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 No. IPR2023-00608
Patent No. 9,051,542

PETITIONERS' EXPLANATION OF MULTIPLE PETITIONS CHALLENGING PATENT NO. 9,051,542 AND RANKING OF PETITIONS

I. INTRODUCTION

Pursuant to the July 2019 Trial Practice Guide Update, Petitioners provide this explanation of filing two petitions, IPR2023-00608 ("the '608 Petition") and IPR2023-00609 ("the '609 Petition"), challenging U.S. Patent No. 9,051,542 ("the '542 patent"). Petitioners submit this paper to identify "a ranking of the petitions in the order in which it wishes the Board to consider the merits" and provide "a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions." Trial Practice Guide Update (July 29, 2019), 26-28.

II. RANKING OF THE PETITIONS

The grounds of the two petitions are summarized below. Although Petitioners believe both petitions are meritorious and, thus, should both be instituted, the following provides a ranking of the Petitions challenging the '542 patent.

Rank	Petition	Claim(s)	Grounds
1	IPR2023-00608	1, 5, 6	Ground 1: Obviousness over Evans in view of Huang and Mingozzi
		2	Ground 2: Obviousness over Evans and Wright in view of Huang and Mingozzi
		1, 2, 5, 6	Ground 3: Obviousness over Frei in view of Huang and Mingozzi

Rank	Petition	Claim(s)	Grounds
2	IPR2023-00609	1, 2, 5, 6	Ground 1: Obviousness over Liu in view of Huang and Mingozzi
		1, 2, 5, 6	Ground 2: Obviousness over Lochrie in view of Huang, Mingozzi, Johnson, and Liu

III. THE DIFFERENCES BETWEEN THE PETITIONS

Petitioners' submission of two petitions is justified due to the number of the claim limitations, abundance of material prior art the Examiner failed to consider during prosecution, and the depth of the analysis required on the merits.

The challenged claims comprise numerous limitations, with independent claim 1 alone comprising six limitations that each require separate and detailed analysis. As the Petitions explain, the numerous limitations came from Patent Owner's repeated attempts to overcome rejections during prosecution by adding known parameters in known combinations. As the Petitions further explain, the Examiner ultimately allowed the repeatedly amended claims because he failed to consider several material prior art references readily available to a POSA at the time of invention that, when combined, yield five new obviousness grounds never considered by the Examiner. Adequately addressing each of the claim limitations and grounds requires two petitions.

The '608 Petition and the '609 Petition rely on different and non-cumulative references to demonstrate the unpatentability of the challenged '542 patent claims.

The ’608 Petition relies on Evans and Frei as primary references, which teach improving the stability of virus compositions and achievement of *formulated* compositions to store virus vector particles at high concentrations. By contrast, the ’609 Petition relies on Liu and Lochrie as primary references that provide similar teachings in different contexts. Specifically, Liu focused on virus purification processes including high salt storage compositions that allowed for testing suitability of the virus product during the purification processes. Lochrie focused on new methods of removing empty capsids yielding final AAV compositions comprising only minor differences for each recited parameter in challenged claim 1.

Thus, the Petitions are not culumative of one another, warranting the Board’s adjudication of both on the merits.

IV. CONSIDERATION OF THE *GENERAL PLASTICS* FACTORS

The Board weighs several factors in determining whether to exercise its discretion under §314(a). *See General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 9-10, 16 (PTAB Sept. 6, 2017) (precedential). Of those seven factors, factor 6 (the finite resources of the Board) and factor 7 (the Board’s ability to issue a final decision within a year of institution) are most pertinent to the concurrently-filed parallel petitions at issue here. *See Chegg, Inc. v. NetSoc, LLC*, IPR2019-01171, Paper 16 at 10-15 (PTAB Dec. 5, 2019) (“[F]actors 1 through 5

apply only to 'follow-on' petitions…."). Neither factor weighs in favor of denying institution.

First, to conserve resources, Petitioners have limited the issues for the Board by presenting a limited number of grounds based on only two primary references in each Petition. *See Abbott Labs. v. Integrated Sensing Sys., Inc.*, IPR2019-01338, Paper 7 at 9-12 (PTAB Jan. 23, 2020) (instituting two concurrent petitions, noting that "there are only two concurrent petitions, each including a reasonable number of grounds. The challenges in each Petition are unique and well described"). The two Petitions also rely on similar background art and state of the art discussions. To further simplify joint consideration, the same expert declaration was submitted to support both Petitions. Thus, it will not strain the Board's finite resources to adjudicate both Petitions.

Second, the two Petitions are filed by the same real parties-in-interest. Because no other defendents are involved in the parallel litigation concerning the '542 patent, this is not a case where the patent owner will face multiple serial IPRs from other defendants. *Chegg, Inc. v. NetSoc, LLC*, IPR2019-01171, Paper 16 at 15 ("the filing of two Petitions on behalf of several parties leads to an efficient administration of the proceedings").

Third, no IPR has been previously filed against the '542 patent. Thus, none of the Petitions is preceded by a preliminary response in any other IPR against the '542

patent. As such, this is not a case of a petitioner seeking to gain an advantage from an earlier-filed petition, as both Petitions were filed simultaneously.

Fourth, the parallel litigation is still in an early stage, as the Markman Hearing has not yet occurred. Patent Owner also moved to file a Second Amended Complaint on February 13, 2023, which, if granted, would significantly extend the length of the parallel litigation. Thus, no other proceedings will interfere with the Board's issuing final determinations for the two IPRs within 1 year of the date on which the Director institutes review.

Thus, neither of the relevant *General Plastics* factors (factors 6 and 7) weigh in favor of denying institution.

Should the Board institute both Petitions, Petitioners will work to streamline these cases. For example, Petitioners would agree to a single deposition of experts for both cases. And Petitioners would agree to consolidate the case schedules as much as possible. Petitioners, therefore, respectfully request institution of both Petitions, or at least the '608 Petition.

Respectfully Submitted

Date: February 22, 2023

By: / John D. Livingstone /
John D. Livingstone
Reg. No. 59,613

Lead Counsel for Petitioners Novartis Gene Therapies, Inc., and Novartis Pharmaceuticals Corporation

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on February 22, 2023, a copy of the foregoing **PETITIONERS' EXPLANATION OF MULTIPLE PETITIONS CHALLENGING PATENT NO. 9,051,542 AND RANKING OF PETITIONS** was served by FedEx on counsel of record for the Patent Owner at the following address:

Courtenay Brinckerhoff, Esq.
Foley & Lardner LLP
3000 K Street, N.W., Suite 600
Washington D.C. 20007
Telephone: (202) 672-5300

Dated: February 22, 2023

By: /*Lauren K. Young*/
Lauren K. Young
Litigation Legal Assistant
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP