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Paper No. 55
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INSTRUMENTATION LABORATORY COMPANY,
Petitioner,

v.

HEMOSONICS LLC,
Patent Owner.

Case IPR2017-00855
Patent 9,410,971 B2

Before JO-ANNE M. KOKOSKI, KRISTINA M. KALAN, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and *37 C.F.R. § 42.73*

I. INTRODUCTION

Instrumentation Laboratory Company ("Petitioner") filed a Petition seeking *inter partes* review of claims 1–20 of U.S. Patent No. 9,410,971 B2 ("the '971 patent," Ex. 1002). Paper 2 ("Pet."). HemoSonics LLC ("Patent Owner") filed a Patent Owner Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). On September 1, 2017, we instituted an *inter partes* review of claims 1, 2, 6, 7, 15, and 16. Paper 14 ("Inst. Dec.") (instituting trial on a subset of the claims and grounds raised in the Petition).

After institution, Petitioner filed a Request for Rehearing (Paper 16), which we denied (Paper 20). Patent Owner filed a Response to the Petition (Paper 21, "PO Response"), and Petitioner filed a Reply (Paper 24, "Reply") to the Patent Owner Response.

On April 26, 2018, we modified our Institution Decision to include review of "all challenged claims and all of the grounds presented in the Petition" in view of *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). Paper 28, 2. Patent Owner chose to forego the opportunity to file a supplemental response, and Petitioner filed a Supplemental Reply addressing the grounds and claims not addressed in its Reply. Paper 29 ("Suppl. Reply").

An oral hearing was held on June 12, 2018, and a supplemental hearing was held on August 14, 2018. A transcript of each hearing has been entered into the record of the proceeding. Paper 46 ("Hearing Tr."); Paper 54 ("Suppl. Hearing Tr.").

On August 28, 2018, the Deputy Chief Administrative Patent Judge determined that there was good cause to extend the one-year period for issuing a Final Written Decision in this proceeding, in accordance with 37

C.F.R. § 42.100(c). Paper 52. On the same day, we issued an order extending the time of pendency in this proceeding by up to six months. Paper 53.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 6–8, 15, and 16 of the '971 patent are unpatentable, and has not shown by a preponderance of the evidence that claims 3–5, 9–14, and 17–20 are unpatentable.

II. BACKGROUND

A. Related Matters

The parties identify the petition for *inter partes* review of related U.S. Patent No. 9,272,280 B2 (IPR2017-00852) as a related matter. Pet. 1; Paper 3, 1. The parties indicate that U.S. Patent Application No. 15/202,059 may be affected by this *inter partes* review (Pet. 1; Paper 3, 1), and Petitioner indicates that U.S. Patent Application No. 15/357,492 may also be affected by this *inter partes* review (Pet. 1).

B. The '971 Patent

The '971 patent, titled "Devices, Systems and Methods for Evaluation of Hemostasis," issued on August 9, 2016. Ex. 1002, at [54], [45]. The '971 patent explains that hemostasis is the physiological control of bleeding, and is "a complex process incorporating the vasculature, platelets, coagulation factors (FI-FXIII), fibrinolytic proteins, and coagulation inhibitors." *Id.* at 1:23–26. The '971 patent states "[d]isruption of hemostasis plays a central role in the onset of myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis and excessive bleeding," and, therefore,

there is a critical need for in vitro diagnostics to "quantify hemostatic dysfunction and direct appropriate treatment." *Id.* at 1:26–31.

Accordingly, the '971 patent is directed to devices, systems, and methods for evaluating hemostasis, specifically "sonorheometric devices for evaluation of hemostasis in a subject by in vitro evaluation of a test sample from the subject." *Id.* at 2:16–19. The '971 patent discloses a device comprising a cartridge having a plurality of test chambers configured to receive a test sample of blood and a reagent or combination of reagents that interact with the blood sample. *Id.* at 2:19–28. The test chambers are also configured to be "interrogated with sound to determine a hemostatic parameter of the test samples" (*id.* at 2:28–31, 2:37–39), and "[s]ound reflected from the blood reagent mixture in the test chamber is received and processed to generate a hemostasis parameter" (*id.* at 2:64–66).

C. Challenged Claims

Petitioner challenges claims 1–20 of the '971 patent. Independent claim 1 is illustrative, and is reproduced below:

> 1. A device for evaluation of hemostasis, comprising:
>
> a plurality of test chambers each configured to receive blood of a test sample, each test chamber comprising a reagent or combination of reagents, wherein each chamber is configured to be interrogated to determine a hemostatic parameter of the blood received therein;
>
> a first chamber of the plurality comprising a first reagent or a first combination of reagents that interact with the blood received therein, wherein the first reagent, or a reagent included in the first combination of reagents, is an activator of coagulation;
>
> a second chamber of the plurality comprising a second combination of reagents that interact with blood of the test sample received therein, the second combination including

> an activator of coagulation and one or both of abciximab and cytochalasin D; and
>
> an interrogation device that measures at least one viscoelastic property of the test sample.

Id. at 18:62–19:13. Independent claim 17 recites limitations similar to those included in claim 1, and further requires the first and second chambers to be configured to be interrogated with ultrasound, a transducer for transmitting and receiving ultrasound, and a processor configured to determine hemostatic parameters from signals transmitted to the transducer. *Id.* at 20:17–41.

D. References

Petitioner relies on the following references:

> Baugh et al., U.S. Patent No. 6,221,672 B1, issued Apr. 24, 2001 ("Baugh," Ex. 1005).
>
> Schubert et al., U.S. Pub. No. 2010/0154520 A1, published June 24, 2010 ("Schubert," Ex. 1006).
>
> Warden et al., U.S. Patent No. 6,016,712, issued Jan. 25, 2000 ("Warden," Ex. 1007).
>
> Lang et al., *Different effects of abciximab and cytochalasin D on clot strength in thrombelastography*, J. THROMB. HAEMOST. 2:147–53 (2004) ("Lang," Ex. 1008).
>
> Viola et al., *A novel ultrasound-based method to evaluate hemostatic function of whole blood*, CLINICAL CHIMICA ACTA. 411 106–13 (2010) ("Viola," Ex. 1012).
>
> Gavin et al., U.S. Patent No. 5,504,011, issued Apr. 2, 1996 ("Gavin," Ex. 1013).
>
> Braun, Sr. et al., U.S. Patent No. 6,613,286 B2, issued Sept. 2, 2003 ("Braun," Ex. 1014)
>
> Ostgaard et al., U.S. Patent No. 5,888,826, issued Mar. 30, 1999 ("Ostgaard," Ex. 1015).

Jina, U.S. Patent No. 6,046,051, issued Apr. 4, 2000 ("Jina," Ex. 1016).

Miller et al., U.S. Pub. No. 2003/0199082 A1, published Oct. 23, 2003 ("Miller," Ex. 1017).

