UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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.

Case IPR2020-00040[1]
Patent 7,326,708

PATENT OWNER'S REPLY IN SUPPORT OF MOTION TO FILE REQUEST FOR CERTIFICATE OF CORRECTION OF CLAIMS 5–7

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[1] 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.

TABLE OF AUTHORITIES

Petitioners' Opposition never disputes the standard for when an error is sufficiently "ministerial" that it can be corrected via a certificate: whether it is "clearly evident from the specifications, drawings, and prosecution history how the error should appropriately be corrected." *ArthroCare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1374–75 (Fed. Cir. 2005). Nor do Petitioners dispute Merck's evidence that the person of ordinary skill in the art ("POSA") would recognize that the "absorption band" claim language should instead have referred to "diffraction peaks," as in the specification. Mot. 6; EX2278 ¶¶ 69–71; EX2280 ¶¶ 14–17. Petitioners are wrong that Merck is relying on the inventors' subjective mindset; the error is plain from the specification, so it is irrelevant that Merck does not look, or need to look, to the prosecution history. Opp. 6–7. These facts establish Merck's entitlement to a certificate on the merits—never mind under the lower threshold that undisputedly applies to whether the Board should grant Merck leave. *Honeywell Int'l, Inc. v. Arkema Inc.*, 939 F.3d 1345, 1349 (Fed. Cir. 2019).

Contrary to the Opposition, nothing further is needed for Merck to show that the error is "clerical or typographical" or "of minor character." 35 U.S.C. § 255. The existence of an error and an appropriate correction that are "clearly evident to one of skill in the art" *establish* that element. *Cent. Admixture Pharm. Servs. Inc. v. Adv. Cardiac Sols. P.C.*, 482 F.3d 1347, 1353 (Fed. Cir. 2007). But even if some further showing were needed, Merck readily meets it. Certificates frequently

are granted to change wording errors that go beyond "obvious misspellings" (Opp. 2). *ArthroCare*, 406 F.3d at 1374 (changing "active electrode" to "electrode terminal"); *ipDataTel, LLC v. ICN Acquisition, LLC*, 2019 WL 1771940, at *5–6 (P.T.A.B. Apr. 22, 2019) (changing "synchronization to associate" to "association to synchronize"). Joinder Petitioners' own expert characterized the amendments here as "a mistake or typographical error." EX2277 at 92:20–23; EX2279 ¶ 46.

Petitioners' argument that certificates of correction cannot correct indefinite claim language is simply wrong. The Federal Circuit has recognized that certificates under § 255 can do just that. *Novo Indus., LP v. Micro Molds Corp.*, 350 F.3d 1348, 1356 (Fed. Cir. 2003). Petitioners dismiss this as "dicta," Opp. 3, but the PTO repeatedly has issued certificates that fix indefinite claim language. *E.g.*, *ipDataTel*, 2019 WL 1771940, at *5–6; *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 718 F. Supp. 2d 529, 569–70 (D. Del. 2010); *see also ParkerVision, Inc. v. Qualcomm Inc.*, 969 F. Supp. 2d 1372, 1379 (M.D. Fla. 2013) (recognizing PTO's authority to correct claims that are otherwise indefinite). That there is no MPEP provision permitting correction of terminal disclaimers, Opp. 4, is irrelevant; here, 35 U.S.C. § 255 and MPEP § 1481 allow correcting mistakes like the one here without regard to whether the mistakes rendered claims indefinite. And the suggestion that certificates can only correct "minor" errors that do *not* affect validity, Opp. 4–5, is backwards; mistakes that are too "trivial" or

"inconsequential" "will not warrant" correction. *Novo*, 350 F.3d at 1356.

There is no basis for Petitioners' argument that the correction constitutes new matter or that reexamination is needed here. The corrected language is directly from the specification. There is no indication that claims reciting the correct language would have been examined any differently. Merck even successfully overcame a double patenting rejection by using diffractograms—*i.e.*, XRPD patterns—to distinguish different crystal forms based on their characteristic diffraction peaks, showing that the examiner understood their relevance. EX1010 at 153–56, 241–42, 245–48. Petitioners, moreover, simply ignore the authority that whether reexamination is required is not a question for the Board. Mot. 8.

Finally, Petitioners' assertions that "good faith" is somehow undermined by the fact that the mistake was inadvertent make no sense. Opp. 7–9. There is no suggestion that the choice of language or the timing is based on gamesmanship, and Merck comes to the Board promptly after the district court held the claims indefinite. Petitioners' cases condemning parties' inattention in reviewing claims are not about the "good faith" prong of 35 U.S.C. § 255 and do not bar correction of inadvertent mistakes that otherwise meet § 255's standards. And again, "good faith" is not for the Board to decide. Mot. 7.

Merck has no objection to the submission of the briefing with its request to the Director, so long as all the briefing—not just the Opposition—is included.

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