

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS GENE THERAPIES, INC. & NOVARTIS PHARMACEUTICALS
CORPORATION,
Petitioners

v.

GENZYME CORPORATION,
Patent Owner.

Case: IPR2023-00609
Patent No. 9,051,542

**PATENT OWNER'S RESPONSE TO NOVARTIS'S
NOTICE REGARDING MULTIPLE PETITIONS**

I. NOVARTIS IPR2023-00609 PETITION SHOULD BE DENIED IF IPR2023-00608 IS INSTITUTED

Novartis has filed two petitions challenging just four claims of U.S. Patent No. 9,051,542 (“the ’542 patent”) totaling nearly 27,000 words. The PTO’s November 2019 Consolidated Trial Practice Guide (“TPG”) states that one petition, in most situations, is sufficient to challenge a patent’s claims. Novartis attempts to justify its parallel request fails to even acknowledge the Board’s guidance regarding multiple petitions. TPG explains that exceptions to the single petition rule should be rare to avoid substantially burdening the Board:

Based on the Board’s 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).

Id. at 59. The TPG also states that it “should be rare” for a petitioner to need two petitions. *Id.* The limited circumstances where more than one petition “may be necessary” include when the patent owner has asserted “a large number of claims,” or when “there is a dispute about priority date.” *Id.* These exceptions do not apply here and Novartis fails to justify the institution of multiple petitions.

II. NOVARTIS’S EXPLANATION DOES NOT SATISFY THE TRIAL PRACTICE GUIDE’S EXCEPTIONS

The “rare” exceptions which justify multiple petitions are when: “[1] the patent owner has asserted a large number of claims in litigation or [2] when there is a dispute about priority date requiring arguments under multiple prior art references.” TPG at 59.

The priority date for the ’542 patent remains undisputed. *See* Paper 2 at 1 n.1. Novartis also cannot claim that Genzyme has asserted a “large number of claims” in the litigation—indeed, both petitions only address *four* claims (claims 1, 2, 5, and 6). *See Applied Materials, Inc. v. Demaray LLC*, IPR2021-00105, Paper 13 at 11 (PTAB May 12, 2021) (noting that “13 claims” is a “relatively small number of claims”). Instead, Novartis suggests, without explanation, that claim one contains “numerous limitations” such that multiple petitions were warranted. Paper 4 at 2. Novartis simply does not explain why the claims were so complex as to warrant multiple petitions. *See Dropbox, Inc. v. Whitserve LLC*, IPR2019-01018, Paper 13 at 6 (PTAB Nov. 1, 2019) (“Petitioner does not provide any meaningful explanation as to why the number, specificity, length, or complexity of the claims . . . justifies our review of both petitions.”).

At most, Novartis’s explanation points to the mere fact that claim one has six limitations in justifying multiple petitions. Yet, Novartis addresses many of the limitations of claim one in less than four pages and all of the limitations in 13 pages.

See Paper 2 at 33-37; *id.* at 25-37. Likewise, Novartis discussed the dependent claims in only a handful of pages. Paper 2 at 38-43. The Board has previously rejected this same argument with respect to more complex claims. See *LifeSpine, Inc. v. Globus Medical, Inc.*, IPR2023-00041, Paper No. 10 at 12 (PTAB Apr. 20, 2023) (“three very lengthy independent claims” did not justify multiple petitions as there was nothing “extraordinary about the length or total number of challenged claims”). Neither of the TPG’s exceptions apply.

III. NOVARTIS’S REMAINING JUSTIFICATIONS SHOULD BE REJECTED

Novartis next argues that *General Plastics* factors 6 and 7 weigh in favor of institution. Not so. Novartis’s argument relies on inaccuracies. Novartis states that “no other proceedings will interfere with the Board’s issuing final determinations for the two IPRs within 1 year of” institution. Paper 3 at 5. This is demonstrably false—the district court has scheduled a five-day jury trial on the ’542 patent for March 25, 2024. EX2010, 2. The Board’s institution decision will be due by mid-September 2023 and any final written decision will be issued approximately a year later in September 2024, well after the jury’s verdict. Moreover, fact discovery is closing this month and expert reports regarding invalidity will have been served by any institution decision. *Id.* Thus, it would be an inefficient use of the Board’s finite resources to institute and proceed with *multiple* petitions given the advanced nature of the parallel litigation. See *Google LLC v. Uniloc 2017 LLC*, IPR2020-00448, Paper

13 at (PTAB Sept. 9, 2020) (“Whenever multiple petitions are filed, it always creates at least some additional work for the Board and Patent Owner, even if those petitions are consolidated.”). *General Plastics* factors 6 and 7 both weigh in favor of *denial* of institution.