E. Reviewed Grounds

Reference(s)	Statutory Basis	Claim(s) Challenged
Baugh	§ 102	1, 2, 6, 7, 15, 16
Schubert	§ 102	1, 2, 6, 7, 8, 15, 16
Baugh and Viola	§ 103	3, 4
Schubert and Viola	§103	3, 4
Baugh and Gavin	§103	5
Schubert and Gavin	§103	5
Baugh and Braun	§103	8, 12, 13
Schubert and Braun	§103	8, 12, 13
Baugh, Gavin, Braun, Ostgaard, Jina, and Miller	§103	9–11
Schubert, Gavin, Braun, Ostgaard, Jina, and Miller	§103	9–11
Baugh and Warden	§103	14
Schubert and Warden	§103	14
Baugh and Viola	§103	17–20
Warden, Lang, and Viola	§103	17–20

F. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art at the time of the '971 patent would have had "a bachelor's or advanced degree in chemistry, biochemistry, mechanical engineering, or a related discipline, with at least four years of experience in an academic research institution, a hospital research laboratory or medical device company designing or creating devices for evaluating hemostasis." Pet. 6–7; Ex. 1003 ¶¶ 14–16. Patent Owner "agrees that a person with a bachelor's degree in a relevant discipline, e.g., biology, chemical engineering, bioengineering or mechanical engineering related to medical devices, plus four years of work experience, would qualify as a person of ordinary skill in the art." PO Resp. 16. Patent Owner also contends that a person of ordinary skill would have had "experience in and an understanding of multiple areas, including hemostasis, [the] blood coagulation pathway, and bioengineering or mechanical engineering related to medical devices." *Id.* Patent Owner, however, does not agree "that a person with an advanced degree, e.g., a PhD plus four years of work experience, would define a person of ordinary skill. That person is one of extraordinary skill." *Id.*

Based on the agreement between the parties, we find that a person of ordinary skill in the art would have had a bachelor's degree in a relevant discipline, e.g., biology, chemical engineering, bioengineering, or mechanical engineering, related to medical devices, plus four years of work experience in areas relating to hemostasis, the blood coagulation pathway, and medical devices for evaluating hemostasis. Pet. 6–7; PO Resp. 16. This level of ordinary skill is reflected by the prior art of record. *Okajima v.*

Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

III. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction[1] in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016). Absent a special definition for a claim term being set forth in the specification, claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner proposes a specific construction for the following four claim terms under the broadest reasonable interpretation standard: (1) "test chamber configured to receive blood of a test sample," (2) "configured to be interrogated to determine a hemostatic parameter of the blood," (3) "activator of coagulation," and (4) "a first chamber of the plurality comprising a first reagent of a first combination of reagents" and "a second chamber of the plurality comprising a second combination of reagents."

[1] The Office recently changed the claim construction standard applicable to an *inter partes* review. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). The rule changing the claim construction standard, however, does not apply to this proceeding because Petitioner filed its Petition before the effective date of the final rule, i.e., November 13, 2018. *Id.* at 51,340 (rule effective date and applicability date), 51,344 (explaining how the Office will implement the rule).

Pet. 7–9. In the Patent Owner Preliminary Response, Patent Owner proposed constructions for "configured to be interrogated to determine a hemostatic parameter of the blood," "activator of coagulation," "viscoelastic property," and "configured for use with a single test sample." Prelim. Resp. 6–12.

In the Institution Decision, we determined that it was only necessary to construe "configured for use with a single test sample," and that the broadest reasonable interpretation of "configured for use with a single test sample" includes a device that is configured for use with a test sample that is separated and provided to different chambers of the device. Inst. Dec. 6–7. Neither party addressed this construction in any subsequent papers. Now, having considered the full trial record before us, we see no reason to revisit or change this construction. Additionally, after considering the full record developed during the trial, we find that it is not necessary to construe any other terms for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy' . . . .") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Challenges Based on Schubert

i. Schubert (Ex. 1006)

Schubert is directed to a "a cartridge device for a measuring system for measuring viscoelastic characteristics of a sample liquid, in particular a blood sample." Ex. 1006 ¶ 25. Schubert discloses using its cartridge device and measuring system to measure characteristics such as coagulation or platelet function of a sample liquid. *Id.* ¶ 78. Schubert's cartridge device

includes a receiving cavity for receiving the sample liquid and a reagent cavity for storing a reagent that is mixed with the sample liquid. *Id.* ¶¶ 78–79. Schubert discloses an embodiment of its cartridge device having four measurement cavities. *Id.* ¶¶ 81–82. Schubert also teaches that, with regard to blood coagulation,

> there are different reagents available which activate or suppress different parts of the coagulation cascade. Pentapharm GmbH (Munich, Germany) for example amongst others provide tests for intrinsic and extrinsic activation of a blood sample (INTEM or EXTEM respectively), and also a test for extrinsic activation in which the thrombocyte function is suppressed by administration of cytochalasin D (FIBTEM). It is state of the art that it is possible by wise combination of such tests to be able to determine very precisely at which point within the coagulation cascade a problem occurs. . . . It is also possible to combine e.g. an INTEM, an EXTEM and a FIBTEM coagulation test with a platelet aggregometry test within one cartridge.

Id. ¶ 83.

ii. Claims 1, 2, 6–8, 15, and 16

Petitioner argues that Schubert anticipates claims 1, 2, 6–8, 15, and 16 of the ’971 patent. Pet. 15–23. To support its argument, Petitioner provides a claim chart and relies on the Mize Declaration (Ex. 1003) to demonstrate how and where it asserts that Schubert discloses all the limitations of claims 1, 2, 6–8, 15, and 16 of the ’971 patent. *Id.*

As to independent claim 1, Petitioner contends Schubert discloses “a cartridge device for a measuring system for measuring viscoelastic characteristics of a sample liquid, in particular a blood sample.” *Id.* at 16 (citing Ex. 1006, Abstract, ¶¶ 2–7, 25). Petitioner notes that Schubert states that its cartridge device has “at least one measurement cavity,” and discloses embodiments wherein the cartridge device has four measurement cavities

and the sample liquid is shared among the cavities. *Id.* at 16 (citing Ex. 1006 ¶¶ 29, 81–82). Petitioner thus argues that Schubert teaches "[a] device for evaluation of hemostasis comprising: a plurality of test chambers, each configured to receive blood of a test sample," as claim 1 requires. *Id.*; Ex. 1002, 18:62–64.

Claim 1 further recites "each test chamber comprising a reagent or combination of reagents." Ex. 1002, 18:64–65. With regard to this limitation, Petitioner directs us to Schubert's discussion of certain embodiments wherein "at least one reagent cavity is integrally formed . . . with the at least one measurement cavity," as well as Schubert's discussion of reagents that can activate or suppress different parts of the coagulation cascade. Pet. 17 (citing Ex. 1006 ¶¶ 40, 83).

