

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 IPR2025-01269
U.S. Patent No. 10,828,345 B2

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

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1001	U.S. Patent No. 10,828,345 B2 (“the ’345 patent”)
1002	File History of U.S. Patent No. 10,828,345 B2
1003	Expert Declaration of Dr. John C. Galanis in Support of Petition for Inter Partes Review of Patent No. 10,828,345 B2 (“Galanis Report”)
1004	Curriculum Vitae of Dr. John C. Galanis
1005	Jocelyn Holash et al., <i>VEGF-Trap: A VEGF Blocker with Potent Antitumor Effects</i> , 99 PROC. NAT’L ACAD. SCI. 11393 (2002) (“Holash”)
1006	Quan Dong Nguyen et al., <i>A Phase I Study of Intravitreal Vascular Endothelial Growth Factor Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration</i> , 116 OPHTHALMOLOGY 2141 (2009) (“Nguyen-2009”)
1007	James A Dixon et al., <i>VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration</i> , 18 EXPERT OPINION ON INVESTIGATIONAL DRUGS 1573 (2009) (“Dixon”)
1008	Adis R&D Profile, <i>Aflibercept: AVE 0005, AVE 005, AVE0005, VEGF Trap – Regeneron, VEGF Trap (R1R2), VEGF Trap-Eye</i> , 9 DRUGS R&D 261 (2008) (“Adis”)
1009	U.S. Patent No. 9,254,338 B2 (“the ’338 patent”)
1010	U.S. Patent No. 7,531,173 B2 (“the ’173 patent”)
1011	U.S. Patent No. 7,396,664 B2 (“the ’664 patent”)
1012	U.S. Patent No. 7,374,758 B2 (“the ’758 patent”)
1013	U.S. Patent No. 10,888,601 B2 (“the ’601 patent”)

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1014	IPR2022-01226, <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , Final Written Decision for U.S. Patent No. 10,888,601 (Jan. 9, 2024) (“FWD IPR2022-01226”)
1015	IPR2021-00881, <i>Mylan Pharmaceuticals Inc., et al. v. Regeneron Pharmaceuticals, Inc.</i> , Final Written Decision for U.S. Patent No. 9,254,338 (Nov. 9, 2022) (“FWD IPR2022-00881”)
1016	Jeffery S. Heier, <i>VEGF Trap-Eye for Exudative AMD</i> , RETINAL PHYSICIAN, Apr. 2009 (“Heier-2009”)
1017	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009), https://clinicaltrials.gov/ct2/show/NCT00509795 (“NCT-795”)
1018	VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), https://clinicaltrials.gov/ct2/show/NCT00637377 (“NCT-377”)
1019	Regeneron. [Press Release] <i>Positive Interim Phase 2 Data Reported for VEGF Trap-Eye in Age-Related Macular Degeneration</i> (Mar. 27, 2007), https://newsroom.regeneron.com/news-releases/news-releasedetails/positive-interim-phase-2-data-reported-vegf-trap-eye-agerelated?releaseid=394105 (“Regeneron (27-March-2007)”)
1020	Regeneron. [Press Release] <i>Regeneron and Bayer HealthCare Initiate Phase 3 Global Development Program for VEGF Trap-Eye in Wet Age-Related Macular Degeneration (AMD)</i> (Aug. 2, 2007), https://investor.regeneron.com/news-releases/news-releasedetails/regeneron-and-bayer-healthcare-initiate-phase-3-global (“Regeneron (2-Aug-2007)”)
1021	Regeneron. [Press Release] <i>Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration</i> (Apr. 28, 2008),

