* 6-7.

Across 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 hundreds of pages of analysis on anticipation and inherency alone. The Federal Circuit has, in turn, heard arguments and issued decisions in the *SB*, *Formycon*, and *Celltrion* appeals that addressed (and affirmed) many of the District Court's findings that Fresenius's Petition seeks to relitigate.

Institution of IPR after such investments by the parties, District Court, and Federal Circuit would be manifestly inefficient. A single preliminary-injunction order addressing patent validity constitutes a substantial investment. *See Fintiv*,

2020 WL 2126495, at *4 & n.16; *Amneal Pharm., Inc. v. Nivagen Pharm., Inc.*, IPR2025-00731, Paper 15, at 2-3 (P.T.A.B. Sept. 3, 2025); *E-One, Inc. v. Oskhosh Corp.*, IPR2019-00162, 2019 WL 2396798 (P.T.A.B. June 5, 2019); *Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01479, 2020 WL 927867, at *4-5 (P.T.A.B. Feb. 26, 2020). Here, there is far more: one post-trial decision addressing and rejecting Fresenius’s sole invalidity theory, along with three preliminary-injunction orders rejecting inherency and affirmed across all three appeals.

Moreover, the parallel litigation is ongoing, and Regeneron expects that the District Court and parties in the parallel litigation will further invest in claim construction, fact discovery, expert discovery, motion practice, and potentially even trial before the Board would issue its final written decision.

3. Fresenius Is an Unrelated Petitioner but Raises Duplicative Theories and Arguments (*Fintiv* Factor 5)

The fifth *Fintiv* factor favors denial. Fresenius is not currently a defendant in the parallel litigation, but “[e]ven when a petitioner is unrelated to a defendant, if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution.” *Fintiv*, 2020 WL 2126495, at *6. That is particularly appropriate here, as Fresenius seeks to “commercialize a proposed Afibercept biosimilar” just like the other defendants in the parallel litigation and thus will become part of the parallel litigation if it elects

to pursue commercialization in the United States. Ex.2008 (Fresenius Press Release). Fresenius's Petition raises an invalidity theory identical to the one raised by Mylan and makes numerous arguments that have already been rejected on numerous occasions in the parallel litigation. Apart from mischaracterizing the *Mylan* oral argument and urging the Director to disregard the *Mylan* decision, Fresenius does not "address [the] 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[s] even if the petition is brought by a different party." *Fintiv*, 2020 WL 2126495, at *6; *see Samsung*, IPR2025-00176, Paper 12, at 22-23. This factor thus strongly favors denial.

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

Neither Regeneron nor any of the defendants in the parallel proceedings has sought to stay the District Court litigation. Nor is a stay likely given the District Court's grant of preliminary injunctions against SB, Formycon, and Celltrion. Accordingly, the first *Fintiv* factor favors discretionary denial or is at least neutral.

C. Trial Will Likely Occur Around the Time the Board Would Issue Its Final Written Decision (*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 January 23, 2027. The '865 patent expires in June 2027. Regeneron expects trial to occur in early 2027, in advance of the '865 patent's expiry. As a result, even though

these trial dates have not yet been set, it is likely that they will occur around the time of the Board’s statutory deadline.³ Given this timing, the second *Fintiv* factor favors discretionary denial or is neutral, and the lack of a trial date does not outweigh the other *Fintiv* factors. *See Samsung*, IPR2025-00176, Paper 12, at 14 (“We decline Petitioner’s invitation to cut the *Fintiv* analysis short here by only considering the current lack of a trial date under factor 2.”); *Celltrion*, IPR2025-00456, Paper 14, at 2 (denying institution without discussing lack of trial date).

D. Other Considerations (*Fintiv* Factor 6)

Finally, the sixth *Fintiv* factor strongly favors discretionary denial. As Regeneron will demonstrate in its Preliminary Response, Fresenius cannot demonstrate a reasonable likelihood that the claims are unpatentable, especially in light of its failure to even mention the numerous above-discussed findings that foreclose its anticipation theory. *Samsung*, IPR2025-00176, Paper 12, at 22-23. Given these findings and decisions supporting the ’865 patent’s validity, as well as Fresenius’s failure even to try to show error in them (apart from its criticality arguments based on its misinterpretation of a subset of questions during the *Mylan* oral argument), Fresenius’s unpatentability challenge is unquestionably “weak[.]”

³ Regeneron, SB, Formycon, and Celltrion all have requested that the District Court conduct a status conference on September 29, 2025, to set a schedule. Ex.2009.

just like the prior IPR challenges. *Id.*; *see also* Interim Processes for PTAB Workload Management at 2 (Mar. 26, 2025) (“Memo”) (considering “[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”).

The parties’ settled expectations further support discretionary denial. The claims of the ’865 patent have been in force for over four years (since August 2021). In that time, the patent has withstood *ten* validity challenges raised across one bench trial, three preliminary-injunction proceedings, three appeals before the Federal Circuit, and three petitions for IPR. It would drastically undermine Regeneron’s settled expectations to grant institution here and thereby allow Fresenius to challenge a patent that has withstood ten other validity challenges—and is the basis for three preliminary injunctions—by raising an invalidity theory that has already been fully litigated and rejected by the District Court. *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”).

III. Conclusion

For the foregoing reasons, Regeneron respectfully requests that the Director exercise his discretion under 35 U.S.C. § 314(a) to deny institution.

Date: September 23, 2025

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CERTIFICATION OF PAGE LIMIT

The undersigned certifies that this Discretionary Denial Brief complies with the 20-page limit provided in Section II.C.iii of the Interim Director Discretionary Process guidance available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Date: September 23, 2025

/David I. Berl/

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Lead Counsel for Patent Owner

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

The undersigned hereby certifies that on September 23, 2025, I caused true and correct copies of the following materials:

- Patent Owner's Preliminary Response
- Patent Owner's Exhibit List
- Exhibits 2001-2009

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