Petitioner notes that Schubert is directed to "provid[ing] a cartridge device for a measuring system for measuring viscoelastic characteristics of a sample liquid, in particular a blood sample," and teaches each cartridge of its device has "<u>at least one probe element arranged in said at least one measurement cavity for performing a test</u> on said sample liquid" to measure a viscoelastic property of the sample liquid. *Id.* at 17–18 (citing Ex. 1006 ¶¶ 11, 29, 88 ("FIG. 7c shows the sample liquid 1, which has been pumped into the measurement cavity 20. The probe pin 3 of the probe element 22 is immersed in the sample liquid 1.")), 20 (citing Ex. 1006 ¶¶ 25, 29, 31). Petitioner contends these disclosures correspond to the limitations in claim 1 requiring "each chamber is configured to be interrogated to determine a hemostatic parameter of the blood received therein" and "an interrogation device that measures at least one viscoelastic property of the test sample." *Id.* at 17–18, 20; Ex. 1002, 18:65–67, 19:11–12.

Having reviewed the cited evidence, and the record as a whole, we find that Petitioner has accurately described the disclosures of Schubert, and, therefore, we agree with, and adopt, Petitioner's contentions that Schubert discloses the aforementioned limitations in claim 1.

Claim 1 further requires "a first chamber of the plurality comprising a first reagent or a first combination of reagents that interact with the blood received therein, wherein the first reagent, or a reagent included in the first combination of reagents, is an activator of coagulation." Ex. 1002, 19:1–5. Petitioner argues that Schubert "provides examples of different reagents that can be included for performing different assays," including reagents "which activate . . . different parts of the coagulation cascade." Pet. 18–19 (citing Ex. 1006 ¶ 83). Petitioner also directs us to Schubert's disclosure of "tests for intrinsic and extrinsic activation of a blood sample (INTEM™ or EXTEM™ respectively), and also a test for extrinsic activation in which the thrombocyte function is suppressed by administration of cytochalasin D (FIBTEM™)." *Id.* (citing Ex. 1006 ¶ 83). Petitioner thus contends that Schubert "includes teachings that a first measurement cavity in a plurality of measurement cavities can include reagents which 'activate different parts of the coagulation cascade' such as intrinsic or extrinsic activators (as would be used in the INTEM™ and EXTEM™ assays, respectively)." *Id.*

Petitioner relies on Schubert's disclosure of "a test for extrinsic activation in which the thrombocyte function is suppressed by administration of cytochalasin D (FIBTEM™)" to demonstrate that Schubert teaches using cytochalasin D in addition to an activator in certain test cells. *Id.* at 19–20 (asserting "a second measurement cavity can include an extrinsic activator in combination with cytochalasin D reagents (as would be used in the

FIBTEM™ assay")) (citing Ex. 1006 ¶ 83). Petitioner therefore argues that Schubert discloses the claim 1 requirement of having "a second chamber . . . comprising a second combination of reagents that interact with blood of the test sample received therein, the combination including an activator of coagulation and one or both of abciximab and cytochalasin D." *Id.* (citing Ex. 1006 ¶ 83); Ex. 1002, 19:6–10.

In the Institution Decision, based on arguments presented in Patent Owner's Preliminary Response, we determined that Petitioner failed to demonstrate sufficiently where Schubert discloses the use of activators of coagulation as a reagent. Specifically, we stated:

> Although Schubert does disclose that activators of coagulation exist and characterizes the INTEM, EXTEM, and FIBTEM tests as tests for intrinsic and extrinsic activation, as Patent Owner points out, Schubert never explicitly states that these tests use, as a reagent, activators of coagulation. *See* Ex. 1006 ¶ 83.
>
> Petitioner asserts that intrinsic or extrinsic activators would be used in the INTEM, EXTEM and FIBTEM assays, but does not provide in the Petition any citation to support those assertions. Pet. 19–20.

Inst. Dec. 22.

We, therefore, determined that the record at that time failed to establish a reasonable likelihood that Petitioner would prevail on its assertion that Schubert anticipates claim 1 of the '971 patent, and declined to include this ground in the *inter partes* review proceeding. *Id.* at 23. We reached the same conclusion regarding dependent claims 2, 6–8, 15, and 16, based on their dependency from claim 1. Because the question of whether Schubert anticipates claims 1, 2, 6–8, 15, and 16 was not part of the trial at

the time Patent Owner's Response was due, Patent Owner did not address this challenge in its Patent Owner Response filed December 1, 2017.

On April 26, 2018, after the Supreme Court's decision in *SAS*, we amended our Institution Decision to include this ground. Paper 28. Subsequently, we offered Patent Owner an opportunity to file a supplemental Patent Owner Response to address Petitioner's grounds based on Schubert, but Patent Owner indicated it did not wish to do so. Ex. 1069, 10:6–12. Petitioner filed a Supplemental Reply addressing our preliminary determinations in the Institution Decision regarding Schubert. In its Supplemental Reply, Petitioner argues:

> The Petition quotes and cites to paragraph 0083 of [Schubert] where consecutive sentences state that (i) "there are different reagents available which activate or suppress different parts of the coagulation cascade" and (ii) Pentaphar[m] GmbH provides tests "for intrinsic and extrinsic activation of a blood sample (INTEM™ or EXTEM™ respectively), and also "for extrinsic activation in which the thrombocyte function is suppressed . . . [cytochalasin D] (FIBTEM™)."

Suppl. Reply 3. Petitioner again contends that a person of ordinary skill in the art would have understood these sentences in Schubert to teach that INTEM and EXTEM include reagents that activate different parts of the coagulation cascade. *Id.* Petitioner further argues that Patent Owner did not contradict Dr. Mize's testimony that INTEM, EXTEM, and FIBTEM are assays with known meanings to a person of ordinary skill in the art, and that the EXTEM assay includes Tissue Factor, the INTEM assay includes ellagic acid plus phospholipid, and the FIBTEM assay incudes Tissue Factor and cytochalasin D. *Id.* at 4–5 (citing Ex. 1003 ¶¶ 19–20, 49, 61).

On July 11, 2018, we granted Petitioner's Motion to file Supplemental Information, allowing three exhibits into the record. Paper 44. These

exhibits include U.S. Patent No. 9,915,671 B2 ("the '671 patent," Ex. 1072) and statements by Patent Owner and Patent Owner's Declarant, Dr. Diamond, regarding a particular portion of the '671 patent (Exs. 1070 and 1071, respectively). These statements appear in a petition (Ex. 1070) and supporting declaration (Ex. 1071) filed in connection with IPR2018-00950 challenging claims of the '671 patent.

The '671 patent is a continuation of Schubert and, like Schubert, is directed to "a cartridge device for a measuring system for measuring viscoelastic characteristics of a sample liquid." Ex. 1072, 1:38–40; *see also id*. at [63] (claiming priority through continuation applications back to Application No. 12/640,374, which is the application number listed on Schubert). The paragraph spanning lines 18 through 55 of column 9 of the '671 patent is identical to paragraph 83 of Schubert. *Compare* Ex. 1072, 9:18–55, *with* Ex. 1006 ¶ 83. As discussed above, this paragraph includes the statement that "there are different reagents available which activate or suppress different parts of the coagulation cascade," and discusses the INTEM, EXTEM, and FIBTEM tests. Ex. 1067, 9:18–55; Ex. 1006 ¶ 83.