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1022	Regeneron. [Press Release] <i>Bayer and Regeneron Dose First Patient in Second Phase 3 Study for VEGF Trap-Eye in Wet Age Related Macular Degeneration</i> (May 8, 2008), http://investor.regeneron.com/releasedetail.cfm?ReleaseID=394065 ("Regeneron (2008-May-08)")
1023	Regeneron. [Press Release] <i>Regeneron and Bayer HealthCare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision Over 52 Weeks in a Phase 2 Study in Patients with Age Related Macular Degeneration</i> (Aug. 19, 2008), https://investor.regeneron.com/news-releases/news-releasedetails/regeneron-and-bayer-healthcare-announce-vegf-trap-eye-achieved?ReleaseID=394056 ("Regeneron (19-August-2008)")
1024	Patrick S. Sharp, <i>The Role of Growth Factors in the Development of Diabetic Retinopathy</i> , 44 METABOLISM No. 10, Suppl. 4, 72-75 (Oct. 1995) ("Sharp")
1025	David M. Brown & Carl D. Regillo, <i>Anti-VEGF Agents in the Treatment of Neovascular Age-Related Macular Degeneration: Applying Clinical Trial Results to the Treatment of Everyday Patients</i> , 144 AM. J. OPHTHALMOLOGY 627 (2007) ("Brown")
1026	Talia N. Crawford, et al., <i>Diabetic Retinopathy and Angiogenesis</i> , 5 Current Diabetes Reviews, 8-13 (2009) ("Crawford")
1027	Napoleone Ferrara & Robert S. Kerbel, <i>Angiogenesis as a Therapeutic Target</i> , 438 NATURE 967 (2005) ("Ferrara-2005")
1028	Ziad F. Bashshur et al., <i>Intravitreal Bevacizumab for the Management of Choroidal Neovascularization in Age-Related Macular Degeneration</i> , 142 AM. J. OPHTHALMOLOGY 1 (2006) ("Bashshur")
1029	LUCENTIS® Prescribing Information (2006) ("Lucentis")

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1031	Jeffrey S. Heier et al., <i>Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-Related Macular Degeneration</i> , 119 OPTHALMOLOGY 2537 (2012) (“Heier-2012”)
1032	J.S. Rudge et al., <i>VEGF Trap as a Novel Antiangiogenic Treatment Currently in Clinical Trials for Cancer and Eye Diseases, and VelociGene®-Based Discovery of the Next Generation of Angiogenesis Targets</i> , 70 COLD SPRING HARBOR SYMPOSIA QUANTITATIVE BIOLOGY 411 (2005) (“Rudge”)
1033	Quan Dong Nguyen et al., <i>A Phase I Trial of an IV-Administered Vascular Endothelial Growth Factor Trap for Treatment in Patients with Choroidal Neovascularization due to Age-Related Macular Degeneration</i> , 113 OPTHALMOLOGY 1522 (2006) (“Nguyen-2006”)
1034	John S. Rudge et al., <i>VEGF Trap Complex Formation Measures Production Rates of VEGF, Providing a Biomarker for Predicting Efficacious Angiogenic Blockade</i> , 104 PNAS 18363 (2007) (“Rudge-2007”)
1035	John S. Rudge et al., <i>Clinical Development of VEGF Trap</i> , ANGIOGENESIS, Chpt. 36 (William D. Figg & Judah Folkman eds. 2008) (“Rudge-2008”)
1036	Candelaria Gomez-Manzano et al., <i>VEGF Trap Induces Antiglioma Effect at Different Stages of Disease</i> , 10 NEURO-ONCOLOGY 940 (2008) (“Gomez-Manzano”)
1037	Regeneron Pharm., Inc., Quarterly Report (Form 10-Q) (Sept. 30, 2009) (“2009 10-Q”)
1038	P Mitchell et al., <i>Ranibizumab (Lucentis) in Neovascular Age-Related Macular Degeneration: Evidence from Clinical Trials</i> , 94 BRIT. J. OPTHALMOLOGY 2 (2009) (date of online publication) (“Mitchell”)

