

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS  
USA, INC., WATSON LABORATORIES, INC., DR. REDDY'S  
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., and  
SUN PHARMACEUTICALS INDUSTRIES LTD.,  
Petitioner,

v.

MERCK SHARP & DOHME CORP.,  
Patent Owner.

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Case IPR2020-00040<sup>1</sup>  
U.S. Patent 7,326,708

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**PATENT OWNER'S MOTION TO FILE  
REQUEST FOR CERTIFICATE OF CORRECTION OF CLAIMS 5-7**

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<sup>1</sup> Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. were joined as parties to this proceeding via Motion for Joinder in IPR2020-01045; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as parties to this proceeding via a Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

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Pursuant to the Board’s Order of November 9, 2020, Paper 61, Patent Owner Merck hereby moves for leave to request a certificate of correction of claims 5–7 of U.S. Patent No. 7,326,708 (“the ’708 patent”), which contain undisputedly mistaken language. Because these claims are not at issue in the IPR, there is no risk of affecting this proceeding or duplicating efforts across different parts of the PTO. The issue for the Board is thus a narrow, threshold question: “whether there is *sufficient basis* supporting Patent Owner’s position that the mistake *may* be correctable” when the merits of the request are considered by the Director. *Honeywell Int’l, Inc. v. Arkema Inc.*, 939 F.3d 1345, 1349 (Fed. Cir. 2019).

Merck’s request readily meets that threshold. Claims 5–7 refer to “*absorption bands* obtained from the X-ray powder diffraction pattern at spectral” d-spacings of particular sizes. EX1001 (’708 Patent). As the district court in the co-pending infringement action put it, the reference to “absorption bands” is “just a mistake.” EX2277 at 94:14. The claims should have referred to “diffraction peaks,” which is the correct term, and the term the specification uses, for the X-ray powder diffraction (XRPD) data that determine the claimed d-spacings. EX1001 at 13:29–36; EX2281 ¶¶ 3–6.

A certificate of correction can fix such a mistake when it is “clearly evident from the specifications, drawings, and prosecution history how the error should appropriately be corrected to one of skill in the art.” *Arthrocare Corp. v. Smith &*

*Nephew, Inc.*, 406 F.3d 1365, 1374–75 (Fed. Cir. 2005) (internal quotation marks omitted). Here, the patent’s specification describes the claimed crystal form, characterized by the exact same claimed d-spacings, using the correct terminology—“diffraction peaks corresponding to” the d-spacings. EX1001 at 13:31–36. The person of ordinary skill would have understood that a correction to the claims should employ this same language.

The Board should grant leave and permit the Director to consider Merck’s request on the merits.

## **BACKGROUND**

The claims of the ’708 patent are directed generally to novel forms of the compound sitagliptin, which are used in Merck’s successful Januvia<sup>®</sup> family of diabetes drugs. Independent claim 1 is directed to a dihydrogenphosphate salt of sitagliptin with a 1:1 stoichiometric ratio; claim 4, on which claims 5–7 depend, is directed to a crystalline monohydrate form of that salt.

Claims 5–7, the claims Merck seeks to correct, limit claim 4 to a particular form of the crystalline monohydrate characterized using XPRD. Petitioners did not challenge these claims before the Board, and they are not at issue in this IPR. Each of claims 5–7 recites “absorption bands obtained from the X-ray powder diffraction pattern at spectral” d-spacings of different sizes. As all parties agree, that language is incorrect. The specification of the patent does not refer to

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