

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HELENA LABORATORIES CORPORATION,
Petitioner,

v.

SEBIA,
Patent Owner.

IPR2024-00801
Patent 7,887,686 B2

Before JO-ANNE M. KOKOSKI, AVELYN M. ROSS, and
JANE E. INGLESE, *Administrative Patent Judges*.

ROSS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Helena Laboratories Corporation (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 7,887,686 B2 (Ex. 1001, “the ’686 patent”). Sebia (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”). With our permission (Paper 7), Petitioner filed a Preliminary Reply (Paper 8, “Reply”), and Patent Owner filed a Preliminary Sur-reply (Paper 9, “Sur-reply”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2023). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition.”

For the reasons set forth below, upon considering the Petition, the Preliminary Response, the Preliminary Reply, the Preliminary Sur-reply, and evidence of record, we exercise our discretion under 35 U.S.C. § 325(d) to deny institution of an *inter partes* review.

A. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 5.

Patent Owner identifies itself as the real party-in-interest. Paper 5 (Patent Owner’s Mandatory Notices), 1.

B. *Related Proceedings*

The parties do not identify any matters related to this proceeding. Pet. 5; Paper 5, 1.

C. The '686 patent

The '686 patent, titled "Method for Analyzing Haemoglobin by Capillary Electrophoresis, a Kit for Capillary Electrophoresis, and Use of a Flow Inhibitor in Said Method," issued February 15, 2011. Ex. 1001, codes (45), (54). The '686 patent relates to "a method for separating haemoglobin [{"Hb"}] by capillary electrophoresis, to buffer compositions for use in said separation, and to kits for analyzing haemoglobin by capillary electrophoresis." *Id.* at 1:7–10. The '686 patent explains that there is "a need for a method for analyzing haemoglobin and in particular haemoglobin A₂ which allows single step analysis without a double coating, which can be carried out automatically and in series, and which guarantees satisfactory resolution between the HbA₂, HbC, HbD, HbE, HbS, HbF and HbA forms in particular." *Id.* at 2:5–10. According to the '686 patent, "by using a zwitterionic analysis buffer associated with a flow inhibitor, it is possible to obtain greatly improved separation of the fractions mentioned above, in a single step, thus avoiding complementary separations and without a double coating, which simplifies its implementation." *Id.* at 2:11–16. The '686 patent's method "can also allow HbA₂ to be quantified even in the presence of HbC or HbE." *Id.* at 3:4–5.

The '686 patent describes a method of separating hemoglobins in biological samples in which the biological samples are passed through a capillary containing a zwitterionic analysis buffer that is associated with at least one flow inhibitor, and the hemoglobins are separated by migration and detected. Ex. 1001, 2:17–26. The zwitterionic buffer used in the '686 patent's method buffers between pH 8 and 10, and comprises "at least one amine function and at least one acidic function and at least one hydroxyl

function in the position opposite to the acidic function.” *Id.* at 2:27–31. A preferred zwitterionic buffer is tricine. *Id.* at 4:4–5. The ’686 patent states that “the flow inhibitors are of the aliphatic or cyclic diamine or polyamine type” and “are selected from aliphatic diamines or polyamines and/or cyclic diamines or polyamines.” *Id.* at 2:40–43. Preferred flow inhibitors include 1,4-diaminobutane (DAB), 1,5-diaminopentane, 1,6-diamino-hexane, diethylenetriamine (DETA), and N,N,N',N'-tetramethyl-1,4-butanediamine, and “1,4-diaminobutane hydrochloride is preferably associated with the tricine.” *Id.* at 4:8–14.

D. Illustrative Claim

Petitioner challenges claims 1–24 of the ’686 patent. Claims 1, 23, and 24 are independent. Independent claim 1 is representative of the challenged claims and is reproduced below.

1. A free solution capillary electrophoresis method for separating and resolving haemoglobins in a biological sample by capillary electrophoresis, said biological sample being a blood sample, said method comprising:

introducing said biological sample into a capillary tube comprising a solution of an analysis buffer, wherein said analysis buffer is of the zwitterionic type and at least one flow inhibitor, and

electrophoresing said biological sample in said analysis buffer and at least one said flow inhibitor, whereby said haemoglobins are separated by migration, and wherein said haemoglobins are a haemoglobin HbA2 and an HbC, an HbD, an HbE, an HbS, an HbF or an HbA haemoglobin.