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1039	Regeneron. [Press Release] <i>VEGF Trap-Eye Final Phase 2 Results in Age-related Macular Degeneration Presented at 2008 Retina Society Meeting</i> (Sept. 28, 2008), https://investor.regeneron.com/newsreleases/news-release-details/vegf-trap-eye-final-phase-2-resultsage-related-macular?ReleaseID=393906 (“Regeneron (28-September-2008)”)
1040	Regeneron. [Press Release] <i>Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD)</i> (Sept. 14, 2009), https://investor.regeneron.com/news-releases/newsrelease-details/enrollment-completed-regeneron-and-bayerhealthcare-phase-3?ReleaseID=408872 (“Regeneron (14-September-2009)”)
1041	Napoleone Ferrara et al., <i>Development of Ranibizumab, and Anti-Vascular Endothelial Growth Factor Antigen Binding Fragment, as Therapy for Neovascular Age-Related Macular Degeneration</i> , 26 RETINA, THE J. OF RETINAL AND VITREOUS DISEASES, No. 8, 859-870 (2006) (“Ferrara-2006”)
1042	Heinrich Heimann, <i>Intravitreal Injections: Techniques and Sequelae</i> , MEDICAL RETINA 67 (Frank G. Holtz & Richard F. Spaide eds. 2007) (“Heimann-2007”)
1043	U.S. Application Publication No. 2007/0190058 (“the ’058 application”)
1044	Pascale Massin, et al., <i>Safety and Efficacy of Ranibizumab in Diabetic Macular Edema (RESOLVE Study)</i> , 33 DIABETES CARE, No. 11 (Nov. 2010) (“Massin”)
1045	Anne F. Fung, et al., <i>An Optical Coherence Tomography-Guided, Variable Dosing Regimen with Intravitreal Ranibizumab (Lucentis) for Neovascular Age-related Macular Degeneration</i> , AM. J. OPHTHAMOLOGY 143:566-583 (Apr. 2007) (“Fung”)

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1046	IPR2022-01225, <i>Mylan Pharmaceuticals Inc., v. Regeneron Pharmaceuticals, Inc.</i> , Final Written Decision for U.S. Patent No. 10,130,681 (Jan. 9, 2024) (“FWD IPR2022-01225”)
1047	U.S. Patent No. 10,888,601, Disclaimer in Patent Under 37 CFR. 1.321(a), dated July 10, 2024
1048	U.S. Patent No. 11,253,572, Disclaimer in Patent Under 37 CFR 1.321(a) dated July 10, 2024
1049	File History of U.S. Patent No. 7,374,758 (“758 FH”)
1050	File History of U.S. Patent No. 7,070,959 (“959 FH”)
1051	File History of U.S. Patent No. 10,130,681 (“681 FH”)
1052	Regeneron. [Press Release] <i>VEGF Trap-Eye Shows Positive Results in a Phase 2 Study in Patients with Diabetic Macular Edema</i> (Feb. 18, 2010), https://investor.regeneron.com/news-releases/news-release-details/vegf-trap-eye-shows-positive-results-phase-2-study-patients (“Regeneron (18-Feb-2010)”)
1053	“History, Policy, and Laws”, clinicaltrials.gov (Apr. 26, 2021) https://clinicaltrials.gov/ct2/about-site/history
1054	EYLEA® Prescribing Information
1055	EYLEA HD® Prescribing Information
1056	Executive Order titled “Lowering Drug Prices by Once Again Putting Americans First” dated April 15, 2025
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Petitioner Fresenius Kabi SwissBioSim GmbH (“Fresenius” or “Petitioner”) files this Opposition to Patent Owner’s Discretionary Denial Brief (Paper 6, hereinafter “Brief” or “Br.”), setting forth reasons why the Director should not exercise discretion to deny the Petition for *inter partes* review (“Petition”) of claims 1-11 (the “challenged claims”) of U.S. Patent No. 10,828,345 B2 (the “’345 Patent”) (Ex. 1001), as asserted by Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”). The Examiner made an error in granting the ’345 Patent, by changing position without any basis, only after Regeneron had an interview and provided inadequate reasoning to distinguish the express prior art.

