

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner

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IPR2021-00880 (Patent 9,669,069 B2)  
IPR2021-00881 (Patent 9,254,338 B2)

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**PETITIONER'S REPLY TO  
PATENT OWNER'S PRELIMINARY RESPONSE**

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As authorized by the Board (Paper 13), Petitioner submits this Reply.

## I. INTRODUCTION.

Discretionary denial is not warranted here. “The Board has consistently declined exercising its discretion under Section 325(d) when the only fact a Patent Owner can point to is that a reference was disclosed to the Examiner during the prosecution.” *Amgen Inc. v. Alexion Pharms., Inc.*, IPR2019-00739, Paper 15 at 62 (P.T.A.B. Aug. 30, 2019) (citing *Amneal Pharms. LLC v. Alkermes Pharma Ireland Ltd.*, IPR2018-00943, Paper 8 at 40 (P.T.A.B. Nov. 7, 2018); *Amazon.com, Inc. v. M2M Solutions LLC*, IPR2019-01205, Paper 14 at 16 (P.T.A.B. Jan. 27, 2020) (“[A] reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor of exercising the Board’s discretion under § 325(d) to deny a petition.”). In neither prosecution did the Examiner consider art or arguments the same or substantially the same as Petitioner’s. Thus, there was no need for Petitioner to address *Becton, Dickinson* factors or allege Examiner error.<sup>1</sup>

**[IPR2021-00880] The ’069 Patent File History Does Not Pass *Advanced Bionics*’ Threshold Inquiry.** Neither “the same [nor] substantially the same” art or arguments were “previously . . . presented to the Office” for U.S. 9,669,069 (“the

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<sup>1</sup> PO raised the Chengdu PGR2021-00035, which is inapposite. The ’345 patent contains *eight pages* of “References Cited.” PGR2021-00035, Ex.1001, 1-8.

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