Ex. 1001, 7:21–34.

E. The Asserted Unpatentability Challenges

Petitioner asserts that claims 1–24 would have been unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–3, 6, 7, 10–14, 17, 18, 23	103	Either Shihabi ² or Huang ³ , each in view of Coufal ⁴
15, 16	103	Either Shihabi or Huang, each in view of Coufal and Camilleri ⁵
4, 5, 8, 9, 19–22, 24	103	Either Shihabi or Huang, each in view of Coufal and Landers ⁶

Pet. 13. Petitioner also relies on declaration testimony of Alan H.B. Wu, Ph.D. (Ex. 1004). Patent Owner relies on declaration testimony of James P. Landers, Ph.D. (Ex. 2001).

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the ’686 patent claims priority and the application from which the ’686 patent issued were filed before this date, the pre-AIA version of § 103 applies.

² Zak K. Shihabi *et al.*, *Hemoglobin A₂ quantification by capillary zone electrophoresis*, 21 ELECTROPHORESIS 749–52 (2000) (Ex. 1011, “Shihabi”).

³ Tung-Liang Huang *et al.*, *The separation of hemoglobin variants by capillary zone electrophoresis*, 17 J. HIGH RESOLUTION CHROMATOGRAPHY 676–78 (1994) (Ex. 1015, “Huang”).

⁴ Pavel Coufal *et al.*, *The magnitude and reproducibility of the electroosmotic flow in silica capillary tubes*, 17 J. HIGH RESOLUTION CHROMATOGRAPHY 325–34 (1994) (Ex. 1013, “Coufal”).

⁵ Camilleri, P., “Capillary Electrophoresis”, 370–71 (2d ed. 1997) (Ex. 1020, “Camilleri”).

⁶ James P. Landers *et al.*, *High-performance capillary electrophoresis of glycoproteins: the use of modifiers of electroosmotic flow for analysis of microheterogeneity*, 205 ANALYTICAL BIOCHEM. 115–24 (1992) (Ex. 1026, “Landers”).

II. DISCRETION TO DENY INSTITUTION UNDER 35 U.S.C. § 325(D)

Patent Owner argues that we should exercise our discretion to deny all of the asserted grounds under 35 U.S.C. § 325(d) because they present substantially the same prior art and arguments the United States Patent and Trademark Office (“the Office”) previously considered during prosecution. *See* Prelim. Resp. 11–28.

Section 325(d) provides that in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2)
- if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

In applying the two-part framework, we consider several non-exclusive factors, including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or

Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

1. *The Applicability of Section 325(d)*

As an initial matter, Petitioner argues “[i]t is not clear that the *Becton, Dickinson* factors are even applicable when Petitioner relies on primary reference[s] not applied to the claims during examination.” Reply 8. According to Petitioner, “the six factor analysis [in *Becton, Dickinson*] does not appear to be required when there is at least one primary reference not previously applied.” *Id.* at 3. Petitioner contends its “primary references, Shihabi (Ex. 1011) and Huang (Ex. 1015) were never applied, for any purpose, to any of the claims.” *Id.* at 1. Petitioner argues that “Patent Owner seeks to equate the unapplied prior art (Shihabi, Huang) to the prior art ‘considered but not applied’ below (Shihabi). Patent Owner is incorrect.” *Id.* at 3.

Patent Owner argues that “Petitioner’s argument that unapplied prior art is *per se* immune from the six-factor *Becton, Dickinson* analysis [] is wrong” 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.” Sur-reply 7–8 (citation omitted).

As discussed above, Section 325(d) provides that the Board may deny institution of an *inter partes* review because “the same *or substantially the same prior art* or arguments previously were presented to the Office” (emphasis added). Section 325(d) does not distinguish between primary and secondary references, and may apply when substantially the same prior art was presented to the Office.

Here, as discussed further below, Patent Owner contends Shihabi and Camilleri were previously presented to the Office, and that Huang, Coufal, and Landers are substantially the same as prior art that was previously presented to the Office. Thus, we evaluate Patent Owner’s arguments under the *Advanced Bionics* framework by considering the *Becton, Dickinson* factors.