I. INTRODUCTION

Even though Regeneron takes credit for Eylea, it cannot take credit for all of its patents being valid. Almost identical claims for other patents in the very same family as the ’345 Patent have already been deemed invalid by the PTAB or disclaimed by Regeneron itself in view of IPR petitions. Regeneron’s argument is that the prior art disclosed dosing that “may” include 12 weeks, but does not “necessarily” require 12 weeks. Br. at 10. The prior art, however, expressly disclosed 12 weeks, and that is enough to invalidate all challenged claims. Nothing more was required, and the Examiner erred by falling for Regeneron’s argument and interview that the prior art’s express disclosure should be disregarded.

Petitioner's IPR is not only appropriate, but necessary to root out weak patents that block President Trump's stated policy for providing affordable drugs to this country's citizens. On April 15, 2025, the White House issued Executive Order 14273 titled "Lowering Drug Prices by Once Again Putting Americans First." Ex. 1056. The Executive Order states that "[i]t is the policy of the United States that Federal health care programs, intellectual property protections, and safety regulations are optimized to provide access to prescription drugs at lower costs to American patients and taxpayers." *Id.* at Section 2. Similarly, Senators Amy Klobuchar (D-MN) and Chuck Grassley (R-IA), Chairman of the Senate Judiciary Committee, introduced two bipartisan bills to reduce drug prices by promoting competition. Ex. 1057.

Despite its family of invalid patents, Regeneron seeks discretionary denial to extend its '345 patent monopoly, not under *Fintiv*, but rather under the standard set forth in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020). As to the first *Advanced Bionics* prong, Regeneron notes that the individual references are cited but were not discussed during prosecution, and the Patent Office did not have the benefit of an expert declaration. As to the second *Advanced Bionics* prong, Regeneron's own brief proves why the Petition should be referred for institution: the Examiner

misapprehended the prior art's express disclosure for "12 weeks" dosing, which anticipated and rendered obvious all challenged claims.

II. BACKGROUND

Fresenius' Petition includes nine grounds, with Grounds 1-4 showing anticipation for claims 1-9, Ground 5 showing obviousness for claims 1-9, and Grounds 6-9 showing obviousness for remaining claims 10 and 11.

As discussed in more detail in the Petition, in response to IPR petitions for claims in related patents with overlapping subject matter, either the PTAB has deemed them unpatentable or else Regeneron has disclaimed its claims. Paper 1, at 4-6. For example, the PTAB deemed invalid claim 1 of the '601 patent, with tertiary dosing "administered every 8 weeks," (Ex. 1014), whereas claim 1 of the presently-challenged '345 Patent claims tertiary dosing "administered every 8 weeks." Regeneron does not dispute this fact. Br. at 20. Instead, Regeneron disputes whether the prior art actually disclosed administering aflibercept for 12 weeks. It did.

Dixon (Ex. 1007) disclosed substantial information about the state of the art, and incorporated by reference NCT-377 (Ex. 1018 at 7), which expressly disclosed "a dose may be administered as frequently as every 4 weeks, but *no less frequently than every 12 weeks.*" NCT-795 (Ex. 1017 at 6) similarly taught that "a dose may be administered as frequently as every 4 weeks, but *no less frequently than every 12 weeks.*" Regeneron's May 2008 Press Release (Ex. 1022 at 1) provided a different

disclosure but still included 12 weeks, explaining that the existing clinical trial patients “will be followed and treated for another year on a flexible, criteria-based extended regimen with a dose *administered at least every 12 weeks*, but not more than 4 weeks until the end of the study.” These references form the basis for Petitioner’s anticipation Grounds 1-4.

