

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HELENA LABORATORIES CORPORATION.,
Petitioner,

v.

SEBIA,
Patent Owner.

Case IPR2024-00801
Patent 7,887,686

PATENT OWNER'S SUR-REPLY

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Petitioner argued that a reply brief was warranted to address discretionary denial issues raised by Patent Owner and the Board granted Petitioner's request to address the three issues raised in Ex. 3001. *See* Paper 7. The Reply is thus merely a last-minute attempt by Petitioner to address foreseeable §§ 325(d) and 314(a) issues that should have been, but were not addressed in its Petition. *Regeneron Pharm., Inc. v. Novartis Pharma Ag*, IPR2020-01317, Paper 12 at 5 (PTAB Nov. 17, 2020) ("Petitioners are expected to address all material issues relevant to institution of trial in their petitions, including discretionary factors that could be case dispositive." "To show good cause, the moving party must explain why patent owner's discretionary arguments were not reasonably foreseeable, and thus not addressed in the petition in the first instance."). Petitioner's proffered excuse for this failure is that an unapplied reference known to the Examiner (Ex. 1011 hereinafter "Shihabi"), *per se* prevents exercise of discretion under 35 U.S.C. §325(d). Petitioner is not only wrong but the arguments presented in the Reply also confirm that the Petition falls squarely in the class of petitions that should be denied under §325(d) or §314(a).

Contrary to Petitioner, Shihabi was previously presented to the Office. Huang (Ex. 1015) is substantially the same prior art as Shihabi, alone or combined with other references previously presented. Coufal (Ex. 1013) and Landers (Ex. 1026) are substantially the same prior art as Camilleri (Ex. 1020).

During prosecution, the Examiner cited art for each of the claim limitations, except for the feature of *resolving* hemoglobins (alternatively identified as “Hbs”), which was added to allow the claims. The feature of a blood sample was added to the independent claims. Shihabi was known to the Examiner for teaching separation of Hbs by CE using ZB, *but not resolving Hbs*. Petitioner *never explains* that Shihabi or Huang teaches *resolving Hbs* or CE of a *blood sample*. Petitioner’s prior art provides nothing not already presented to the Office and known to the Examiner when allowing the claims.

I. Petitioner Failed to Address the Same or Substantially the Same Art and Arguments Previously Presented to the Office

35 U.S.C. §325(d) provides that the Board may exercise its discretion not to institute the present Petition where “the same or substantially the same prior art or arguments previously were presented to the Office.” In deciding whether to exercise its discretion, the Board may therefore consider (1) whether the *same prior art* was previously presented to the Office, (2) whether *substantially the same prior art* was previously presented to the office or, (3) whether *the same or substantially the same arguments* were previously presented to the Office.

35 U.S.C. §325(d) requires analysis of whether the *same prior art* was “previously presented” to the Office. “Previously presented” prior art includes that listed on an IDS and acknowledged by the Examiner. *Fitesa Simpsonville, Inc. v. The Procter and Gamble Co.*, IPR2023-01450, Paper 11 at 11-12 (PTAB March 20,

2024) (citing *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-8 (PTAB Feb. 13, 2020) (precedential)) (“[p]reviously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.”). Shihabi was previously presented to the Office, having been listed on an IDS and acknowledged by the Examiner. POPR, Paper 6 at pp. 14-16. Further, Petitioner admits that Shihabi was known to the Examiner and discussed in the specification of the ‘686 Patent for disclosing separation of Hbs by CE using ZB. Reply, Paper 8 at pp. 4, 10. Accordingly, Petitioner was obligated to address the foreseeable 35 U.S.C. §325(d) issues described above with respect to Shihabi in its Petition and erred in not doing so.

