UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS GENE THERAPIES, INC. and
NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2023-01044
Patent No. 10,429,288

PETITIONER'S SUPPLEMENTAL PAPER AND NOTICE RANKING PETITIONS[1]

[1] Petitioner is filing a substantively identical document in IPR2023-01045.

Per the Consolidated Trial Practice Guide, Petitioner Novartis Gene Therapies, Inc. and Novartis Pharmaceuticals Corporation ("Novartis") files this paper for two petitions against U.S. Patent No. 10,429,288, IPR2023-01044 (Petition 1) and IPR2023-01045 (Petition 2), asserting these grounds:

Petition	**Claims**	**Grounds**
IPR2023-01044 (Petition 1)	1, 17-18, 20-21, 23, 32-33	Anticipated by *Le Bec*
	1, 17-18, 20-21, 23, 32-33	Obvious over *Le Bec* alone
	1-3, 17-26, 31-33	Obvious over *Le Bec* in view of *Berkowitz* and/or *Cole*
	27-30	Obvious over *Le Bec* in view of *Berkowitz* and *Schuck* and/or *Zhao*
	34	Obvious over *Colosi* in view of *Le Bec*
IPR2023-01045 (Petition 2)	4-8, 10-15	Anticipated by *Le Bec*
	4-8, 10-15	Obvious over *Le Bec* alone
	4-16	Obvious over *Le Bec* in view of *Berkowitz*

I. TWO PETITIONS ARE NEEDED HERE

Petitioner is filing two petitions because of the large number of asserted claims. There are thirty-four challenged claims in total, seven of which are independent claims. Genzyme has alleged infringement of all thirty-four claims in a recently filed district court action. In the petitions, the claims have been divided into two distinct claim sets, with the claims of Petition 1 relating primarily to claimed parameters of performing SV-AUC and the claims of Petition 2 relating

primarily to analyses of SV-AUC data. None of the claims challenged in Petition 2 are addressed in Petition 1. Thus, the two petitions differ both in substance and in the defenses Patent Owner may potentially raise.

II. THE BOARD SHOULD INSTITUTE BOTH PETITIONS

The two petitions challenge different, non-overlapping claims of U.S. Patent No. 10,429,288. The thirty-four challenged claims of the '288 patent cannot be addressed in one petition because of the word-count limit and non-overlapping scope of the challenged claims. If the Board "discretionarily dismissed one petition or the other, some claims of the ['288] patent would be left uncovered by any ground alleged by Petitioner." *Marvell Semiconductor, Inc. v. Uniloc 2017 LLC*, IPR2019-01349, Paper 9 at 14 (PTAB Feb. 4, 2020) (instituting review); *see also Google LLC v. Hammond Dev. Int'l, Inc.*, IPR2020-00413, Paper 16 at 42 (PTAB July 14, 2020); *Apple Inc. v. Seven Networks, LLC*, IPR2020-00157, Paper 10 at 28 (PTAB June 15, 2020).

The Board should exercise its discretion under § 314(a) to institute both petitions. The first five *General Plastic* factors favor institution: Petitioner filed both petitions for the first time and on the same day. *Intex Recreation Corp. v. Team Worldwide Corp.*, IPR2018-00873, Paper 14 at 8-12 (PTAB Oct. 29, 2018). Specifically, Novartis has not previously filed a petitions challenging the '288 patent (*General Plastic* Factor 1), Novartis has not already received Patent

Owner's preliminary response (*General Plastic* Factor 3), and the factors concerning knowledge of the art in the petitions (*General Plastic* Factors 2, 4, and 5) are inapplicable because the petitions are being filed on the same day. As to factor 6 (the finite resources of the Board), both petitions apply the same prior art references (albeit to different claims), which will lower the burden associated with consideration of the second petition. As to factor 7 (the Board's ability to issue a final decision within a year of institution), a total of six prior art references are addressed in the two petitions, so the Board's ability to render timely final decisions should not be impeded.

III. RANKING OF PETITIONS

If the Board decides to institute only a single petition against the '288 patent, Petitioner requests it institute Petition 1 (IPR2021-01044).

Respectfully submitted,

Date: June 30, 2023

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), the undersigned certifies that on June 30, 2023, a copy of the foregoing **Petitioner's Supplemental Paper and Notice Ranking Petitions** was served by FedEx Priority Overnight on the correspondence address of record indicated in the Patent Office's Patent Center website for U.S. Patent No. 10,429,288:

Lisa P. Rasmussen
Sanofi
450 Water Street
Cambridge, MA 02141

A courtesy copy of the foregoing was also served by FedEx Priority Overnight upon the following counsel of record for the Patent Owner in litigation pending before the United States District Court for the District of Delaware Case No. 1:23-cv-00554:

David E. Wilks
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Date: June 30, 2023

By: /William Esper/
William Esper
Case Manager and PTAB Coordinator
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