During patent prosecution, Regeneron does not point to express discussion of these references, but Regeneron asserts that the Examiner considered a Regeneron 2009 Press Release that also disclosed 12-week tertiary dose administration. Br. at 16. The Examiner at first clearly understood the 2009 Press Release disclosure to mean what it says: the express reference to administration at 12 weeks meant administration at 12 weeks. Ex. 1002 at 243, 325. In its January 23, 2020 Response, Regeneron asserted—incorrectly—that “the Press Release did not explicitly disclose a dosing regimen having a 12 week dosing (q12w) component,” and then for some reason introduced an inherency analysis as to the 12-week term. *Id.* at 233. Regeneron concluded by asking for an interview. *Id.* at 235. The Examiner complied, calling Regeneron on March 6, 2020 “to discuss the amendment filed 23 January 2020 and the rejections of record[.]” including over the 2009 Regeneron press release. *Id.* at 163. Regeneron responded with its own interview summary, and argued that “[a]s explained in our January 23, 2020 Response, this is not a disclosure of a regimen having 12-week tertiary dosing as specified in the claims.” *Id.* at 193-

194. On March 25, 2020 the Examiner issued a Notice of Allowability that identified the 2009 “Regeneron Press Release Publication” and said “[t]here are 3 separate studies disclosed in the Press Release, and none of them teach or fairly suggest the dosing regimen recited in the instant claims.” *Id.* at 160-161. The Examiner provided no explanation for how this erroneous conclusion was reached, or why the prior rejections based on the very same disclosures were suddenly withdrawn.

III. DISCRETIONARY DENIAL UNDER *ADVANCED BIONICS* IS NOT WARRANTED

Claim 1 of the '345 Patent is the only independent claim, and it is the only claim that identifies a dosing frequency. It requires a tertiary dose given at 12 weeks, and several prior art references already disclosed that regimen. While Regeneron argued otherwise during prosecution—and repeats that same flawed argument now—it led to the Examiner’s error in granting the '345 Patent for all of the reasons stated in the Petition. In addition, the *Advanced Bionics* factors do not apply.

A. The First Factor Weighs Against Discretionary Denial

Regeneron’s argument fails the first factor for several reasons.

First, the four central prior art references in Petitioner’s IPR—Dixon, NCT-377, NCT-795, and Regeneron 2008—were cited but not discussed in detail by the Examiner. Regeneron points instead to the Regeneron 2009 Press Release, and asserts that all four references would have been cumulative, but Regeneron fails to

compare the references as a whole, and their respective teachings. One way in which the references are distinct is because the Regeneron 2009 Press Release addressed by the Examiner listed “PRN regimen,” whereas the NCT-377, NCT-795, and Regeneron 2008 press release do not require PRN for the 12-week administration. Yet this is a material distinction based on Regeneron’s own argument about the supposed import of the “PRN” disclosure as used in the Regeneron 2009 press release. Br. at 8-10.

Second, even assuming the Examiner considered these references individually, Regeneron does not address obviousness combination. The four central references are listed on the face of the patent along with 250 other references. Grounds 5-9 are based on combinations of the four central references, and those combinations were not previously considered. Grounds 6-7 and 9 are based on combinations, plus the knowledge of a POSA (as evidenced by the Galanis Declaration, Ex. 1003), which was also not previously considered. Regeneron therefore has not shown the “cumulative nature” of the Petition art or “the extent to which the asserted art was evaluated during examination.” *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017).

Third, since the first factor is about the same prior art or arguments in prior proceedings, due consideration must be given to the prior IPRs that found related

Regeneron patents invalid. In IPR2022-1266, the PTAB found claims invalid to administration “once every 8 weeks or once every 2 months” and “at least 8 weeks after the immediately preceding dose,” in part by referencing the earlier IPR2021-0881, which had found claims invalid to administration for “at least 8 weeks.” Ex. 1014 at 82. This invalidating decision relied on the same Dixon reference presented here, and did not need to reach other grounds that included the Regeneron 2008, NCT-795, and NCT-377 references. *Id.* at 5 n.4 & 93 n.17. These references anticipate the challenged 12-week claims, and at a minimum, the challenged 12-week claims are obvious in view of the fact that the “at least 8 weeks” claims were already invalidated in these prior IPR proceedings over the same art. Thus, looking to related proceedings only further supports institution. *Becton, Dickinson*, IPR2017-01586, Paper 8 at 17-18.