Even if Huang, Coufal and Landers are not the same prior art, 35 U.S.C. §325(d) requires analysis of whether *substantially the same prior art* was “previously presented” to the Office. Substantially the same prior art does not “identify any specific information . . . that is ‘additional’ to or ‘different’ than” ***the combination*** of other previously considered references. See *NXP USA, Inc. v. Impinj, Inc.*, IPR2020-00519, Paper 7 at 7–12 (PTAB Aug. 17, 2020). A reference is cumulative when it “teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO.” *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559, 1575 (Fed. Cir. 1997). Petitioner fails to

identify any specific information in Huang (Ex. 1015) that is additional to or different from Shihabi alone or combined with other references of record. Similarly, Petitioner fails to identify any specific information in Coufal or Landers that is additional to or different from Camilleri.

Petitioner attempts to correct its failure by now arguing that Huang is not merely cumulative of Shihabi because Huang further teaches: (1) the bis-tris propane (ZB) of claim 15; (2) the naked capillary of claim 10; and (3) the fused silica capillary of claim 11. Reply at p. 3 and fn 1. However, the Examiner cited Sunzeri for teaching tricine from among the species of ZB in claim 15 (pending claim 35), the naked capillary of claim 10 (pending claim 49) and the fused silica capillary of claim 11 (pending claim 50). Ex. 1003, pp. 1003-0415-1003-0416. Petitioner fails to identify Huang teaching anything additional to or different than Shihabi, alone, or in combination with Sunzeri, when seeking to invalidate the claims. Huang, therefore, is substantially similar to previously considered art under *NXP USA*.

Petitioner states that “Camilleri is applied as a tertiary reference but for a different technical proposition, namely, tricine as a ZB.” Reply at p. 4 fn 2. But, Camilleri is cumulative of Sunzeri which the Examiner cited as teaching tricine as a ZB. Ex. 2001, ¶ 75.

Petitioner relies on Coufal for teaching a combination of ZB and FI. Reply at p. 7. However, even Petitioner admits that the Examiner cited Camilleri for teaching

CE using a ZB and an FI. POPR at p. 22. Petitioner further states that Coufal is relied on for teaching features of claim 6 (20mM to 500mM analysis buffer concentration), claim 12 (pH from 8 to 10), claim 18 (pH modifier sodium hydroxide) and claim 23 (ZB and FI for CE migration). Reply at p. 7. However, Sunzeri was cited for teaching 50mM tricine buffer (issued claim 6, pending claim 43), CE migration using ZB and quaternary amine CTAB (issued claim 23, pending claim 56), and pH of about 7.2 (issued claim 12, pending claim 51.). Ex 1003, pp. 1003-0415; 1003-0416. Nouadje was cited for teaching the pH modifier sodium hydroxide (issued claim 18, pending claim 48). *Id.*, 1003-0419; 1003-0420. Petitioner also states that Landers is relied on for teaching “a specific FI [an aliphatic diamine] corresponding to patent claims 5 and 6.” Reply at p. 8. However, Camilleri was cited for teaching 1,4-diaminobutane which is an aliphatic diamine (issued claim 5, pending claim 38). Ex. 1003, pp. 1003-0418. Because Coufal and Landers do not address any claim feature additional to or different from claim features already addressed by Sunzeri, Camilleri and Nouadje; Coufal and Landers are substantially similar to previously considered references under *NXP USA*. Accordingly, Petitioner was obligated to address the foreseeable 35 U.S.C. §325(d) issues described above with respect to Huang, Coufal and Landers in its Petition and erred in not doing so.

Regardless of whether Shihabi (or Huang) were previously presented to the Office, §325(d) requires analysis of whether *substantially the same arguments* were

“previously presented” to the Office. Petitioner’s same arguments were previously presented during examination, namely Hb separation using CE and ZB and the combination of a ZB and FI. Also, Petitioner erroneously states that “[n]o prior art disclosing Hb variant separation by CE using ZB *was applied* to any claim during examination” and that “[t]he prior art, applied to the claims during examination, are neither the same, nor substantially the same, nor cumulative of, the prior art applied by Petitioner.” Reply at p. 4 (emphasis added).

