UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ACERTA PHARMA B.V.,
Patent Owner

Case IPR 2023-00478
Patent No. 10,272,083

PATENT OWNER'S MOTION FOR LEAVE TO FILE REQUEST FOR CERTIFICATE OF CORRECTION

TABLE OF AUTHORITIES

Cases

Arkema Inc. and Arkema France v. Honeywell International Inc.,
PGR2016-00011, Paper 77 (P.T.A.B Apr. 27, 2020).....2,6

Commonwealth Sci. and Indus. Research Org. v. Basf Plant Sci. Gmbh,
PGR2020-00033, Paper 26, Paper 33 (P.T.A.B. Mar. 18, 2021).....2, 5

Honeywell Int'l, Inc. v. Arkema Inc.,
939 F.3d 1345, 1349 (Fed. Cir. 2019).....1.4

Intuitive Surgical, Inc. v. Ethicon LLC,
IPR2020-00050, Paper 13 (P.T.A.B. Feb. 26, 2020).....5

United Servs. Auto. Ass'n v. Asghari-Kamrani,
CBM2016-00063, Paper 10 (P.T.A.B. Aug. 4, 2016).....5

Statutes and Other Authority

35 U.S.C. § 102(b)(2)(C).....3

35 U.S.C. § 102(c).....3

35 U.S.C. § 255.....4,5

37 C.F.R. § 1.71(g)(3).....1,5,6

37 C.F.R. § 1.9(e).....4,5

MPEP §§ 717.02(a)(II) (June 2020).....1,6

MPEP 717.02(b)(IV) (June 2020).....1,6

Pursuant to the Board's authorization, EX3002, Patent Owner Acerta Pharma B.V. ("Acerta") moves for leave to request a certificate of correction from the Director. Acerta seeks to correct U.S. Patent No. 10,272,083 ("the '083 patent") to reference a written joint research agreement (the "JRA") between Acerta's predecessor-in-interest and a third party, MSD Oss BV ("Merck")[1]. The JRA was effective by January 21, 2014, which is the '083 patent's earliest effective filing date. The issue for the Board is the 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).

Here, the claimed invention disclosed in the '083 patent is the subject of a timely, written joint research agreement, EX2004, but the patent mistakenly does not reference it. A patent's failure to identify parties to a joint research agreement is a correctable mistake that the Director has the authority to correct. 37 C.F.R. § 1.71(g)(3); *see also* MPEP §§ 717.02(a)(II), 717.02(b)(IV) ("If the patent as issued does not include the names of the parties to the joint research agreement, the patent must be corrected to include the names of the parties to the joint research agreement by a certificate of correction."). In line with these authorities, the Board has

[1] MSD Oss BV is the predecessor-in-interest to Merck Sharp & Dohme B.V. EX2010.

previously permitted leave to seek such a correction from the Director. *See Commonwealth Sci. and Indus. Research Org. v. Basf Plant Sci. Gmbh*, PGR2020-00033, Paper 26 at 5 (P.T.A.B. Mar. 18, 2021). Likewise, the Director has issued certificates to correct a patent's specification that omitted reference to a joint research agreement. *Id*., Paper 33 at 1, Ex. 2043.

Petitioner Sandoz Inc. ("Sandoz") will not be prejudiced by Acerta's requested relief.[2] The Board has already authorized Sandoz to file a response to this motion, EX3002, so Sandoz will have an opportunity to present its position. Further, this proceeding was only recently initiated and the Board has not determined whether to institute trial. Accordingly, it is unlikely that any deadlines set by the Board will be affected by a certificate of correction. On the other hand, the Board has previously found that a patent owner is prejudiced when denied an opportunity to seek a certificate of correction. *See Arkema Inc. and Arkema France v. Honeywell International Inc.*, PGR2016-00011, Paper 77 at 12 (P.T.A.B Apr. 27, 2020).

Acerta respectfully requests that the Board grant leave and cede jurisdiction to the Director to consider Acerta's request on the merits.

[2] The relevant prejudice, if any, to consider is that caused by "granting Patent Owner's Motion," not that caused by a certificate of correction should the Director issue one. *Arkema Inc. and Arkema France v. Honeywell International Inc.*, PGR2016-00011, Paper 77 at 5 (P.T.A.B Apr. 27, 2020).

BACKGROUND

The claims of the '083 patent are directed to novel methods of treating various lymphomas using acalabrutinib, a targeted inhibitor of Bruton's tyrosine kinase, using specified doses and dosing regimens. The correction Acerta seeks bears on whether art cited in the Petition could qualify as prior art to the '083 patent. Sandoz's challenge relies on three references, including U.S. Patent No. 9,758,524 (EX1005) ("Barf"). Barf issued on September 12, 2017, and on its face is assigned to Merck. Sandoz claims that Barf is prior art under 35 U.S.C. § 102(a)(2) and, in combination with another reference, renders the challenged claims obvious.

