

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ACERTA PHARMA B.V.,
Patent Owner.

Case IPR2023-00478
Patent 10,272,083 B2

**PETITIONER'S AUTHORIZED RESPONSE IN OPPOSITION
TO PATENT OWNER'S MOTION FOR LEAVE TO FILE
REQUEST FOR CERTIFICATE OF CORRECTION**

Patent Owner's motion for leave to request a certificate of correction should be denied. Patent Owner seeks correction to add Merck—the assignee of the Barf patent cited in the Petition (EX1005)—to the face of the '083 patent to disqualify Barf as prior art. Mot. 3–4. As shown below, however, Patent Owner fails to provide the “sufficient basis” to find a correctable mistake that is required to obtain leave. Mot. 1. Moreover, Patent Owner's request is futile and would be a waste of Office resources because any correction would not apply retroactively to this IPR. Alternatively, to the extent Patent Owner contends that correction would be retroactive, it would be prejudicial because Petitioner relied on the '083 patent as issued in filing the Petition, whereas Patent Owner strategically waited until after the Petition was filed—and after Petitioner's statutory bar date—to seek correction. Thus, leave to file a request for correction should be denied.

I. Patent Owner has not provided a “sufficient basis” to seek correction.

In deciding a motion for leave to seek correction, the Board determines “whether there is *sufficient basis* supporting Patent Owner's position that the mistake *may* be correctable.” *Honeywell Int'l, Inc. v. Arkema Inc.*, 939 F.3d 1345, 1349 (Fed. Cir. 2019). “The party filing the motion has the burden of proof to establish that it is entitled to the requested relief.” 37 C.F.R. § 41.121(b).

Under 35 U.S.C. § 255, correction is available only for “a mistake of a clerical or typographical nature, or of minor character,” and only if “a showing has

been made that such mistake occurred in good faith” and its “correction does not involve such changes in the patent as would constitute new matter or would require reexamination.” Patent Owner fails to show a basis to meet these requirements.

A. Patent Owner has not shown “a mistake . . . in good faith.”

First, Patent Owner provides no basis to find that its failure to disclose Merck on the face of the ’083 patent was a “mistake,” let alone one made “in good faith.” It offers only a single conclusory sentence that “[t]he mistaken omission of any reference to the joint research agreement was inadvertent and made in ‘good faith.’” Mot. 6. But Patent Owner attaches no affidavit or other evidence to support its assertion, and “[a]ttorney argument is not evidence.” *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017).

With no evidence to meet its burden, Patent Owner argues that “the Board ‘lack[s] authority to determine’ whether a mistake ‘occurred in good faith.’” Mot. 6 (quoting *Arkema Inc. v. Honeywell Int’l Inc.*, PGR2016-00011, Paper 77 at 11 (PTAB Apr. 27, 2020)). Patent Owner misunderstands the legal standard. While the Board should not weigh the evidence on whether to grant correction, it still should “determine whether there is *sufficient basis* . . . that the mistake *may* be correctable.” *Honeywell*, 939 F.3d at 1349. In *Arkema*, the panel cited “testimony of [the] prosecuting attorney” as a basis to find a correctable mistake. PGR2016-00011, Paper 77 at 11. Patent Owner offers no such testimony here.

Moreover, *Arkema* was the panel decision on remand following *Honeywell*, where the Federal Circuit noted that “in response to the Board’s questions about whether the change would satisfy the ‘good faith’ requirement of 35 U.S.C. § 255,” the patent owner identified when it “learned of the [mistake] for the first time” and “file[d] its motion for leave promptly upon discovering the mistake.” 939 F.3d at 1347 (internal quotations omitted). By contrast, here, Patent Owner has not identified when it allegedly discovered its “mistake,” so there is no basis (let alone a sufficient basis) to evaluate Patent Owner’s “good faith” in seeking correction.

The only available evidence suggests that omitting Merck was *not* a good-faith mistake but a strategic choice. Patent Owner and Merck are co-plaintiffs asserting both the ’083 patent and Barf (i.e., U.S. Patent No. 9,758,524) in parallel district court litigation. EX1046 ¶ 1. Their complaint, filed over a year ago on February 4, 2022, asserts that “all rights, title, and interest in the ’083 patent” are held by “AstraZeneca” (*id.* ¶ 115), which the complaint defines as including Patent Owner, but not Merck (*id.*, 1). Patent Owner was clearly aware of any relationship it had with its co-plaintiff Merck and must have investigated whether the parties listed on the ’083 patent were accurate and complete before bringing suit, yet it strategically waited over a year after asserting the ’083 patent and Barf in the same lawsuit—and after Petitioner’s statutory bar date for filing another petition under 35 U.S.C. § 315(b)—before seeking correction. That is not a good-faith mistake.