2. Advanced Bionics Framework Part (1)

Under the first part of the *Advanced Bionics* framework, we consider whether the same or substantially the same art or arguments were previously presented to the Office. *Advanced Bionics*, Paper 6 at 8. Relevant to the first part of the *Advanced Bionics* framework, we evaluate *Becton, Dickinson* factors (a), (b), and (d).

a) *Prior Art References*

The grounds of unpatentability set forth in the Petition rely on Shihabi, Huang, Coufal, alone or in combination with Camilleri or Landers. Pet. 13. We determine below that each of the asserted references are the same as, or cumulative to, references presented to the Examiner during prosecution and, thus, we determine that the “same or substantially the same

prior art” previously was presented to the Office. We discuss each of the references below.

(1) *Shihabi*

Petitioner contends Shihabi “was mentioned in the background of the ’686 patent but never applied against any of the claims.” Pet. 16. Petitioner argues 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” because “each primary reference, Shihabi (Ex. 1011) and Huang (Ex. 1015) discloses Hb variant separation by CE [i.e., capillary electrophoresis] using ZB [i.e., zwitterionic buffer]. No prior art disclosing Hb variant separation by CE using ZB was applied to any claim during examination. That should be dispositive of the *Becton, Dickinson* factors.” Reply 3–4.

According to Petitioner, “[t]he ‘closest’ prior art ‘known’ to the Examiner, Shihabi, a reference teaching CE of Hb variants using a ZB, was never applied against any claim.” Reply 4. Petitioner explains that Shihabi provides “at least one ‘missing link’ – separation of Hb by CE using a ZB” and “[t]hat alone is a material difference.” *Id.* at 8–9 (emphasis omitted). According to Petitioner, “[t]here are no similarities between primary references which do not disclose separation of Hb into its variants by CE using a ZB (Nouadje, Sunzeri) and those unapplied references that do disclose separation of Hb by CE using a ZB. (Shihabi, Huang).” *Id.* at 9 (emphasis omitted).

Patent Owner argues Shihabi meets the first part of the *Advanced Bionics* framework because “Shihabi was expressly described in the ’686 patent as failing to teach resolution of ‘HbC/HbE and HbA₂ fractions’” and

“was also considered by the Examiner during prosecution.” Prelim. Resp. 15 (citing Ex. 1001, 1:65–2:1; Ex. 1003, 269; Ex. 2001 ¶¶ 60–61); *see also id.* at 14; Sur-reply 3.

We agree with Patent Owner. We observe that Shihabi is discussed in the background section of the ’686 patent (Ex. 1001, 1:65–2:1), was listed on an Information Disclosure Statement (“IDS”) by Applicant, and marked as considered by the Examiner on December 30, 2008 (Ex. 1003, 269). A reference submitted, but not substantively discussed during prosecution, nonetheless qualifies as prior art previously presented to the Office. As *Advanced Bionics* makes clear, “[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.” *Advanced Bionics*, Paper 6 at 7–8. Accordingly, we determine that Shihabi was previously presented to the Office.⁷

(2) *Huang*

Petitioner contends Huang was not cited by Patent Owner or the Examiner during prosecution and constitutes newly cited prior art. Pet. 16–17; Reply 4. Petitioner argues 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 4. According to Petitioner, “each primary reference, Shihabi (Ex. 1011) and Huang

⁷ We note that the parties’ briefs also include arguments about the applicability of *Becton, Dickinson* factor (b) to Shihabi. Because we determine Shihabi itself was previously presented to the Office, we need not determine if Shihabi is also cumulative of other prior art evaluated during examination.

(Ex. 1015) discloses Hb variant separation by CE using ZB” and “[n]o prior art disclosing Hb variant separation by CE using ZB was applied to any claim during examination.” *Id.* at 3–4, 8–9. Therefore, Petitioner asserts that Huang is not cumulative because “[t]here are no similarities between primary references which do not disclose separation of Hb into its variants by CE using a ZB (Nouadje, Sunzeri) and those unapplied references that do disclose separation of Hb by CE using a ZB. (Shihabi Huang).” *Id.* at 9 (emphasis omitted).

Petitioner further contends Huang is “not merely cumulative of Shihabi” because Huang discloses limitations in some of the dependent claims of the ‘686 patent. *Id.* at 3, n.1. For example, Petitioner argues “Huang discloses use of bis-tris propane as a ZB (Ex. 1015, page 1) -- claimed in the ‘686 patent, claim 15[.]. Shihabi discloses Tris but not bis-tris propane. Huang, but not Shihabi, disclose[s] details of the CE tubes[] claimed in the ‘686 patent claims 10 and 11[.]” *Id.* (citations omitted).