In IPR2018-00950, referring to the '671 patent, Patent Owner states "[t]he patent discloses incorporating several existing blood coagulation reagent compositions into the cartridge. [Ex. 1072], 9:18-55. These reagents include compounds that activate blood coagulation through the intrinsic pathway (INTEM) and extrinsic pathway (EXTEM), and compounds that suppress thrombocyte (a.k.a. platelet) function (FIBTEM). *Id.*, 9:18-55." Ex. 1070, 9.[2] Dr. Diamond states "[t]issue factor is an

[2] For Exhibits 1070 and 1071, we refer to the page numbers printed at the bottom, center of each page.

activator of the extrinsic coagulation pathway," and cites to column 9, lines 18 through 25 of the '671 patent to support this statement. Ex. 1071, 50–51. Dr. Diamond also states that the '671 patent "acknowledg[es] that EXTEM is an extrinsic activator of coagulation" (*id.* at 51 (citing Ex. 1072, 9:18–25)) and "acknowledg[es] INTEM as an intrinsic activator of coagulation assay" (*id.* at 56 (citing Ex. 1072, 9:20–25)).

The statements by Patent Owner and Dr. Diamond are consistent with those made by Petitioner and Dr. Mize, namely, that the language in paragraph 83 of Schubert (which is identical to the language in column 9, lines 18 through 55 of the '671 patent) discloses the use of coagulation activators among the reagents in the chambers of Schubert's device. For example, both Patent Owner and Petitioner state that EXTEM and FIBTEM tests, disclosed in paragraph 83 of Schubert, include compounds that activate blood coagulation. Pet. 18; Ex. 1070, 9. Similarly, both Dr. Mize and Dr. Diamond state that tissue factor is an activator of the extrinsic coagulation pathway, and conclude that EXTEM includes an extrinsic activator of coagulation. Ex. 1071, 50–51; Ex. 1003 ¶ 39, n. xxiv (p. 117) ("The EXTEM™ assay includes an extrinsic activator (Tissue Factor) as a reagent . . . ."). Thus, although Schubert may not expressly state that EXTEM, INTEM, and FIBTEM include coagulation activators, it is undisputed that a person of ordinary skill in the art would have understood that these tests include coagulation activators. *In re Preda*, 401 F.2d 825, 826 (CCPA 1968) ("[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.").

In view of the foregoing, after considering the full record, we agree with Petitioner that Schubert, through its discussion of EXTEM and FIBTEM tests in paragraph 83, discloses the use of activators of coagulation as a reagent in first and second chambers. As noted above, Patent Owner did not address Petitioner's arguments regarding Schubert in its Patent Owner Response, and chose not to file a supplemental response. We, therefore, find that Petitioner has demonstrated, by a preponderance of evidence, that Schubert discloses every limitation of claim 1.

Petitioner directs us to its claim chart that identifies portions of Schubert that disclose the limitations recited in dependent claims 2, 6–8, 15, and 16. Patent Owner does not dispute that Schubert discloses the limitations recited in claims 2, 6–8, 15, and 16. Based on our review of the totality of the record after trial, we agree with, and adopt, Petitioner's arguments and evidence that Schubert discloses the limitations of claims 2, 6–8, 15, and 16.

Thus, we determine that the preponderance of evidence supports a finding that Petitioner has demonstrated that Schubert anticipates claims 1, 2, 6–8, 15, and 16.

iii. Claims 3 and 4

Petitioner contends that the subject matter of claims 3 and 4 would have been obvious in view of the combined teachings of Schubert and Viola. Pet. 25.

1. Viola (Ex. 1012)

Viola is directed to "an ultrasound-based technology, named sonorheometry, which uses the phenomenon of acoustic radiation force to make repeated viscoelastic measurements of a whole blood sample."

Ex. 1012, 107. Viola explains that sonorheometry is performed using acoustic radiation force to generate small and localized displacements in a blood sample, and determines viscoelastic properties by processing returned echoes from the sample. *Id.* According to Viola, sonorheometry has been implemented in a prototype bench-top instrument, and "can measure the function of plasma coagulation factors (including fibrinogen), platelets, and fibrinolytic factors from a small sample of whole blood." *Id.*

2. Analysis

Claim 3 depends from claim 1, and requires the interrogation device of claim 1 to be "configured to use acoustic radiation force." Ex. 1002, 19:24–25. Claim 4 also depends from claim 1, and requires the interrogation device to be "configured to transmit sound into one or more test chamber." *Id.* at 19:26–27.

In the Petition, Petitioner states that Schubert in combination with Viola "renders obvious IPR claims 3 and 4, by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 107-112." Pet. 25. Petitioner provides a claim chart describing where Viola discloses the limitations in claims 3 and 4. *Id.* at 24–25. According to Petitioner, this claim chart shows how the prior art "discloses and enables each and every limitation of claims 3 and 4 of the '971 patent." *Id.* at 25.

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the

elements in the way the claimed new invention does." *Id.* Furthermore, a party seeking to demonstrate that a patent would have been obvious must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (quoting *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)).

Furthermore, it is Petitioner's burden to establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e). "Failure to prove the matter as required by the applicable standards means that the party with the burden of persuasion loses on that point—thus, if the fact trier of the issue is left uncertain, the party with the burden loses." *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008).

In the Petition, Petitioner provides a claim chart and argues that the combined teachings of Schubert and Viola disclose or suggest each and every limitation of claims 3 and 4. Pet. 24–25. Petitioner, however, does not identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in the claims of the '971 patent. Nor does Petitioner address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. To the extent Petitioner contends its statement that the claim chart shows how Viola, in combination with Schubert, "enables each and every limitation of claims 3 and 4" (*id.* at 24) addresses an expectation of

success, we note that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Schubert and Viola disclose and enable each and every element of the claims. Pet. 25 (citing Ex. 1003 ¶¶ 107–112). As noted in our Institution Decision, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14. Arguments and information that are not presented and developed in the Petition, but instead are incorporated by reference, are not entitled to consideration, as it is improper to incorporate by reference arguments from one document into another document. 37 C.F.R. § 42.6(a)(3); *see also DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999) (Incorporation "by reference amounts to a self-help increase in the length of the [] brief[,]" and "is a pointless imposition on the court's time. A brief must make all the arguments accessible to the judges, rather than ask them to play archeologist with the record."); *Cisco Sys., Inc. v. C-Cation Techs., LLC*, Case IPR2014-00454, slip op. at 7–10 (PTAB August 29, 2014) (Paper 12) (informative) (discussing incorporation by reference). Accordingly, we decline to consider information that Petitioner does not discuss sufficiently in the Petition, but instead simply incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence, that claims 3 and 4 are unpatentable as obvious in view of Schubert and Viola.

