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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

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[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]

[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").

Although Merck concedes that the district court in related litigation where claims 5–7 are (or were) at issue determined that it could not fix the mistake and held those claims indefinite, Merck contends that does not stop the Patent Office from fixing the claims by certificate of correction. Mot. 3, 5–6, 8–10. Merck cites *Novo Indus., LP v. Micro Molds Corp.*, 350 F.3d 1348, 1356 (Fed. Cir. 2003) for the proposition that "an error that 'makes a claim indefinite' can be fixed via a certificate." *Id.* at 5–6. Further to this point, Merck contends that, while the court may have believed it could not interpret the claims to correct them, the Patent Office has a different or broader authority under the statute to correct errors in a patent. *Id.* at 9 (citing the court's discussion in *Novo*, 350 F.3d at 1356, that "we do not think that Congress intended that the district courts have authority to correct any and all errors that the PTO would be authorized to correct under sections 254 and 255").[5]

Merck also argues that the mistake in claim language occurred in good faith. Mot. 7. According to Merck (and its declarant, named inventor Robert M. Wenslow, Ph.D.), "absorption bands" is a different "concept from spectrographic techniques . . . [that was] incorrectly imported into the claims when they were drafted" and the mistake went unnoticed upon review of the application and during prosecution. Ex. 2281 ¶ 6; Mot. 7.

[5] The *Novo* court "conclude[d] that the district court can correct only *Essex*-type errors" where "the correction is not subject to reasonable debate based on consideration of the claim language and the specification" and "the prosecution history does not suggest a different interpretation of the claims." *Novo*, 350 F.3d at 1357; *see also id.* at 1354 (discussing the Supreme Court's holding in *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429 (1926)).

Finally, Merck contends that fixing the claims adds no new matter because the proposed change to "diffraction peaks" finds support in the Specification. Mot. 7–8. Merck also argues that reexamination of the claims with the corrected language is not required and, even if were, that is not for the Board to decide. Mot. 7–8; Mot. Reply 3.

Petitioner raises several arguments in opposition. Petitioner contends that the claim language includes no mistake of a clerical or typographical, or otherwise minor character. Opp. 2–3, 4–5 (citing case law, the MPEP, and other decisions on petitions for a certificate of correction). The problem for Petitioner, relative to the relief Merck requests from the Board in this motion, is that Petitioner's argument goes directly to whether Merck satisfies the elements of § 255 and is entitled to a certificate on the merits. As explained above, we are not authorized to decide that question. Merck has provided a reasonably detailed analysis of what it regards as the allegedly obvious mistake, accompanied by facts and law that Merck alleges supports its position. Merck might (or might not) prevail in showing that the mistake is "minor" and correctable. On that, however, we must defer to the Director's judgment.

Petitioner argues that Merck cites no authority permitting the Patent Office to correct claims found to be indefinite in court, as Merck requests the Office do now. Opp. 3–4. According to Petitioner, the reference in *Nova* to correcting indefinite claims through a certificate of correction is dicta. *Id.* at 3 (citing *Novo*, 350 F.3d 1348, 1356 (Fed. Cir. 2003)).

Petitioner criticizes Merck's alleged lack of authority, but Petitioner provides no authority that persuades us the type of relief Merck is requesting is necessarily foreclosed. Even if we agreed that the excerpt in *Novo* quoted

by Merck is dicta, the decision still suggests that indefinite claims may be corrected by the Office under its § 255 authority. In its more complete context, the sentence including the quoted excerpt stands for the proposition that even courts might sometimes correct errors that would render a claim indefinite. *Novo*, 350 F.3d at 1356 (noting that "if we were to hold that the district court was powerless to correct any and all errors when construing the patent, every patent containing an error that makes a claim indefinite would be invalid until and unless corrected by the PTO," then rejecting that holding). We see no basis in the cited authority to conclude that courts might correct an indefinite claim term, but the Patent Office could not. In any event, Merck identifies cases where the Office has, in fact, done just that through the certificate of correction process—together, with Merck's discussion of what the error is, why it is allegedly minor, and how it should be fixed, raising a legitimate question of whether correction is appropriate. Mot. Reply 2 (citing, e.g., *ipDataTel, LLC v. ICN Acquisition*, IPR2018-01822, Paper 19 at 13–14 (PTAB Apr. 22, 2019)).[6] Whether the Office will do so here is, again, a matter for the Director.