Patent Owner argues Huang meets the first part of the *Advanced Bionics* framework because “Huang’s teachings are the same as or substantially similar to Shihabi’s teachings relied on by Petitioner.” Prelim. Resp. 26–27 (citing Ex. 2001 ¶ 73). Patent Owner contends “[t]he Petitioner identifies no reason how or why Huang is a better teaching than Shihabi” and “treats Huang (which separates HbF, HbA, HbS and HbC) as interchangeable with Shihabi (which also separates HbF, HbA, HbS and HbC).” *Id.* at 27. Patent Owner further asserts Huang is substantially similar to previously considered art because “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).” Sur-reply 4 (citing Ex. 1003, 415–16).

It is undisputed that Petitioner relies on both Shihabi and Huang as disclosing Hb variant separation by capillary electrophoresis using a zwitterionic buffer. *See* Pet. 21–22; Reply 3–4. While there are some differences between Shihabi and Huang regarding the zwitterionic buffer and capillary tubes recited in the ’686 patent’s dependent claims, those differences do not affect our analysis of the independent claims in the ’686 patent. We also agree with Patent Owner that the Examiner applied Sunzeri’s teachings for the same limitations regarding the zwitterionic buffer and capillary tubes that Petitioner argues are disclosed by Huang. *Compare* Reply 3, n.1 *with* Ex. 1003, 415–16. For the foregoing reasons, we are persuaded that Huang is substantially the same as Shihabi and Sunzeri, which were both previously presented to the Office.

(3) *Camilleri*

Petitioner admits that the Examiner cited Camilleri during prosecution. Pet. 17–18. But, according to Petitioner “there are material differences because Camilleri is applied [in this proceeding] for a different teaching.” Reply 9. Petitioner argues that “Camilleri [] was relied on during examination for the disclosure of CTAB added to a CE buffer to reverse the charge [] and combined with Sunzeri in a second rejection, as using ZB and additives such as 1,4 DAB as an FI.” *Id.* at 6 (citations omitted). Petitioner contends it “relies on Camilleri as a tertiary reference for a different proposition, namely, a specific ZB (tricine) found in dependent claims 15 and 16 of the ’686 patent.” *Id.* at 7.

Patent Owner argues Camilleri meets the first part of the *Advanced Bionics* framework because “Camilleri was expressly considered by the office for teaching the combination of a ZB and a[n] FI [i.e., flow inhibitor] (1,4-diaminobutane in particular).” Prelim. Resp. 15–16 (citing Ex. 1003, 418; Ex. 2001 ¶ 75, Appx. A ¶ 31).

We agree with Patent Owner. We observe that the Examiner substantively discussed Camilleri by applying the reference as prior art in an Office Action mailed on January 29, 2010. *See* Ex. 1003, 412, 415, 417–18. As *Advanced Bionics* makes clear, “[p]reviously presented art includes art made of record by the Examiner.” *Advanced Bionics*, Paper 6 at 7–8. Accordingly, we determine that Camilleri was previously presented to the Office.⁸

(4) *Coufal*

Petitioner contends Coufal was not cited by Patent Owner or the Examiner during prosecution and constitutes newly cited prior art. Pet. 17. Petitioner also argues that Coufal is not cumulative. Reply 7; *see also id.* at 9. Petitioner asserts that “Patent Owner erroneously attempts to treat Coufal as being relied on for the same reason as Chen and thus argues it is merely cumulative.” *Id.* at 7. According to Petitioner,

Petitioner relies on Coufal not only for teaching the combination of FI and ZB as a flow reducer (not a flow reversal) but also for teaching specific ZB concentrations . . . corresponding to the ‘686 patent claim 6; a buffer pH range greater than that of the primary references and substantially the same as the ‘686 patent

⁸ We note that the parties’ briefs also include arguments about the applicability of *Becton, Dickinson* factor (b) to Camilleri. Because we determine Camilleri itself was previously presented to the Office, we need not determine if Camilleri is also cumulative of other prior art evaluated during examination.

claim 12; the use of a specific pH modifier corresponding to patent claim 18; and Coufal refers to “migration time” (patent claim 23 refers to migration).

Id. (citations omitted).

