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

Statutes and Other Authority

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 (§

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