

Filed on behalf of: Amneal Pharmaceuticals, Inc.
By: Lora M. Green (lgreen@geminilaw.com)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS INC. AND KASHIV BIOSCIENCES, LLC,
Petitioner,

v.

GENENTECH, INC. AND NOVARTIS PHARMACEUTICALS CORP.,
Patent Owner.

Case No.: IPR2026-00260
Patent No. 12,030,959

NOTICE OF PETITIONER'S *SOTERA* STIPULATION

Pursuant to the Interim Processes for PTAB Workload Management, issued March 26, 2025,¹ Amneal Pharmaceuticals Inc. and Kashiv Biosciences, LLC (collectively, “Petitioner”) stipulate as follows:

A Biologics License Application has been filed with the U.S. Food and Drug Administration for a proposed omalizumab biosimilar to XOLAIR. As of the date of this stipulation, no patent litigation has commenced concerning *US959*.

If the Patent Trial and Appeal Board (PTAB) institutes this *inter partes* review, unless institution is later vacated, reversed, or otherwise withdrawn, Petitioner will not pursue in any other fora, including any district court action in which *US959* is asserted against Petitioner:

the specific grounds [asserted in IPR2026-00260], or on any other ground ... that was raised or could have been reasonably raised in an IPR (i.e., any ground that could be raised under §§ 102 or 103 on the basis of prior art patent or printed publications).

¹ Available at

<https://www.uspto.gov/sites/default/files/documents/InterimProcessesPTABWorkloadMgmt-20250326.pdf>.

See Sotera Wireless, Inc. v. Masimo Corp., IPR2020-01019, Paper 12 at 13-14
(PTAB Dec. 1, 2020) (precedential as to § II.A).

Respectfully submitted,

September 4, 2026

/Lora M. Green/
Lora M. Green, Lead Counsel
Reg. No. 43,451

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned hereby certifies that a true and correct copy of the foregoing NOTICE OF PETITIONER'S *SOTERA* STIPULATION was served on September 4, 2026, by electronic mail on Patent Owner's lead and backup counsel at the following email addresses:

Thomas S. Fletcher (Reg. No. 72,383)
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Patent Owner has consented to electronic service.

Respectfully submitted,

Date: September 4, 2026

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