During prosecution, both Chen (Ex. 1017) and Mohammad (Ex. 1019) were cited for teaching Hb variant separation using CE, albeit using different buffers. Sunzeri (Ex. 1018) was cited for teaching CE of a blood sample using a ZB (tricine). POPR at p. 23; *see also* Ex. 1003, pp. 1003-0418; Ex. 2001, ¶ 75 and Appendix A, ¶ 31. Combined, these disclosures teach features of Hb variant separation using CE and ZB, just like Shihabi or Huang. Therefore, prior art teaching Hb variant separation by CE using ZB (Chen and Mohammad and Sunzeri) *was applied* to claims during examination.

Further, Petitioner’s argument of invalidity based on Shihabi (i.e., Hb separation using CE and ZB) is the same as the Shihabi disclosure in the ‘686 patent used by the Patentee to distinguish the invention. *Compare* Ex. 1001 at col. 1 lines 65-67 (“Tris/arginine combinations (Shihabi) (6) have been used and even though

they allowed HbA/HbSA separation”) with Reply at p. 3 (“CE of HB variants using ZB.”). Petitioner advances nothing new in Shihabi not already of record.

Accordingly, Petitioner was obligated to address the foreseeable 35 U.S.C. §325(d) issues described above with respect to its Petition arguments and erred in not doing so.

II. 35 U.S.C. §325(d) Provides No Safe Harbor for a Primary Reference Previously Presented But Not Applied by the Examiner

Realizing its error, Petitioner now seeks to supplement and correct its Petition by Reply. Ex. 3001. Petitioner fails by arguing that *Becton, Dickinson* and therefore, 35 U.S.C. §325(d), provides a safe harbor for prior art that was not applied to the claims during examination. Reply at p. 1. Petitioner’s argument that unapplied prior art is *per se* immune from the six-factor *Becton, Dickinson* analysis (Reply at p. 3) is wrong. While *Becton, Dickinson* instituted an IPR based on the “Van Heugten” prior art in combination with Tauschinski, there is no discussion in *Becton, Dickinson* of whether Van Heugten was substantially the same prior art as that previously presented to the Office or whether Van Heugten raised the same as or substantially similar arguments that were previously presented to the Office.

35 U.S.C. §325(d) provides no such *per se* safe harbor because institution may be denied (1) where Petitioner presents unapplied prior art that is *substantially the same prior art* as was previously presented to the Office, or (2) where Petitioner’s arguments based on applied or unapplied prior art are *substantially the same*

arguments as previously presented to the Office. *See e.g.*, 35 U.S.C. § 325(d); *Dorco Co., Ltd. v. The Gillette Co., LLC*, IPR2017-00500, Paper 7, slip op. at 15 (PTAB June 21, 2017) (denying institution pursuant to § 325(d) based on references that were not the same as those previously presented to the Office but presenting the same question of patentability as previous references considered by the Examiner). Whether Shihabi or Huang were never applied is irrelevant. An “unapplied” reference may still be the basis for the Board denying institution under 35 U.S.C. §325(d). *Advanced Bionics*, at 7-8.

III. Petitioner Has Not Shown Any Office Error Material to Patentability

Since Shihabi and its teaching of Hb separation by CE using ZB were previously presented to the Office (and Huang is redundant thereof), Petitioner must demonstrate that the Office made an error material to patentability. *Advanced Bionics*, at 10 (“[P]etitioner’s showing under factors (e) and (f)[] focus on the petitioner’s evidence of previous Office error regardless of the context in which the same or substantially the same art or arguments were previously presented.”). Petitioner carries the burden of showing material differences, particularly where PO made an initial contrary showing. *Id.*, at 16–17, 19.

Petitioner fails to demonstrate any material difference or material error by the Office. Shihabi was listed on an IDS and acknowledged by the Examiner. *See e.g.*, POPR at pp. 14-15. Petitioner also admits that Shihabi was known to the Examiner.