Petitioner contends that our rule against incorporation by reference is meant to streamline the IPR process, and argues that "[a]lthough *SAS* did not invalidate specific regulations that streamlined the IPR process, it overturned a central practice of that streamlining, in favor of fulsome review of patents for improper issue." Suppl. Reply. 1. Petitioner further contends that "*SAS's* deference to the petitioner over the Director should be applied to the statutory . . . standard" in 35 U.S.C. § 312(a), which states that the petition must identify the evidence that supports the ground for the challenge to each claim. *Id.* at 2 (internal citations and footnote omitted). Petitioner argues that "[t]he statute does not require the petition to repeat the evidence." *Id.* Petitioner contends we should consider certain paragraphs in Dr. Mize's declaration simply because they are cited in the Petition and are part of the record.

We disagree. The Supreme Court's decision in *SAS* did not change the language or meaning of 35 U.S.C. § 312. According to 35 U.S.C. § 312(a), which lists the requirements of petitions, "[a] petition . . . may be considered only if . . . (3) the petition identifies, in writing and with particularity . . . the evidence that supports the grounds for the challenge to each claim," including "affidavits or declarations of supporting evidence and opinions." Section 312 further states that a petition may be considered only if "(4) the petition provides such other information as the Director may require by regulation." Pursuant to 37 C.F.R. § 42.22, a petition must include "a detailed explanation of the significance of the evidence"

supporting the grounds for each challenge. Taken together, 35 U.S.C. § 312 and 37 C.F.R. § 42.22 require that the petition itself identify with particularity, and explain the significance of, the evidence that supports the grounds for the challenge to each claim, and also identify affidavits or declarations of supporting evidence. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularly . . . the evidence that supports the grounds for the challenge to each claim")).

Here, Petitioner repeatedly makes conclusory statements regarding unpatentability, and cites to certain paragraphs in the Mize Declaration that allegedly support Petitioner's conclusion. Petitioner, however, provides no substantive discussion of the contents of the cited paragraphs in the Mize Declaration. At best, Petitioner's citations may satisfy the requirement in 35 U.S.C. § 312(a)(3) that the petition identifies the evidence that supports the grounds for the challenge to each claim. We are not persuaded, however, that listing a paragraph number in a declaration, without more, satisfies the requirement in 37 C.F.R. § 42.22(a)(2) that the petition explain the significance of this evidence in detail.

Additionally, incorporating evidence into a petition by reference to another document is prohibited under 37 C.F.R. § 42.6(a)(3). One purpose of the prohibition against incorporation by reference is to eliminate abuses that arise from incorporation, such as circumventing the page limits or word count limits imposed on petitions for *inter partes* review. *See* Rules of Practice for Trials Before The Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48,612, 48,617 (Aug. 14, 2012). As affidavits and declarations are not subject to any

page number or word count limits, Petitioner's position increases the potential for abuse of the review process by requiring nothing more than a citation to multiple paragraphs of a declaration without discussing the substance of those paragraphs in the petition itself.

For all of the foregoing reasons, we are not persuaded by Petitioner's contention that we should consider certain paragraphs in Dr. Mize's declaration merely because they are cited in the Petition and are part of the record.

Nevertheless, for the reasons discussed below, the outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner discusses the content of the paragraphs of the Mize Declaration cited in the Petition. Suppl. Reply 6–8 (stating that "the Petition cites to limited and specific paragraphs of the Mize declaration as evidentiary support relating to factual findings for how a [person of ordinary skill in the art] would understand the references in conjunction with one another"). Specifically, Petitioner contends that "[p]aragraphs 111 and 140 of the Mize Declaration provide expert testimony that it would have been obvious [for a person of ordinary skill in the art] to combine the teachings of [Viola] relating to acoustic interrogation with the teachings of" Schubert. *Id.* at 6. In paragraphs 111 and 140, Dr. Mize testifies that (1) Schubert contemplates modifications to the interrogation techniques described therein, and (2) Viola provides a measurement of a response curve over time that is comparable to the data provided by the mechanical type interrogation techniques described in Schubert and teaches that acoustic interrogation techniques are an improvement over mechanical methods. Ex. 1003 ¶¶ 111,

140. Petitioner asserts that Dr. Mize "concludes that a [person of ordinary skill in the art] would therefore be motivated to replace the mechanical interrogation methods of . . . [Schubert] with acoustic interrogation." Suppl. Reply 7.

After reviewing the specific paragraphs of the Mize Declaration cited in the Petition, and Petitioner's accompanying arguments in the Supplemental Reply, it is evident that Dr. Mize and Petitioner focus only on why a person would have combined the teachings of Viola and Schubert. Suppl. Reply 6–8; Ex. 1003 ¶¶ 111, 140. Petitioner does not direct us to evidence sufficient to show, or even any meaningful discussion of, whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. *Kinetic Concepts*, 688 F.3d at 1360. Thus, even considering substantively the cited paragraphs in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record lacks articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Kahn*, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence, that claims 3 and 4 are unpatentable as obvious in view of Schubert and Viola.

iv. Claim 5

Petitioner contends that the subject matter of claim 5 would have been obvious in view of the combined teachings of Schubert and Gavin. Pet. 26–27.

1. Gavin (Ex. 1013)

Gavin is directed to a portable device for performing coagulation tests on a patient's blood. Ex. 1013, Abstract. According to Gavin, blood is

supplied to a disposable cuvette that is placed within the device, and the blood is drawn into multiple conduits within the cuvette. *Id.* Each conduit contains a dried or lyophilized activation reagent that is rehydrated by the blood. *Id.* The blood moves across a restricted region until a predetermined amount of coagulation occurs, and the coagulation time is monitored. *Id.*

2. Analysis

Claim 5 depends from claim 1, and further requires that the "first reagent and the second combination of reagents are lyophilized prior to interacting with the test samples." Ex. 1002, 19:28–30.

In the Petition, Petitioner states that Schubert in combination with Gavin "renders obvious IPR claim 5, by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 113-117." Pet. 26–27. Petitioner also provides a claim chart describing where Gavin allegedly discloses the limitations in claim 5. *Id.* According to Petitioner, this claim chart further shows how the prior art "discloses and enables each and every limitation of claim 5 of the '971 patent." *Id.*

As with claims 3 and 4, Petitioner fails to identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in claim 5 of the '971 patent. Nor does Petitioner address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. To the extent Petitioner contends its statement that the claim chart shows how Gavin, in combination with Schubert, "enables each and every limitation of claim 5" addresses an expectation of success, we note that "rejections on obviousness

grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Kahn*, 441 F.3d at 988.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Schubert and Gavin disclose and enable every element of the claims. Pet. 26–27 (citing Ex. 1003 ¶¶ 113–117). As noted in our Institution Decision, and discussed above, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute improper attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons discussed above, we decline to consider information that Petitioner incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence, that claim 5 is unpatentable as obvious in view of Schubert and Gavin.

The outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner discusses the content of one paragraph of the Mize Declaration cited in the Petition. Suppl. Reply 8. Specifically, Petitioner contends that paragraph 116 of the Mize Declaration "provides expert testimony that 'the relevant teachings in [Gavin] provide improved reagent storage within a test channel/chamber.'" *Id.* In paragraph 116, Dr. Mize indeed states that Gavin teaches improved reagent storage within a test channel/chamber. Ex. 1003 ¶ 116. Petitioner thus argues that a person of ordinary skill in the art would have been motivated to combine the

teachings of Gavin and Schubert to "include improved reagent storage within the context of the test chambers in . . . [Schubert]." *Id.*

After reviewing the paragraph of the Mize Declaration cited in the Petition, and Petitioner's accompanying arguments in the Supplemental Reply, it is evident that Dr. Mize and Petitioner focus only on why a person would have combined the references. Petitioner does not direct us to evidence sufficient to show, or even any meaningful discussion of, whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. *Kinetic Concepts*, 688 F.3d at 1360. Thus, even considering substantively the cited paragraphs in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Kahn*, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence, that claim 5 is unpatentable as obvious in view of Schubert and Gavin.

v. Claims 8, 12, and 13

Petitioner contends that the subject matter of claims 8, 12, and 13 would have been obvious in view of the combined teachings of Schubert and Braun. Pet. 29.

1. Braun (Ex. 1014)

Braun discloses an apparatus for testing liquid/reagent mixtures. Ex. 1014, at [54]. Braun's apparatus comprises a cartridge having a fluid receiving/dispensing reservoir, one or more fluid-receiving chambers, and one or more conduits that permit fluid communication between the reservoir and chambers. *Id.* at [57]. Braun teaches that the one or more conduits may

have a constricted passage to increase the velocity of fluid flow through the constricted passage, which provides for more thorough mixing of a liquid sample and a reagent. *Id.* Braun also describes introducing fluids into the fluid-receiving chambers in a substantially tangential flow pattern, i.e., being directed toward the periphery of the chamber instead of being directed toward the center of the chamber. *Id.* at 4:60–5:2. According to Braun, these aforementioned features help a test apparatus produce more accurate test results. *Id.* at 5:49–51.

2. Analysis

Claim 8 depends, indirectly, from claim 1, and requires "a fluid pathway having an inlet for receiving a test sample, wherein the fluid pathway is in communication with at least one test chamber to deliver the test sample, or a portion thereof, to one or more of the test chambers." Ex. 1002, 19:36–40. Claim 12 depends from claim 8, and requires "the fluid pathway further comprises a channel in communication with a least one test chamber, and wherein sample delivered from the channel into the test chamber results in mixing of at least a portion of the sample and the reagent within the test chamber." *Id.* at 19:49–53. Claim 13 depends from claim 12 and further requires the fluid pathway comprises "a channel that opens into at least one test chamber on the side and at a tangent to the test chamber." *Id.* at 20:1–3.

In the Petition, Petitioner states that Schubert in combination with Braun "renders obvious IPR claims 8, 12, and 13 by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003,

¶¶ 118-123." Pet. 29.[3] Petitioner provides a claim chart describing where Braun discloses the limitations in claims 12 and 13. *Id.* at 27–28. According to Petitioner, this claim chart shows how the prior art "discloses and enables each and every limitation of claims . . . 12[] and 13 of the '971 patent." *Id.* at 29.

With regard to claim 12, Petitioner contends Braun "teaches three features which offer improved fluid flow and mixing over a previous iteration of the cartridge/device." *Id.* at 28. These improvements "relate to (i) a constricted passageway into the receiving chamber(s), (ii) tangential flow into the receiving chamber(s) and (iii) a fluid exit conduit." *Id.* (citing Ex. 1014, 4:16–5:48). In view of this, Petitioner asserts that a person of ordinary skill in the art "would have been motivated to implement fluid flow into the receiving chambers which promotes mixing of a sample and a reagent." *Id.*

Here, unlike in its analysis of claims 3–5, Petitioner directs us to an argument in the Petition itself that a person of ordinary skill in the art would have had a reason to combine the teachings of Schubert and Braun. *Id.*; Suppl. Reply 9. It is evident, however, from Petitioner's argument and from Braun itself, that Braun's purported improvements in fluid flow and mixing are relative to a specific prior art device. Pet. 28; Ex. 1014, 4:16–5:48 (reciting physical differences between Braun's device and the device

[3] Because we find Schubert anticipates claim 8, we decline to address Petitioner's argument that claim 8 is unpatentable as obvious in view of Schubert and Braun. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("Though it is never necessary to so hold, a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness.'") (internal citation omitted).

disclosed in U.S. Patent No. 5,269,209 ("the '209 patent")). For example, Braun states that "applicants have found that their use has a very significant effect on the reliability of test results produced by use of the cartridges of this patent disclosure vis-a-vis the results produced by the cartridges described in the '209 patent." Ex. 1014, 4:11–15; *see also id.* at 4:53–57 (stating that "the increase in liquid velocity in the restricted passage serves to mix the reagent with the liquid much more thoroughly than the system taught in the '209 patent").

Although Braun's teachings appear to be directed to making specific physical changes to one particular prior art test cartridge/device, in the Petition, Petitioner concludes that a person of ordinary skill in the art would have been motivated to apply these changes to any test cartridge/device, including the ones disclosed in Schubert. Petitioner, however, fails to direct us to evidence or argument addressing whether a person of ordinary skill in the art would have considered these improvements applicable to Schubert's cartridges/devices.

For example, Schubert discloses that the reactant is stored in reagent cavity 19', which is separated from measurement cavity 20' by outlet duct 15'. Ex. 1006 ¶ 81 and Fig. 6 (both cited by Petitioner in support of its argument that Schubert anticipates claim 8 (*see* Pet. 22)). Schubert further discloses that the sample mixes with the reagent "during transport" to the measuring chamber. Ex. 1006 ¶ 81. By way of contrast, the portion of Braun Petitioner cites states that "[t]he reagent can be mixed with the liquid *before said liquid enters the cartridge*, or the reagent be positioned *in the conduit such* that it comes into contact with the incoming liquid before the resulting liquid/reagent mixture enters the constricted passage." Ex. 1014,

4:47–51 (emphasis added). Neither of these examples appears to describe the configuration of Schubert, wherein the reagent is included in a separate chamber in the device itself, not a duct or conduit, and mixing occurs during transport to the measuring chamber. In view of this, we are not persuaded by Petitioner's conclusory statement, based on Braun alone, that a person of ordinary skill in the art "would have been motivated [to] implement fluid flow into the receiving chambers which promotes mixing of a sample and reagent." *Kahn*, 441 F.3d at 998.