B. The Second Factor Weighs Against Discretionary Denial

Regeneron spends barely two and a half pages on the second factor, reflecting the insufficiency of its position. Of course, *Advanced Bionics* requires meeting **both** factor one “and” factor two to support a discretionary denial request. *Advanced Bionics*, Paper 6, at 8. “An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims. Another example may include an error

of law, such as misconstruing a claim term, where the construction impacts patentability of the challenged claims.” *Id.* at 8-9 n.9.

Regeneron’s entire argument is premised on the allegation that prior art did not teach 12-week administration, even though the prior art expressly taught 12-week administration. The Examiner misapprehended claim scope and misapprehended prior art, only after Regeneron’s flawed arguments. Discretionary denial should be rejected. *See Samsung Bioepis Co. Ltd. v. Alexion Pharms., Inc.*, IPR2023-01070, Paper 9 (P.T.A.B. Dec. 19, 2023).

As a preliminary matter, Regeneron does not address the claim scope itself, as opposed to what Regeneron argued during patent prosecution. In particular, claim 1 relates to dosing including “***one or more*** tertiary doses of the VEGF antagonist” and “wherein each tertiary dose is administered ***12 weeks after the immediately preceding dose.***” Ex. 1001 at Claim 1 (emphases added). Regeneron does not address the language of the claim: “one” tertiary dose administered 12 weeks after the immediately preceding dose is sufficient to meet the claim. The four central prior art references in the Petition all disclosed this limitation, and Regeneron’s own table summary proves the point. Br. at 14-15.

Rather than rely on the claim term itself, Regeneron relies on its prosecution history argument to the Examiner, which did not properly compare the prior art and the claim term. As reported above, in its pivotal January 23, 2020 Response,

Regeneron asserted—incorrectly—that “the Press Release did not explicitly disclose a dosing regimen having a 12 week dosing (q12w) component.” *Id.* at 233. That was incorrect: all four central prior art references did include—explicitly—a dosing regimen having a 12 week dosing component. Moreover, the sheer number of cited references—over 250 (10 times the average number)—also shows discretionary denial is inappropriate. *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 6-7 (P.T.A.B. May 19, 2025).

To the extent that Regeneron in its argument was attempting to distinguish the prior art based on the requirement of multiple 12-week administrations, that distinction fails. *First*, the claim only requires “one” 12-week administration, and there is no dispute that all prior art, including the Regeneron 2009 press release, permitted at least one 12-week administration. *Second*, if Regeneron had intended to argue that claim 1 means something other than at least one 12-week administration, it should have written its claim differently, and Regeneron cannot now rewrite the claim. *Third*, to the extent that Regeneron is implying some new construction for the “tertiary administration” claim term, Regeneron failed to present any claim construction, much less one that would justify its argument.

In addition, the Examiner did not have the benefit of an expert declaration, which Petitioner provided by Dr. John C. Galanis. In the declaration, he explained why the 12-week tertiary dose disclosure from the prior art met the claim term

requirement for a 12-week tertiary dose. Ex. 1003 at ¶¶ 218-219, 263-264, 292-293.

In contrast, Regeneron's request is based on unsupported attorney argument that purports to recite medical practice and interpretation, without citation. Br. at 2-3.

At a minimum, the prior art disclosures even if viewed as a range, still expressly disclosed the range of 4 to 12 weeks. For example, NCT-377 reported that aflibercept could be "administered as frequently as every 4 weeks, but no less frequently than 12 weeks." E.g., Ex. 1018 at 6. The prior art range is limited in scope and includes the 12-weeks required by all challenged claims, thereby anticipating the claims as proposed in Grounds 1-4 of the Petition. *ClearValue Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012). In the alternative, the prior art range at least includes 12-weeks and therefore renders *prima facie* obvious all challenged claims, particularly since Regeneron never showed any criticality to any of the examples of 4 to 12 weeks. *In re Bergen*, 120 F.2d 329, 332, (CCPA 1941).