Patent Owner argues Coufal meets the first part of the *Advanced Bionics* framework and is cumulative to Camilleri because “Petitioner relies on Coufal [] for the very same teachings of Camilleri relied on by the Office during prosecution, e.g. a combination of a ZB and a[n] FI (1,4-diaminobutane in particular).” Prelim. Resp. 20 (citing Pet. 3, 17–18); *see also id.* at 17–18 (“Camilleri, in general, teaches the use of cationic amines as a[n] FI.”) (citing Ex. 1003, 418; Ex. 2001 ¶ 64, Appx. A ¶¶ 26–32; Ex. 1020, 2). According to Patent Owner, these teachings are the same as Coufal’s teachings because Camilleri’s “1,4-diaminobutane is an aliphatic diamine just like the ethylenediamine of Coufal” and Coufal’s ethylenediamine is a cationic amine like that of Camilleri. *Id.* at 17–18 (citing Ex. 1020, 2; Ex. 2001 ¶ 64); *see also id.* at 19 (citing Ex. 2001 ¶ 65). Patent Owner argues “Petitioner has provided no explanation of how or why Coufal is a better reference than Camilleri with respect to claims 1 and 23 of Ground 1 for the teaching of a ZB and a[n] FI and Coufal’s teachings for the use of ZB and FI are the same as Camilleri.” *Id.* at 18.

With respect to dependent claims 6, 12, 17, and 18, Patent Owner argues that Coufal is substantially similar to previously considered references because Coufal does not address any claim feature additional to or different from claim features already addressed by Sunzeri, Camilleri, and Nouadje. Sur-reply 5. Specifically, Patent Owner argues that “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),” and “Nouadje was cited for teaching the pH modifier sodium hydroxide (issued claim 18, pending claim 48).” *Id.* (citing Ex. 1003, 415–16, 419–20); *see also* Prelim. Resp. 18 (stating that “[t]he Examiner considered Shihabi (Claim 12) and relied on Sunzeri (Claims 6, 12) and Nouadje (Claims 17 and 18) for teaching these limitations”) (citing Pet. 27, 30, 38, 40; Ex. 1003, 416–19, 251; Ex. 2001 ¶¶ 66, 69–71, Appx. A ¶ 5).

We agree with Patent Owner. Petitioner incorrectly asserts that Patent Owner “attempts to treat Coufal as being relied on for the same reason as Chen.” Reply 7. Rather, Patent Owner contends Coufal is cumulative to Camilleri (*see* Prelim. Resp. 17–20) and substantially similar to Sunzeri, Camilleri, and Nouadje (Prelim. Resp. 18; Sur-reply 5). It is undisputed that Petitioner relies on Coufal to disclose the combination of a zwitterionic buffer and a flow inhibitor (*see* Pet. 21–23)—i.e., the same teachings the Examiner determined were taught by Camilleri during prosecution (*see* Ex. 1003, 418). While Petitioner contends it relies on Coufal as teaching additional limitations recited in dependent claims 6, 12, 17, and 18, the Examiner found that Sunzeri, Camilleri, and Nouadje taught those additional limitations. *See* Ex. 1003, 415–16, 419–20. Accordingly, we agree with Patent Owner that Coufal is cumulative to Camilleri, and Coufal’s teachings are substantially similar to those in Sunzeri, Camilleri, and Nouadje—all of which were previously presented to the Office.

(5) *Landers*

Petitioner contends Landers was not cited by Patent Owner or the Examiner during prosecution. Pet. 18. Petitioner argues that Landers and Coufal are not redundant because “Coufal teaches the combination of ZB

and FI. Landers teaches putrescine (DAB) as a[n] FI added to a borate buffer (Ex. 1026, page 2), and is relied on here as a tertiary reference for details of a specific FI corresponding to patent claims 5 and 6.” *Id.* at 8 (emphasis omitted).