Reply at pp. 4, 10. Further, the ‘686 Patent distinguished the invention over Shihabi’s Hb separation using CE and ZB *based on resolution*. Ex. 1001 at col. 2 lines 5-10. (“...there exists a need for a method for analyzing haemoglobin and in particular haemoglobin A₂ which ... guarantees satisfactory resolution between HbA₂, HbC, HbD, HbE, HbS, HbF and HbA forms in particular.”). While Shihabi was not a basis for a rejection, Shihabi and its teaching in the ‘686 Patent were considered during examination. *See* MPEP 2103(I)(“Examiners will review the complete specification . . .”).

The only Office error alleged by Petitioner is that “the Examiner erred in not identifying Shihabi as the closest prior art” based on Shihabi teaching Hb variant separation by CE using ZB. Reply at p. 10. But, Shihabi (as well as Huang, Coufal, Camilleri and Landers) fails to teach a CE method using ZB with a *blood sample* (POPR at p. 45) which was taught by Sunzeri. Accordingly, Petitioner has far from demonstrated that Shihabi is the closest prior art. Furthermore, not applying Shihabi as the closest prior art or otherwise is not material error. *Advanced Bionics* at 9 (“[I]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”). The Office was well aware of Shihabi teaching Hb separation by CE using ZB, *but not resolution*. The Office was well aware that the ‘686 Patent described that its invention was different over Shihabi *based on Hb variants being*

resolved. The Office allowed the ‘686 Patent after having considered the relevant teachings of Shihabi and by requiring that the independent claims recite “resolution” of Hbs which the Examiner stated was lacking in the applied art (e.g., Sunzeri and Nouadje). Ex. 1003, pp. 1003-0472-1003-0473; Ex. 2001 ¶ 112, Appendix A, ¶ 39.

Petitioner provides no record evidence that the Examiner erred in the technical evaluation of Shihabi or overlooked any teaching that the Petitioner now attributes to Shihabi (*i.e.*, separation of Hb by CE using ZB, which is the very same technical description in the ‘686 patent) to allege invalidity and over which the Examiner allowed the claims. The Examiner’s reasons for allowance readily support patentability over Shihabi insofar as Shihabi does not teach resolution, which Sunzeri and Nouadje also failed to teach. Petitioner’s disagreement with the Examiner’s allowance of the claims does not support material error by the Office.

Petitioner has presented no additional evidence or facts that warrant reconsideration of the prior art or arguments. Notably Shihabi, acknowledged by the Examiner on an IDS and previously presented during Examination, was described in the ‘686 Patent as teaching Hb separation by CE using ZB. Accordingly, Petitioner’s “missing link” of Hb separation by CE using ZB is a red herring and institution should be denied under §325(d) or §314(a).

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By: / John P. Iwanicki /

John P. Iwanicki (Reg. No. 34,628)
BANNER & WITCOFF, LTD.
28 State Street, Suite 1800
Boston, MA 02109
Tel: (617) 720-9400
Email: jiwanicki@bannerwitcoff.com

Robert F. Altherr (Reg. No. 31,810)
Christopher B. Roth (Reg. No. 49,007)
BANNER & WITCOFF, LTD.
1100 13th Street, NW, Suite 1200
Washington, DC 20005
Tel: (202) 824-3000
Email: raltherr@bannerwitcoff.com
Email: croth@bannerwitcoff.com

Christopher Galfano (Reg. No. 73,263)
BANNER & WITCOFF, LTD.
71 South Wacker Drive, Suite 3600
Chicago, IL 60606
Tel: (312) 463-5000
cgalfano@bannerwitcoff.com

Attorneys for Patent Owner Sebia

CERTIFICATE OF SERVICE

The undersigned certifies service on the Petitioner, under 37 C.F.R. § 42.6(e) by electronic (e-mail) delivery of a true copy of the foregoing PATENT OWNER'S SUR-REPLY to the attorneys of record for Petitioner:

JEROLD.SCHNEIDER@SCHNEIDERIPLAW.LEGAL
SCOTT@CONCEPTLAW.COM

Dated: August 23, 2024

By: /Valerie Koleno/

Valerie Koleno