Ultimately, the Examiner made an error, and that error should be corrected now. The Examiner had it right until Regeneron's later inappropriate assertions that led to the Examiner misapprehending claim scope and prior art disclosures. The Regeneron 2009 press release included the "12 week" tertiary administration as an option, and including 12 weeks as an option was more than enough to meet the claim language. See *Upsher-Smith Lab'ys, Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (finding anticipation met where prior art disclosure would infringe claim).

There was no requirement for anything more. The Examiner took and maintained that correct position, until an interview, and for some reason thereafter withdrew the rejection and concluded the Regeneron 2009 press release did not include “12 week” tertiary administration. The record does not identify what changed or what difference was actually identified over the prior art, from which to glean any meaningful patentable distinction. Regeneron’s request for discretionary denial does not include an explanation for why its argument was correct, relevant to the claim language, and should have been accepted. It should not have been accepted then, and it should not be accepted now. The Examiner erred.

The Examiner was also likely to have been confused by additional surrounding circumstances in Regeneron’s argument. Regeneron disputed the prior art status of the Regeneron 2009 press release, Ex. 1002 at 193, whereas Regeneron does not at this stage challenge the prior art status of the four central prior art references in the Petition. While Regeneron now claims that the Examiner could not have believed the Regeneron 2009 press release to be prior art, Br. at 11-12, that remained Regeneron’s lead argument during prosecution.

Regeneron also for some reason discussed inherency during prosecution, making an assumption that the Examiner had inherency in mind. *Id.* at 233. But that doctrine applies where a term is missing in the prior art, and to propose inherency as a means to provide that otherwise missing term. But that doctrine applies where a

term is missing in the prior art, and to propose inherency as a means to provide that otherwise missing term. *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Here, however, the 12-week administration was cited by the Examiner as expressly disclosed in the Regeneron 2009 press release. These distractions, coupled with the interview discussions for which there is an incomplete record, provide additional bases explaining why the Examiner erred. Yet Regeneron repeats that same defective argument in its request for discretionary denial, and credits the inherency argument as reason “[t]he Examiner was persuaded.” Br. at 10-11.

Regeneron makes no other argument other than as to the “12-week” claim term in claim 1. Regeneron makes no other unique argument for terms in any other challenged claim. Its sole argument that the 12-week disclosure was not in the prior art is shown to be incorrect by the prior art itself, repeatedly disclosing 12-week tertiary administration.

For these reasons *Becton, Dickinson* factors under this *Advanced Bionics* factor favor Petitioner: the “extent of overlap” between the arguments supports institution to correct the Examiner’s error, Petitioner has “pointed out sufficiently how the Examiner erred,” and additional facts including the expert declaration by Dr. Galanis all support denying the request for discretionary denial. *Becton, Dickinson*, IPR2017-01586, Paper 8 at 17-18. As in *Samsung*, discretionary denial should be declined. *Samsung*, Paper 9 at 61-67.

IV. CONCLUSION

Petitioner respectfully requests that the Director reject Patent Owner's request for discretionary denial and refer Petitioner's Petition to a panel for an institution decision on the merits.

Dated: October 23, 2025

Respectfully submitted,

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CERTIFICATE OF PAGE LIMIT

The undersigned certifies that Petitioner's Opposition to Patent Owner's Request for Discretionary Denial complies with the 20-page limit provided in Section III.C.iii of the Interim Director Discretionary Process guidance available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Dated: October 23, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on October 23, 2025, a complete and entire copy of Petitioner's Opposition to Patent Owner's Request for Discretionary Denial, and all supporting exhibits were provided by electronic email on the following counsel of record:

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