Barf is not prior art because it falls within the joint research exception under 35 U.S.C. § 102(b)(2)(C) and § 102(c). On August 20, 2012, Merck and Covalution Pharma B.V., which is Acerta's predecessor-in-interest, EX2008; EX2009, entered into an agreement for the development and commercialization of BTK inhibitor compounds. EX2004 at 2. Merck provided know-how (§ 4.01) and a license (§ 2.01) to intellectual property, including Barf and related patents (§§ 2.01, 1.25; Schedule 1.25 (listing PCT application to which Barf claims priority)) for the purpose of allowing Acerta to research and develop such compounds as a treatment for cancer (§ 2.01, 1.11). EX2004 at 3, 5, 7–8, 10–11, 43. Further evincing the collaborative intent of the JRA, the agreement required Acerta to use reasonable efforts to develop acalabrutinib (§ 1.08), provide reports to Merck on progress (§

3.03), and contemplated that any new patent applications from that work would be filed and owned by Acerta (§§ 8.01, 8.02, 1.18). EX2004 at 4, 14–15.[3] The specification of the ’083 patent mistakenly does not reference the JRA between Merck and Acerta (the developers of Barf and the ’083 patent respectively).

Accordingly, Acerta seeks a certificate of correction to fix that mistake and insert the following text at the beginning of the ’083 patent:

> The subject matter disclosed herein was developed and the claimed invention was made by or on behalf of one or more of the following parties to a joint research agreement: Covalution Pharma B.V. (a/k/a Acerta Pharma B.V.) and MSD Oss BV (a predecessor-in-interest to Merck Sharp & Dohme B.V.). The joint research agreement was in effect on and before the effective filing date of the claimed invention and the date the claimed invention was made, and the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement.

ARGUMENT

35 U.S.C. § 255 permits the PTO to correct “a mistake of a clerical or typographical nature, or of minor character” that “occurred in good faith” upon a request by the patent owner. The Federal Circuit has held that 35 U.S.C. § 255 expressly “authorizes the Director—*not the Board*—to determine whether a Certificate of Correction should be issued.” *Honeywell*, 939 F.3d at 1349–50

[3] *See* 37 C.F.R. § 1.9(e) (explaining that “[t]he term joint research agreement . . . means a written contract, grant, or cooperative agreement entered into by two or more . . . entities for the performance of experimental, developmental, or research work in the field of the claimed invention”).

(emphasis added). Review of a patentee's motion for leave to petition for a certificate of correction therefore does not involve a decision on the merits of the patentee's petition, only whether the patent owner is to be granted "*authorization for filing such a request*." *See, e.g.*, *United Servs. Auto. Ass'n v. Asghari-Kamrani*, No. CBM2016-00063, Paper 10 at 6 (P.T.A.B. Aug. 4, 2016). The Board has found a "sufficient basis," and that leave should be granted, if there is at least 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*, IPR2020-00050, Paper 13, at 4–5 (P.T.A.B. Feb. 26, 2020).

Acerta's request amply meets every requirement of § 255. As such, the Board should grant that authorization. *See Commonwealth*, PGR2020-00033, Paper 26 at 2, 5 (granting leave to seek a certificate of correction to amend specification to list a joint research agreement).

"Clerical" or "Minor" Error. Acerta seeks to correct the omission of the details of the JRA in the specification of the '083 patent. That is a "mistake of a clerical . . . nature, or of minor character" under 35 U.S.C. § 255. Rule 1.71 expressly provides that "[t]he specification may disclose or be amended to disclose the names of the parties to a joint research agreement as defined in § 1.9(e)." 37 C.F.R. § 1.71(g)(1). It goes on to state:

> If the patent as issued does not include the names of the parties to the joint research agreement, the patent must be

> corrected to include the names of the parties to the joint research agreement by a certificate of correction under 35 U.S.C. 255 and § 1.323 . . . .

37 C.F.R. § 1.71(g)(3); *see also* MPEP §§ 717.02(a)(II), 717.02(b)(IV).

"Good Faith." The mistaken omission of any reference to the joint research agreement was inadvertent and made in "good faith." However, in this threshold posture, the Board "lack[s] authority to determine" whether a mistake "occurred in good faith." *Arkema*, PGR2016-00011, Paper 77, at 11.

"New Matter." Granting Acerta's proposed correction also will not add "new matter" or "require re-examination." 35 U.S.C. § 255. The correction would only be a reference to a joint research agreement and would not include the addition of substantive material. The MPEP specifically indicates that such a correction does not require reexamination. (MPEP § 717.02(a)(II) ("It is unnecessary to file a reissue application or request for reexamination of the patent to submit the amendment and other information necessary to establish that the prior art exception under 35 U.S.C. 102(b)(2)(C) applies in view of a joint research agreement..."). Once again, moreover, whether re-examination is required is a question for the Director rather than the Board. *Arkema*, PGR2016-00011, Paper 77, at 11.

CONCLUSION

For the foregoing reasons, the Board should grant Acerta's motion and authorize it to petition the Director for a certificate of correction.

Date: May 24, 2023

Respectfully submitted,

/*Stanley E. Fisher*/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a true and correct copy of the foregoing was served on May 24, 2023, by delivering a copy via electronic mail on the following counsel of record for the Petitioner:

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May 24, 2023 /*Stanley E. Fisher*/
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