Patent Owner argues Landers meets the first part of the *Advanced Bionics* framework because “Petitioner relies on [] Landers for the very same teachings of Camilleri relied on by the Office during prosecution, e.g. a combination of a ZB and a[n] FI (1,4-diaminobutane in particular)” and is “therefore cumulative of Camilleri.” Prelim. Resp. 20 (citing Pet. 3, 17–18). Patent Owner argues “Petitioner has provided no explanation of how or why Landers is a better reference than Camilleri with respect to a teaching of the aliphatic diamine of claims 4, 5 and 24 or a teaching of 1,4-diaminobutane of claims 19–22, and the specific FI concentrations of claims 8 and 9.” *Id.* at 20–21; Sur-reply 5. Specifically, Patent Owner contends “Camilleri was cited by the Examiner” and “Camilleri teaches specific concentrations of 1,4-diaminobutane, which is an aliphatic diamine.” Prelim. Resp. 20 (citing Ex. 1003, 418; Ex. 2001 ¶¶ 76–78); Sur-reply 5. Patent Owner argues “Landers’s teaching of the use of the aliphatic diamine and specific concentrations of 1,4-diaminobutane is the same as Camilleri.” Prelim. Resp. 20. (citing Ex. 2001 ¶¶ 76–78).

While Petitioner argues that Landers and Coufal are not redundant (Reply 8–9), Patent Owner contends Landers is *cumulative of Camilleri* (not Coufal) (Prelim. Resp. 20–21). It is undisputed that Petitioner relies on Landers as disclosing putrescine (1,4-diaminobutane) as a flow inhibitor (*see* Pet. 49–67)—the same reason the Office relied on Camilleri during prosecution (*see* Ex. 1003, 418). Based on the foregoing, we agree with

Patent Owner that Landers is cumulative of Camilleri, which was previously presented to the Office.

b) *Conclusion as to Advanced Bionics Framework Part (1)*

In view of the foregoing discussion, we conclude that the prior art relied upon in the Petition is the same or substantially the same art that previously was presented to the Office. Accordingly, the first condition of the *Advanced Bionics* framework is satisfied. Because we determine that the same or substantially the same art was before the Examiner during examination, we need not consider *Becton, Dickinson* factor (d) and we turn to the second step of the *Advanced Bionics* framework.

3. *Advanced Bionics Framework Part (2)*

Having determined that the “same or substantially the same prior art” previously was presented to the Office, we now consider whether Petitioner sufficiently demonstrates that the Office materially erred. In assessing the second part of the *Advanced Bionics* framework, we consider *Becton, Dickinson* factors (c), (e), and (f) to determine whether material error has been shown. *Advanced Bionics*, Paper 6 at 10. “An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.* at 6 n.9. However, “[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.” *Id.* at 9. Petitioner bears the burden of showing that the Examiner materially erred. *Id.* at 8.

Petitioner argues that “Camilleri is the only prior art used as a basis for rejection . . . that is applied here albeit for a different [t]eaching.” Reply

9 (*Becton, Dickinson* factor (c)). Petitioner further contends that though Shihabi appeared in an IDS, “both Shihabi and Huang provide at least one ‘missing link’ and neither is cumulative to any prior art applied during examination.” *Id.* at 10 (*Becton, Dickinson* factor (f)). And lastly, Petitioner asserts that “[t]he Examiner erred when identifying Sunzeri as the closest prior art because it did not separate Hb variants at all. . . . Since Shihabi did disclose Hb variant separation by CE using ZB, as pointed out in the ‘686 patent (Ex. 1001, page 16, col. 1, line 65 through col. 2, line 1) the Examiner erred in not identifying Shihabi as the closest prior art.” Reply 10 (*Becton, Dickinson* factor (e)). Furthermore, Petitioner alleges that the Examiner erred in the interpretation of Sunzeri and Nouadje. *Id.* Therefore, Petitioner reasons that the second part of the *Advanced Bionics* framework favors institution. *Id.* at 9–10.

Patent Owner contends *Becton, Dickinson* factor (c) “weighs in favor of the Board exercising its discretion to deny institution because the Examiner considered Shihabi and Camilleri, even though Shihabi was not used expressly for a rejection.” Prelim. Resp. 24. Patent Owner argues that “[t]he Examiner was well aware of Shihabi because Shihabi was described in the ‘686 patent as using a zwitterionic buffer to separate HbA and HbS but that ‘HbC/HbE and HbA2 fractions were not resolved,’” and “Camilleri was expressly relied upon by the Examiner for teaching a zwitterionic buffer and a flow inhibitor (1,4-diaminobutane in particular).” *Id.* at 24–25 (citing Ex. 1001, 1:65–2:1; Ex. 1003, 269, 418; Ex. 2001 ¶ 64, Appx. A ¶ 31); Sur-reply 8–9 (noting also that that “Shihabi was listed on an IDS and acknowledged by the Examiner” and discussed in the ‘686 patent).

