

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 SUR-REPLY IN OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

TABLE OF CONTENTS

I.	The Patent and File History Do Not Support Discretionary Denial.....	1
II.	Fresenius Responded To Regeneron’s Arguments, Which Regeneron Misconstrues As New Petition Arguments.....	3
III.	Institution Supports Policy Goal To Provide Affordable Drugs	5
IV.	Conclusion	5

Regeneron incorrectly asserts that Fresenius's Opposition to Patent Owner's Request for Discretionary Denial (Paper 7, hereinafter "Opp.") mischaracterizes the patent and its file history and includes "new theories", allegedly not present in its Petition. The prior art on which Fresenius relies was not discussed during prosecution. The Examiner erred in reviewing *other* clinical trial prior art, and distinguishing it as not anticipatory, but the Examiner failed completely to consider obviousness even over that art. The Board has already invalidated 8-week dosing claims based on the same art in the Petition, and the Petition should be referred for institution because that art also disclosed "12 week" dosing.

I. THE PATENT AND FILE HISTORY DO NOT SUPPORT DISCRETIONARY DENIAL

Regeneron points out that claim 1 recites 12-week dosing and not 8-week dosing. Patent Owner's Reply in Support of Discretionary Denial (Paper 9, hereinafter "Reply"), 1. That is apparent from all of Fresenius's arguments—that the '345 patent recites 12-week dosing which is disclosed in the prior art. Opp., 3.

Regeneron admits that the reference during prosecution was a *different* reference (with an allegedly "nearly identical" disclosure) than the references in the Petition. Reply, 1. Regeneron's dispute is thus with Fresenius's characterization of the 2009 Press Release (Ex. 1040), an issue not fairly resolved at this discretionary-denial stage. Patent Owner's Discretionary Denial Brief (Paper 6, hereinafter "DD Brief"), 8-10; Opp., 5-6, 9, 10-11.

Regeneron also takes issue with whether or not the 2009 Press Release's status as prior art was a "lead" argument during prosecution. Reply, 1-2. Regeneron has taken contradictory positions on the prior art status of the 2009 Press Release. Opp., 11. It is not disputed that, during prosecution, Regeneron asserted the 2009 Press Release was not prior art. In any event, Fresenius already addressed the merits of the issue and all of the Examiner's comments, not just the prior art status issue. (Pet., 18; DD Brief, 11-12; Opp., 11-12).

There is no dispute that the PTO lacked an expert declaration, despite Regeneron's protestations. Reply, 2. Regeneron instead argues that the Petition does not cite the paragraphs of the Galanis declaration (Ex. 1003) showing that the prior art disclosed a 12-week dose. However, that declaration anticipated the full institution process, and Fresenius did cite the relevant paragraphs in its Opposition to show that Regeneron's request should be denied. Opp., 9-10, citing Ex. 1003 ¶¶ 218-29, 263-64, 292-93. Regeneron's suggestion that this evidence should be ignored is contradicted by the "FAQs for Interim Processes for PTAB Workload Management" pursuant to which Fresenius did not present affirmative arguments in anticipation of Regeneron's discretionary denial arguments. Pet., 59. With or without the Galanis declaration, the prior PTAB final decisions already found 8-week dosing invalid over the same art, and the art itself also already showed 12-week dosing.

II. FRESENIUS RESPONDED TO REGENERON’S ARGUMENTS, WHICH REGENERON MISCONSTRUES AS NEW PETITION ARGUMENTS

Under Regeneron’s view, any response to a discretionary denial request would be “new” unless it rehashed the Petition itself. That ignores established protocol in view of the FAQs for Interim Processes. Regeneron argues that Fresenius presents a new argument regarding the absence of a PRN dosing in NCT-377, NCT-795 and the 2008 Press Release as distinct from the 2009 Press Release which includes PRN dosing. Reply, 3. Not so. Fresenius does not rely on the 2009 Press Release in its Grounds. Fresenius merely responded to the argument Regeneron made, and it did not have an opportunity to do so any earlier. Opp., 6 (citing DD Brief, 8-10). NCT-377 (Ex. 1018), NCT-795 (Ex. 1078), and the 2008 Press Release (Ex. 1039) do not refer to “PRN” dosing. *See* Petition, 33-38, 42-51.

Regeneron next takes issue with Fresenius’s assertion that Grounds 5-9 are based on combinations of four references not previously considered by the Examiner. Reply, 3. The obviousness grounds were not considered, and the key Reasons for Allowance upon which Regeneron relies addressed anticipation. *See* Petition, 11, 51-59; Opp., 5-7. Regeneron’s actual argument is about the merits—just like its argument that 12-weeks was not disclosed in the prior art that expressly taught dosing at 12 weeks—but those are subjects for POPR. The relevant inquiry

here is whether the Examiner discussed the references and obviousness arguments included in Fresenius's grounds; the Examiner did not.

Regeneron suggests that Fresenius's use of the word "range" in reference to the disclosed 4 to 12-week dosing regimens creates a "new" obviousness argument. This is incorrect. In its Discretionary Denial Brief, Regeneron argued that the disclosed dosing range is not invalidating because the dose interval is flexible and the claim allegedly requires a "*fixed* time period of twelve weeks after the preceding dose[.]" DD Brief, 13. In response to this new argument, Fresenius noted that even if the prior art disclosure included flexible dosing throughout the 4 to 12 week range, that would still render the claims anticipated and/or obvious. Reply, 10.

The Petition explains in detail how at least Dixon (Ex. 1007) and NCT-377 (Ex. 1018) disclose each limitation recited in claims 1-9, including 4- to 12-week dosing intervals. Pet., 46-47 and 51-52; *see also* Ex. 1003, ¶¶ 218-19, 263-64, 292-93 (explaining why the 12-week dose disclosure in the prior art met the claimed 12-week dose). The Petition and Galanis declaration further explain that a POSA would have been motivated to use the disclosed 12-week dose at least because of the desire to reduce the frequency of intravitreal injections. Pet., 3; Ex. 1003, ¶¶ 244, 312, and 315. Regeneron is wrong about the Examiner's error on anticipation, and ignores the Examiner's omission of any obviousness analysis.

III. INSTITUTION SUPPORTS POLICY GOAL TO PROVIDE AFFORDABLE DRUGS

Regeneron is incorrect in its implication that institution of this Petition would not protect American jobs and the U.S. economy. Reply, 5. Petitioner is a subsidiary of Fresenius Kabi AG which includes American-based entities and employs Americans who will be marketing a biosimilar to help serve untold numbers of American patients needing affordable medicines. In addition, the critical nature of providing affordable drugs and rooting out weak patents—as evidenced by the April 15, 2025 Executive Order (Ex. 1056)—is not outweighed by the general economic concerns Regeneron identifies.

IV. CONCLUSION

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

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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 November 5, 2025, a complete and entire copy of Petitioner's Sur-Reply in 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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