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Paper 76
Date: Dec. 23, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-00040[1]
Patent 7,326,708 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLLOCK, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

ORDER
Granting Patent Owner's Motion to File Request for Certificate of Correction of Claims 5–7
37 C.F.R. §§ 1.323, 42.20

[1] 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.

I. BACKGROUND

Mylan Pharmaceuticals Inc. ("Mylan"), on October 30, 2019, filed a Petition to institute *inter partes* review of claims 1–4, 17, 19, and 21–23 of U.S. Patent No. 7,326,708 B2 (Ex. 1001, "the '708 patent"). Paper 1. On May 12, 2020, after considering a Preliminary Response (Paper 10) by Patent Owner Merck Sharp & Dohme Corp. ("Patent Owner" or "Merck") (as well as other pre-institution papers that we authorized for filing), we instituted trial. Paper 21. Other parties were later joined as petitioners (*supra* n.1) and we refer to all petitioners, including Mylan, collectively as "Petitioner" in this Order.

On November 6, 2020, the Board held a conference call with the parties to discuss Merck's request for authorization to file a motion seeking leave to petition the Director for a certificate of correction related to certain claims of the '708 patent. More specifically, Merck seeks to file a request for a certificate of correction on claims 5–7, which claims Merck contends include a mistake by the patent applicant correctable under 35 U.S.C. § 255. Claims 5–7 are not challenged in this IPR. Although the patentability of claims 5–7 is not at issue in this proceeding, Merck is not permitted to file its request for a certificate of correction of those claims absent the Board's permission. 37 C.F.R. § 1.323*; Honeywell Int'l Inc. v. Arkema Inc.*, 939 F.3d 1345, 1349–50 (Fed. Cir. 2019) (explaining the steps required by a patent owner seeking the Board's leave to petition the Director for a certificate of correction for a patent undergoing post-grant proceedings

before the Board).[2] After hearing from the parties at the conference, we allowed Merck to file the present motion. Ex. 2275 (transcript of conference); Paper 63 ("Mot."). Petitioner opposed, and Merck filed a reply in support of its motion. Paper 70 ("Opp."); Paper 71 ("Mot. Reply").

II. DISCUSSION

The Federal Circuit explains that a patent owner seeking a certificate of correction on a patent undergoing post-grant review must take three steps. *Honeywell*, 939 F.3d at 1349. Those steps are:

(1) seek authorization from the Board to file a motion, 37 C.F.R. § 42.20(b);

(2) if authorization is granted, file a motion with the Board, asking the Board to cede its exclusive jurisdiction so that the patentee can seek a Certificate of Correction from the Director, 37 C.F.R. § 1.323; MPEP § 1485; and

(3) if the motion is granted, petition the Director for a Certificate of Correction under 35 U.S.C. § 255.

Id. (citing *Plastic Dev. Grp., LLC v. Maxchief Investments, Ltd.*, IPR2017-00846, Paper 16 at 2 (PTAB Nov. 13, 2017)). Merck completed steps (1) and (2). What remains is Board authorization for Merck to take step (3) and to petition the Director for the desired certificate correcting claims 5–7, which Board authorization is the subject of this motion.

[2] Because claims 5–7 are not at issue in this IPR, the parties agree that, whether the Board grants Merck's motion to file a request for certificate of correction of those claims and cedes jurisdiction over the patent for that limited purpose, the present IPR will otherwise be unaffected and will remain on its existing schedule. Ex. 2275, 20:14–21:17.

The Board's inquiry in resolving the present motion is limited. The inquiry does not, as the Federal Circuit instructs, include deciding the merits of whether a certificate of correction should issue under 35 U.S.C. § 255. *Honeywell*, 939 F.3d at 1348–50 (holding the Board abused its discretion in (i) requiring patent owner to show the requirements of § 255 have been met before authorizing the motion and (ii) assuming the authority reserved for the Director in deciding the merits of patent owner's request for the certificate).[3] To the contrary, the question for the Board is "'whether there is *sufficient basis* supporting Patent Owner's position that the mistake *may* be correctable.'" *Id.* at 1349 (quoting *Plastic Dev. Grp.*, Paper 16 at 2 (with the court's emphasis)) ("We hold that this standard of review is appropriate and consistent" with, *inter alia*, § 255 and the relevant regulations). In resolving that limited question, the Board is *not* permitted to decide whether, for example, the alleged mistake is of a "minor character" or "occurred in good faith" as recited under § 255—those questions are for the Director. 35 U.S.C. § 255; *Honeywell*, 939 F.3d at 1349.[4]

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[3] "[W]e conclude that the Board abused its discretion by assuming the authority that 35 U.S.C. § 255 expressly delegates to the Director: to determine when a Certificate of Correction is appropriate." *Honeywell*, 939 F.3d at 1348.

[4] Other Board decisions have, in determining if a "sufficient basis" exists, assessed if "there appears to be a legitimate question as to whether the issuance of a Certificate of Correction is an appropriate course of action." *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2020-00051, Paper 13, 4–5 (PTAB Feb. 26, 2020) ("[W]ith the recognition of that legitimate question is the logical conclusion that Patent Owner has shown a sufficient basis in support of its position and that the matter should be considered by the appropriate official charged with answering the question, namely, the Director.").

Under 35 U.S.C. § 255, the Director may correct "a mistake of a clerical or typographical nature, or of minor character," which "appears in a patent and a showing has been made that such mistake occurred in good faith."

Merck argues that claims 5–7 of the '708 patent contain such a mistake and that it should be permitted to request that the Director make an appropriate correction. Mot. 1–3. Merck contends that claim 5–7 relate to particular crystalline monohydrate forms of a dihydrogenphosphate salt of sitagliptin, characterized by X-ray powder diffraction or "XRPD." *Id.* Claim 5 recites the following and is illustrative of the alleged mistake in each of claims 5–7: "The salt of claim 4 characterized by characteristic ***absorption bands*** obtained from the X-ray powder diffraction pattern at ***spectral*** d-spacings of 7.42, 5.48, and 3.96 angstroms." Ex. 1001, 16:49–52 (emphases added).

According to Merck, claims 5–7 should *not* have referred to "absorption bands" or "spectral" d-spacings. *Id.* at 4–6. Merck argues that such "obviously mistaken wording" makes no sense in the context of XRPD, which produces "diffraction peaks," not "absorption bands" with "spectral" characteristics. *Id.* Moreover, Merck contends, the mistake and how it should be corrected would have been "clearly evident" to an ordinarily skilled person reading the intrinsic evidence, which does not refer to "absorption bands" and instead describes XRPD using the allegedly correct terminology—"diffraction peaks." *Id.* at 6 (citing Specification (Ex. 1001, 13:31–33): "[t]he monohydrate exhibited characteristic diffraction peaks corresponding to d-spacings of 7.42, 5.48, and 3.96 angstroms").

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