Novartis also suggests that it has “limited” the issues for the Board. Paper 4 at 4. But it is hard to see how; Novartis has presented four primary references across two petitions. Institution would require the Board to consider twice as many grounds when a parallel litigation is scheduled to resolve those grounds beforehand. Novartis also admits that the Petitions “rely on similar background art and state of the art discussions,” but fails to explain why it could not present all the grounds in a single petition. *Id.* Indeed, a comparison of the Petitions shows that the background, claim construction, and discussion of secondary references are identical. In addition, portions of the Grounds are nearly identical or repeat similar arguments and the Petitions only address *four* claims. See Paper 4 at 3 (admitting that “Liu and Lochrie . . . provide similar teachings”). Novartis provides no explanation for why they could not address four Grounds in a single petition. Paper 4 at 2.

Novartis’s cited Board decisions are inapposite. Novartis first relies on *Chegg, Inc. v. NetSoc, LLC*, IPR2019-01171, Paper 16 at 15 (PTAB Dec. 5, 2019). Paper 4 at 3. But *Chegg* involved a situation where the “Patent Owner [could] antedate multiple references.” *Chegg, Inc.*, IPR2019-01171, Paper 16 at 14-15. In contrast,

the issue of antedating references—which falls under the TPG’s exceptions—is not applicable here. Novartis also relies on *Abbott Labs. v. Integrated Sensing Sys., Inc.*, IPR2019-01338, Paper 7 at 9-12 (PTAB Jan. 23, 2020). In *Abbott Labs*, one petition challenged additional claims that were not a part of the second petition (*id.* at 10), and there were references which could be “antedated” by the patentee. *Id.* Moreover, *Abbott Labs* states that the Board’s discretionary determination “takes into consideration guidance in the Board’s Consolidated [TPG],” which Novartis entirely ignores. *Id.* at 10. Novartis’s cases thus do not support institution of both petitions.

IV. CONCLUSION

Having failed to present any compelling reason why nearly 27,000 words were needed to explain why four claims of the ’542 patent are allegedly obvious, Novartis’s request for institution of two petitions is nothing more than a thinly veiled attempt to avoid the word count limitations. Novartis should not be rewarded for its failure to present its arguments in a single petition, and Genzyme respectfully requests that the Board reject this attempt.

Respectfully submitted,

Dated: June 15, 2023

/ Blaine M. Hackman /
Blaine M. Hackman, Ph.D.
Reg. No. 67,479
Counsel for Patent Owner

CERTIFICATE OF SERVICE

I certify that today in:

*Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation v.
Genzyme Corporation, IPR2023-00608 (U.S. Patent 9,051,542)*

I caused to be served a copy of:

**PATENT OWNER'S RESPONSE TO NOVARTIS'S
NOTICE REGARDING MULTIPLE PETITIONS**

upon:

Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation, c/o
John D. Livingstone, john.livingstone@finnegan.com
Amanda K. Murphy, Amanda.murphy@finnegan.com
Yieyie Yang, yieyie.yang@finnegan.com
M. David Weingarten, m.david.weingarten@finnegan.com
Cora Holt, cora.holt@finnegan.com
Christopher Weber, christoper.weber@finnegan.com

via:

electronic service to the email addresses above.

Dated: June 15, 2023

By: /Blaine M. Hackman/
Blaine Hackman, Reg. No. 67,479
Dechert LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036-6797
Tel: 212-698-3500
Fax: 212-698-3599
Blaine.hackman@dechert.com