B. Patent Owner’s alleged mistake is not “clerical” or “minor.”

Second, Patent Owner provides no basis to find that the alleged mistake is “of a clerical or typographical nature, or of minor character.” 35 U.S.C. § 255. Patent Owner simply argues that under Rule 1.71, a patent may “be amended to disclose the names of the parties to a joint research agreement.” 37 C.F.R. § 1.71(g)(1). But this does not mean all party omissions are “clerical” or “minor.” Rule 1.71 makes clear that a patentee must obtain “a certificate of correction under 35 U.S.C. 255 . . . for the amendment to be effective.” *Id.* § 1.71(g)(3). Thus, a patentee must satisfy § 255, which requires showing that the mistake is “clerical” or “minor.” Patent Owner’s reliance on Rule 1.71 is therefore circular. The rule does not show that omitting Merck was clerical or minor, as Patent Owner contends; it requires Patent Owner to prove that. Patent Owner cites no evidence to meet its burden, and its argument that adding Merck would alter the scope of the prior art belies any notion that the alleged mistake is “minor” or “clerical.”

C. Patent Owner has not shown that reexamination is unnecessary.

Third, Patent Owner provides no basis to find that “the correction does not involve such changes in the patent as would . . . require reexamination.” 35 U.S.C. § 255. Patent Owner quotes MPEP § 717.02(a)(II) as providing that “[i]t is unnecessary to file a reissue application or request for reexamination . . . to establish that the prior art exception under 35 U.S.C. 102(b)(2)(C) applies in view

of a joint research agreement” (Mot. 6), but it ignores the next paragraph, which makes clear that “an amendment may necessitate the reopening of prosecution (e.g., for entry of a double patenting rejection).” MPEP § 717.02(a)(II). That is a key concern because, as shown in the Petition, the challenged claims of the ’083 patent are obvious over Barf’s claims. Pet. 27–49. While Barf is already a double-patenting reference based on an overlap in inventorship, adding Merck (Barf’s assignee) to the face of the ’083 patent would be a new, additional basis for double-patenting. Moreover, reopening prosecution would be required to assess whether other Merck patents warrant additional double-patenting rejections.

II. Patent Owner’s request for correction is either futile or prejudicial.

Patent Owner’s motion should also be denied because it is futile: Even if the Director were to grant Patent Owner’s request, certificates of correction do not apply retroactively to IPR (or PGR) proceedings. *See Emerson Elec. Co. v. SIPCO, LLC*, IPR2016-00984, Paper 52 at 17–26 (PTAB Jan. 24, 2020); *Election Sys. & Software, LLC v. Hart InterCivic, Inc.*, PGR2020-00031, Paper 18 at 6–10 (PTAB Feb. 5, 2021); *see also* 35 U.S.C. § 255 (correction is only effective in a “trial of actions for causes *thereafter arising*”) (emphasis added).

In holding that a certificate of correction is not retroactive, the panel in *Emerson* emphasized that “Patent Owner did not even seek correction until after Petitioner had filed its Petition,” which is also true here. IPR2016-00984, Paper 52

at 18. While the certificate in *Emerson* issued after the final written decision, *Election Systems* holds that certificates are not retroactive even if issued earlier. PGR2020-00031, Paper 18 at 6. As the panel explained, giving retroactive effect to a certificate of correction “would displace the role of the Petition,” contrary to *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018). *Id.* at 7–8.

Because any correction would not apply to the Petition, leave should be denied or deferred until after this IPR proceeding is over to avoid wasting Office resources on a correction that may be moot if the claims are found unpatentable.

Conversely, to the extent Patent Owner contends that correction would be retroactive, it would be highly prejudicial to Petitioner. The public is entitled to “allocate its affairs based on the patent as issued,” and “[p]ermitting the patentee to alter the patent document with retroactive effect could have negative consequences for unsuspecting parties.” *Emerson*, IPR2016-00984, Paper 52 at 23. Here, Petitioner relied on the face of the ’083 patent to challenge the claims based on Barf. Allowing Patent Owner to disqualify Barf as prior art now would be highly prejudicial, especially since Patent Owner strategically waited until after the Petition was filed and after Petitioner’s statutory bar date.

Thus, Patent Owner’s motion for leave should be denied. To the extent leave is granted, however, Patent Owner should be required to attach this response to its request for correction, which it has agreed to do. EX3002, 2.

Dated: June 8, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I certify that, on June 8, 2023, I caused to be served true and correct copies of “PETITIONER’S AUTHORIZED RESPONSE IN OPPOSITION TO PATENT OWNER’S MOTION FOR LEAVE TO FILE REQUEST FOR CERTIFICATE OF CORRECTION,” by electronic mail on counsel of record for Patent Owner:

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