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Subject: Request for Director Review in PGR2023-00026 (U.S. Patent No. 11,395,838)
Date: Thursday, December 21, 2023 2:40:47 PM
Attachments: [PGR2023-00026 Petitioner's Request for Director Review \(002\).pdf](#)

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The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office (USPTO)

Dear Honorable Director Vidal,

Please let this email serve as notification of the filing today, December 21, 2023, of Petitioner's Request for Director Review in PGR2023-00026 through the PTAB E2E portal (Paper No. 13). A copy of the Petitioner's Request for Director Review in PGR2023-00026 (Request) is attached hereto, and counsel of record for the Patent Owner and for the Petitioner are copied on this email.

Vacatur of the Board's Preliminary Decision to not institute Post Grant Review (PGR), PGR2023-00026, Paper No. 12 ("Decision"), and institution of PGR Proceedings on all grounds raised by Petitioner as to US Patent No. 11,395,838 are respectfully requested. This Request presents two issues for Director Review (in priority order).

First, the Request presents an early opportunity for the Director to address, as a matter of first impression in a PGR, the applicability of the Supreme Court's decision in *Amgen v. Sanofi*, No. 21-757, 598 U.S. ___, Slip op. (S.Ct. May 18, 2023) to pharmaceutical patent examination and review. The Board's analysis of patentability in the Decision ignores *Amgen* entirely, and the Board's denial of institution is irreconcilable with *Amgen*. Thus, this case raises important public policy issues.

Second, the Request demonstrates material errors of fact and law resulting from the Board's failure to analyze of the scope of the challenged claims (*i.e.*, construe the meaning of the claims) in order to identify written description support commensurate with that scope. The Board's failure to construe the claims taints all of the Board's views on patentability (including under § 112(a), § 112(b), and § 103).

As such, the Request respectfully requests vacatur of the Decision and institution of PGR on all grounds raised by the Petitioner.

Respectfully submitted,

/Patrick D. McPherson/
Patrick D. McPherson

PGR2023-00026
Ex. 3100

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