Furthermore, Petitioner again fails to address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. *Kinetic Concepts*, 688 F.3d at 1360. For example, claim 12 requires that "sample delivered from the channel into the test chamber results in mixing of at least a portion of the sample and the reagent *within the test chamber*." Ex. 1002, 19:51–53 (emphasis added). Petitioner does not address whether a person of ordinary skill in the art would have had a reasonable likelihood of successfully arriving at a device wherein at least a portion of the sample and reagent are mixed within the test chamber itself. This is especially true considering the aforementioned differences between Schubert and Braun. To the extent Petitioner contends its statement that the claim chart shows how Braun, in combination with Schubert, "enables each and every limitation of claims . . . 12[] and 13" addresses an expectation of success, we note that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Kahn*, 441 F.3d at 988.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Schubert and Braun disclose and enable each and every element of the claims. As noted in our Institution Decision, and discussed above, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons discussed above, we decline to consider information that Petitioner incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence that claims 12 and 13 are unpatentable as obvious in view of Schubert and Braun.

The outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner directs us to paragraph 122 of the Mize Declaration, noting that Dr. Mize explains that Braun "is intended to be a general construct that can be adapted for any number of different types of tests/assays that involve mixing a sample with a reagent in a receiving chamber." Suppl. Reply 8–9; Ex. 1003 ¶ 122. Petitioner and Dr. Mize cite to column 5, line 49 through column 6, line 4 of Braun in support of the assertion that a person of ordinary skill in the art would have been motivated to apply the teachings in Braun to improve mixing and fluid flow in Schubert. Suppl. Reply 9; Ex. 1003 ¶ 122.

The cited portion of Braun states that "each of the above noted fluid flow features, in its own right, will help a given test apparatus produce more

accurate test results," and that "improvements appear to be the case, regardless of the nature of the liquid being tested, regardless of the nature of the reagent mixed with the liquid in the test cartridges of this patent disclosure and regardless of the type test performed on a liquid/reagent mixture in the fluid-receiving chamber." Ex. 1014, 5:49–66. It is in this context that Braun concludes that its cartridges "can be used in virtually any test wherein changes in a property of a liquid/reagent mixture is to be measured." *Id.* at 5:66–6:1. The next sentence of Braun, not cited by Dr. Mize or Petitioner, goes on to explain that even though a biological fluid (i.e., blood) is used as the primary example in Braun, other fluids can also be tested using Braun's cartridge features. *Id.* at 6:4–12.

The cited language in Braun thus appears to indicate that the "improvements" achieved by Braun's cartridges are not limited to a particular test *sample* (i.e., blood), but rather that Braun's cartridges will provide similar results when used with other biological (e.g., urine) and non-biological (e.g., industrial chemical compositions) fluids. We are not persuaded that this language supports Petitioner's "general construct" argument, namely that Braun's teachings lead to improvements when implemented in any existing *cartridge* used for tests that involve mixing a sample with a reagent. Further, Dr. Mize does not explain adequately why a person of ordinary skill in the art would have had a reasonable expectation of successfully arriving at the claimed invention, based on the combined teachings of Braun and Schubert. *Kinetic Concepts*, 688 F.3d at 1360. In particular, Dr. Mize never presents evidence sufficient to demonstrate that, in view of the combined teachings of Braun and Schubert, a person of ordinary skill in the art would have had a reasonable expectation of

achieving a device wherein the sample and reagent are mixed within the test chamber itself.

Thus, even considering substantively the cited paragraph in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Kahn*, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence, that claim 12 is unpatentable as obvious in view of Schubert and Braun. Because claim 13 depends from claim 12, we reach the same conclusion regarding claim 13.

vi. Claims 9–11

Petitioner contends that the subject matter of claims 9–11 would have been obvious in view of the combined teachings of Schubert, Braun, Ostgaard, Jina, and Miller. Pet. 31–32.

1. Ostgaard (Ex. 1015)

Ostgaard discloses "cartridges for use in the assay of a liquid sample, wherein the assay includes at least one step during which the sample to be assayed and one or more components of the assay system are kept separated." Ex. 1015, 2:66–3:2. Ostgaard describes one embodiment wherein a test cartridge comprises a holding chamber and test chamber separated by a pierceable member, a partition member disposed in the test chamber containing at least one reagent, and a transfer member that can be moved towards and pierce the pierceable member. *Id.* at 3:10–27. Upon moving the transfer member, "a negative pressure is created in the test chamber, liquid sample moves through the transfer member, into the test chamber and through the opening in the partition member." *Id.* at 3:27–33.

Ostgaard also states that its cartridge can be adapted for use in an assay system that involves an incubation step, which includes heating the test sample and other components of the assay system to a predetermined temperature. *Id.* at 3:34–42.

2. Jina (Ex. 1016)

Jina discloses a "single-use electronic device and test card for use therein which performs a coagulation or lysis assay of a blood sample." Ex. 1016, at [57]. Jina's device includes "means for measuring the viscosity of the sample and generating an electrical signal which correlates to a curve of the coagulation/lysis assay." *Id.*

3. Miller (Ex. 1017)

Miller discloses thermally conductive biological assay trays made from a polymer composition comprising a base polymer matrix and a thermally conductive material. Ex. 1017, at [57].

4. Analysis

Claim 9 depends from claim 8 and requires that "the housing defines at least a portion of the fluid pathway, and wherein at least a portion of the housing is thermally conductive." Ex. 1002, 19:41–43. Claim 10 depends from claim 9 and requires "the thermally conductive portion of the housing defines at least a portion of the fluid pathway." *Id.* at 19:44–46. Claim 11 depends from claim 10 and requires "the thermally conductive portion comprises a thermally conductive polymer." *Id.* at 19:47–48.

Petitioner contends that Schubert, in combination with Ostgaard, Jina, and Miller, "renders obvious IPR claims 9, 10, and 11, by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in

Ex. 1003, ¶¶ 124-129." Pet. 31–32. Petitioner also provides a claim chart showing how these references purportedly disclose the limitations in claims 9–11. According to Petitioner, this claim chart further evidences how the prior art references "disclose and enable each and every limitation of claims 9, 10, and 11 of the '971 Patent." *Id.* at 32.

As stated above, claim 9 requires the housing of the assay device (a limitation in claim 6) to define a portion of the fluid pathway (a limitation in claim 8). In its claim chart, however, Petitioner does not clearly articulate how or where the prior art references disclose or suggest a housing that defines a portion of the fluid pathway. For example, according to Petitioner, Ostgaard teaches the use of housings and thermal transfer, as well as making the bottom surface of a sample holding chamber from a conductive material. Pet. 30 (citing Ex. 1015, 5:41–44, 7:38–44). We are not persuaded that these disclosures demonstrate Ostgaard teaches a housing defining a portion of the required fluid pathway. In particular, it is not clear from Ostgaard whether the "sample holding chamber" referred to in Petitioner's claim chart is part of the housing or the fluid pathway.

