

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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FRESENIUS KABI USA, INC. and FRESENIUS KABI SWISSBIOSIM GmbH  
Petitioner,

v.

AMGEN, INC. and AMGEN MANUFACTURING LIMITED  
Patent Owner.

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IPR2020-00314

Patent No. 9,856,287

Title: REFOLDING PROTEINS USING A CHEMICALLY CONTROLLED  
REDOX STATE

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**PETITIONERS' UPDATED MANDATORY NOTICES**

Mail Stop PATENT BOARD  
Patent Trial and Appeal Board  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Petitioners hereby submit the following updated mandatory notices in connection with the above captioned *inter partes* review of U.S. Patent No. 9,856,287.

**A. Real Party-In-Interest (No Change)**

The real parties in interest are Fresenius Kabi USA, LLC, Fresenius Kabi SwissBioSim GmbH, Fresenius Kabi AG, Fresenius Kabi Pharmaceuticals Holding, Inc., Fresenius Kabi Deutschland GmbH, Fresenius SE & Co. KGaA, Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, S.A., and Dr. Reddy Laboratories Inc.

**B. Related Matters (Updated)**

The '287 patent is not currently the subject of any district court litigation. U.S. Patent Application 15/889,559 is pending and claims priority to the '287 patent. The '287 patent is a continuation of pending U.S. Patent Applications 14/611,037 and 14/793,590.

There are no currently pending Patent Trial and Appeal Board ("PTAB") proceedings that address the validity of the '287 patent. The Board instituted PGR2019-00001, *Adello Biologics, LLC v. Amgen Inc. et al.* ("the Adello PGR"), which challenged the '287 patent, on April 19, 2019, and subsequently terminated the proceeding on December 6, 2019 due to settlement between the parties. PGR2019-00001, Paper 28 (PTAB Dec. 6, 2019). Before the Adello PGR was

instituted, Petitioners filed a previous IPR petition challenging the '287 patent, but the Board found that the petition was duplicative of the then-pending but now-terminated Adello PGR, and used its discretion to deny institution under § 314(a) without evaluating the merits of the petition. *Fresenius Kabi USA, LLC et al. v. Amgen, Inc. et al.*, IPR2019-00971, Paper 13 (PTAB Oct. 16, 2019).

**C. Identification of Counsel (§ 42.8(b)(3)) and Service Information (§ 42.8(b)(4)) (Updated)**

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**D. Electronic Service (Updated)**

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Respectfully Submitted,

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