Petitioner argues that Merck's and the patent applicant's "inattentive review" of the '708 patent's claims does not show good faith. Opp. at 8–10. According to Petitioner, the notion that the error is so "obvious" and "apparent" is at odds with Merck's explanation for why the error was not caught during prosecution, or in the twelve years since the patent's issuance.

[6] In *ipDataTel*, after a petition for *inter partes* review was filed, a district court found in October 2018 that claims of the patent challenged in the IPR were indefinite, a certificate of correction for the indefinite claims was filed in January 2019, and a certificate correcting the claims was issued in March 2019. *ipDataTel*, Paper 19 at 13–14.

Opp. 8–9. Instead, as Petitioner highlights, it took Merck more than a year into the related litigation, and a finding of indefiniteness by the district court, before Merck approached the Patent Office about a possible correction. *Id.* at 9. Those strike us as fair points raised by Petitioner. Whether and how such points factor into the "good faith" or other inquiry under § 255 is, however, a matter better left for the Director.

Petitioner also contends that the corrected claims would add new matter and require reexamination. Opp. 5–7. But Petitioner does not address the disclosures cited by Merck that purport to provide explicit descriptive support for the "diffraction peaks" language when characterizing the relevant compounds according to XRPD. *See* Mot. 1 (citing Ex. 1001, 13:29–36). Even if there is written description support for the proposed corrections, Petitioner argues there are other conditions for patentability (e.g., novelty) that will require reexamination because the newly claimed subject matter was never actually examined during prosecution. Opp. 6. And, Petitioner contends, there is "nothing from the prosecution history" itself showing any recognition of the alleged error or how it should be corrected.[7] As there was little or no substantive discussion of claims 5–7

[7] Insofar as Petitioner reads *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1374–75 (Fed. Cir. 2005) as requiring something *explicit* in the prosecution history that makes an error in the claims "clearly evident," that overstates the reasoning and holding of *Arthrocare*. Based on the claim language itself, which made no sense in the original form, and the language of the specification, the *Arthrocare* court concluded "[t]hat evidence indicates that it was clear how the typographical error in the original claims should have been corrected." *Id.* at 1375. The fact that the court continued, remarking that the prosecution history "further support[ed]" patentee's position on the error does not mean the court would have ruled against patentee if the prosecution history shed no light, either way, on whether the

during the original examination, it is not apparent to us that the prosecution history favors or disfavors Merck's allegations that the claims are correctable as proposed or that such corrected claims need not be reexamined. Mot. 7–8. Heeding the Federal Circuit's guidance, we leave such a determination to the Director.

Finally, Petitioner argues that, if Merck's motion is granted, Merck should include Petitioner's Opposition with any request for certificate of correction submitted to the Director. Opp. 10. We agree. Like other panels in similar situations, "we discern that Petitioner's Opposition may be . . . useful to the Director in determining whether the issuance of a Certificate of Correction is appropriate." *Intuitive Surgical,* IPR2020-00051, Paper 13, at 4–5. We also agree with Merck, however, that it should provide "all the briefing" on this issue, not just the Petitioner's Opposition. Mot. Reply 3; *Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 77 at 13 (PTAB Apr. 27, 2020) (requiring patent owner to submit, with request for certificate of correction, copies of all documents submitted to or generated from the Board in connection with patent owner's motion). Thus, Merck is instructed to provide with its request for certificate of correction the full briefing on this motion (including exhibits), as well as the Board's decision on the motion.

claims included an error. Rather, we understand the court as indicating that an error to the claims may be correctable when it is clearly evident based on the totality of the relevant intrinsic evidence.

III. ORDER

In consideration of the foregoing, it is:

ORDERED that Patent Owner's Motion for Leave to File Request for Certificate of Correction of Claims 5–7 (Paper 63) is *granted*; we cede jurisdiction but only for the limited purpose of Patent Owner seeking correction of claims 5–7, which are not at issue in this proceeding, and this proceeding will therefore continue on its existing schedule;

FURTHER ORDERED that Patent Owner will file, within ten (10) days of the entry of this Order, its Request for a Certificate of Correction, and also file a copy of that request as an exhibit in this proceeding;

FURTHER ORDERED that Patent Owner must include with its Request for Certificate of Correction the briefing and other related documents on this motion as provided above; and

FURTHER ORDERED that when a decision is rendered on Patent Owner's request for a Certificate of Correction, Patent Owner will file, within ten (10) days of such decision, a copy of the decision as an exhibit in this proceeding.

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