Patent Owner also contends that *Becton, Dickinson* factor (e) “weighs in favor of the Board’s exercise of discretion” because “Petitioner has not pointed out how the Examiner erred in the evaluation of Shihabi and Camilleri.” Prelim. Resp. 25. Patent Owner argues “Petitioner provides no explanation of what material error was made by the Examiner with respect to the teachings of either Shihabi or Camilleri that warrants the Board to revisit patentability of the ‘686 patent claims based on Shihabi and Camilleri or the redundant references Coufal or Landers.” *Id.*

Patent Owner contends *Becton, Dickinson* factor (f) “weighs heavily in favor of the Board’s exercise of its discretion” to deny institution because “Shihabi and Camilleri were presented to the Office” and “Coufal and Landers are relied on by the Petitioner for the same teachings as Camilleri.” Prelim. Resp. 26. Patent Owner argues that “Petitioner did not submit any experimental data or scientific explanation in support of its Petition. Therefore, there is no additional evidence or science to consider.” *Id.*; Sur-reply 10. Patent Owner argues further that “although Petitioner provided a declaration in support of its Petition, that declaration is largely repetitive of the asserted references, references described in the ‘686 patent, references cited by the Examiner during prosecution, and otherwise includes conclusory statements regarding motivation and predictability found in the Petition.” Prelim. Resp. 26. Patent Owner argues that because Shihabi was acknowledged by the Examiner on an IDS and described in the ‘686 patent, “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).” Sur-reply 10.

Lastly, Patent Owner explains that “[t]he 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. . . . But, Shihabi (as well as Huang, Coufal, Camilleri and Landers) fails to teach a CE method using ZB with a blood sample [] which was taught by Sunzeri.” Sur-reply 9 (citations and emphasis omitted). Patent Owner argues that “[t]he Office was well aware of Shihabi teaching Hb separation by CE using ZB, but not resolution” and “was well aware that the ‘686 Patent described that its invention was different over Shihabi based on Hb variants being resolved.” *Id.* at 9–10 (emphasis omitted). Patent Owner contends “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” and “[t]he 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.” *Id.*

We agree with Patent Owner. Petitioner must demonstrate that the Examiner erred in the evaluation of the prior art, for example, by showing that the Examiner misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 21. Here, (1) Camilleri was evaluated and used by the Examiner as a basis to reject the then-pending claims during prosecution of the ‘686 patent (Ex. 1003, 412–421); (2) Camilleri was understood by the Examiner to teach “capillary electrophoresis . . . without chemically modifying the capillary using a zwitterionic buffer and additives such as 1,4 diaminobutane” (Ex. 1003, 418); (3) Shihabi was present on an IDS during prosecution of the ‘686 patent (Ex. 1003, 42, 269); and (4) Shihabi was discussed in the Background section of the ‘686 patent (Ex. 1001, 1:65–2:1 (describing

Shihabi as “using a zwitterionic buffer to separate HbA and HbS but that HbC/HbE and HbA2 fractions were not resolved”). In light of the Examiner’s consideration of Camilleri, prominence of Shihabi in the prosecution history, and Petitioner’s failure to identify any specific teaching in Sunzeri or Nouadje that the Examiner misapprehended or overlooked, we find the evidence of record insufficient to establish that the Office erred. Rather, Petitioner merely disagrees with the Examiner’s findings and conclusions, which is insufficient to establish material error. *Advanced Bionics*, Paper 6 at 9.

We acknowledge Petitioner’s argument that the Examiner erred in not identifying Shihabi as the closest prior art, where “Shihabi did disclose Hb variant separation by CE using ZB” and Sunzeri, instead, disclosed capillary electrophoresis, using a zwitterionic buffer, of a blood sample. Reply 10. But here, where “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.” *Advanced Bionics*, Paper 6 at 9.

In view of the foregoing discussion, we conclude that Petitioner fails to sufficiently demonstrate that the Office erred in a manner material to the patentability of challenged claims. Accordingly, the second condition of the *Advanced Bionics* framework is not satisfied.

4. Conclusion

For the foregoing reasons, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

III. CONCLUSION

Accordingly, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

IV. ORDER

After due consideration of the record before us, and for the foregoing reasons, it is:

ORDERED that the Petition is denied as to all challenged claims, and no trial is instituted.

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