Nor are we persuaded that Petitioner's citations to Jina and Miller, as evidence that using thermally conductive materials in biological assay devices was well known, demonstrates that these references disclose a housing that defines at least a portion of the fluid pathway, as claim 9 requires. Furthermore, although not expressly cited with regard to claim 9, Petitioner directs us to Schubert paragraph 81 and Figure 6 as evidence of a fluid pathway. Neither paragraph 81 nor Figure 6, however, demonstrates that the fluid pathway is part of the housing. We, therefore, find that Petitioner has failed to demonstrate by a preponderance of evidence that

Schubert, Ostgaard, Jina, and Miller disclose every limitation of claim 9. Because claims 10 and 11 depend from claim 9, we reach the same conclusion for these claims.

Additionally, Petitioner fails to address sufficiently whether one of skill in the art would have had a reasonable expectation of success in arriving at the claimed invention in view of the combined disclosures of the cited prior art references. *Kinetic Concepts*, 688 F.3d at 1360. To the extent Petitioner contends its statement that the claim chart shows how Schubert, in combination with Ostgaard, Jina, and Miller, "enables each and every limitation of claims 9, 10, and 11" addresses likelihood of success, we note that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Kahn*, 441 F.3d at 988.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that the combined teachings of Schubert, Ostgaard, Jina, and Miller disclose and enable each element of the claims. As noted in our Institution Decision, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). As discussed above, we decline to consider information that Petitioner simply incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence, that claims 9–11 are unpatentable as obvious in view of Schubert, Ostgaard, Jina, and Miller.

The outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner directs us to paragraphs 127 and 128 of the Mize Declaration, noting that Dr. Mize explains that Ostgaard and Jina teach "including a thermally conductive material to effect heat transfer with respect to a test card/cartridge and that motivation exists for maintaining a temperature at 37 degrees Celsius 'so that the test results can readily [be] compared to other standardized test results without interpolation.'" Suppl. Reply 10. The Mize Declaration, which appears to be directed to a motivation to combine references, does not cure the deficiencies noted above. In particular, Dr. Mize does not address with specificity how or where the prior art discloses or suggests all limitations of claim 9, and does not explain adequately why a person of ordinary skill in the art would have had a reasonable expectation of successfully arriving at the claimed invention.

Thus, even considering substantively the cited paragraphs in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Kahn*, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence that claims 9–11 are unpatentable as obvious in view of Schubert, Ostgaard, Jina, and Miller.

vii. Claim 14

Petitioner contends that the subject matter of claim 14 would have been obvious in view of the combined teachings of Schubert and Warden. Pet. 33.

1. Warden (Ex. 1007)

Warden discloses "a device for receiving and processing a sample" in the field of diagnostic assays. Ex. 1007, 6:20–21, 1:6–7. Warden teaches that its device may include a sample receiving element to allow for the introduction of a sample into the device, a first chamber in fluid communication with the sample receiving element, one or more second chambers in fluid communication with the first chamber, and ports that provide for venting the device and "establishing communication between the device and means for moving the sample from the sample receiving element to the first chamber and for moving the sample from the first member to the one or more second members." *Id.* at 6:21–34. According to Warden, the second chambers are adapted for processing the sample. *Id.* at 6:36–38. As one example, Warden teaches that the second chamber can contain various reagents for conducting an assay, which are mixed with the sample in the second chamber. *Id.* at 11:57–61.

2. Analysis

Claim 14 depends from claim 7 and requires "one or more test chamber of the plurality of test chambers further comprises a magnetic stirring structure." Ex. 1002, 20:4–6.

Petitioner contends that Schubert in combination with Warden "renders obvious IPR claim 14, by disclosing each and every element of the claim, arranged as claimed in a manner enabling to a [person of ordinary

skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 130-134." Pet. 33. Petitioner also provides a claim chart showing how these references purportedly disclose the limitations in claim 14. *Id.* at 32–33. According to Petitioner, this claim chart further evidences how the prior art references "disclose[] and enable[] each and every limitation of claim 14." *Id.* at 33.

We are not persuaded by Petitioner's arguments. Petitioner fails to identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in claim 14 of the '971 patent. Nor does Petitioner address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable likelihood of success in arriving at the claimed limitation. To the extent Petitioner contends its statement that the claim chart shows how Warden, in combination with Schubert, "enables each and every limitation of claim 14" addresses an expectation of success, we note that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Kahn*, 441 F.3d at 988.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Schubert and Warden disclose and enable each and every element of the claims. As noted in our Institution Decision, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons

discussed above, we decline to consider information that Petitioner simply incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence, that claim 14 is unpatentable as obvious in view of Schubert and Warden.

The outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner directs us to paragraph 133 of the Mize Declaration, stating that Dr. Mize explains that the relevant teachings of Warden provide improved reagent mixing within a test chamber. Suppl. Reply 10; Ex. 1003 ¶ 133. Dr. Mize's declaration, however, does not cure the deficiencies noted above. For example, Dr. Mize cites column 11, lines 59 through 66 of Warden, which states that a mixing ball susceptible to a magnetic force is a "suitable mixing means." Ex. 1003 ¶¶ 132–133. Dr. Mize does not explain why he characterizes the mixing means in Warden as "improved," when Warden describes it as "suitable" (Ex. 1007, 11:59–66). Moreover, Dr. Mize does not address why a person of ordinary skill in the art would look to Warden when, as noted above, Schubert states that the reagent and sample are mixed during transport. Additionally, Dr. Mize does not address the issue of whether a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention.

Thus, even considering substantively the cited paragraphs in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Kahn, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence that claim 14 is unpatentable as obvious in view of Schubert and Warden.

C. Challenges Based on Baugh

i. Baugh (Ex. 1005)

Baugh is directed to an improved method for measuring the effectiveness of antiplatelet reagents or platelet inhibitors on the coagulation of blood. Ex. 1005, 3:47–50. Baugh's method includes

> placing a predetermined amount of heparin in each cell of a multicell test cartridge, placing an optimized amount of a mechanical platelet and/or clotting activator in each cell, and placing a measured amount of platelet inhibitor in each cell, the amount of inhibitor in each cell differing from the amount in each other cell. An aliquot of a blood sample is added to each cell, and the blood sample aliquot, platelet and/or clotting activator and platelet inhibitor are mixed. Each cell sample is allowed to clot, and the clotting time for each cell is measured. The relative clotting times are used to calculate and determine the platelet inhibition effect of the platelet inhibitor.

Id. at 4:1–13. Baugh discloses abciximab as an example of a platelet inhibitor that can be used to evaluate the function of platelets in the blood sample tested. *Id.* at 5:26–40.

ii. Claims 1, 2, 6, 7, 15, and 16

Petitioner argues that Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971 patent. Pet. 9–15. Because we find Schubert anticipates claims 1, 2, 6, 7, 15, and 16, and because we find that Petitioner's obviousness grounds based on Baugh are otherwise deficient for the reasons explained below, we do not address this ground.

iii. Claims 3, 4, and 17–20

Petitioner contends that the subject matter of claims 3, 4, and 17–20 would have been obvious in view of the combined teachings of Baugh and Viola. Pet. 24–25, 33–40. With regard to limitations in claims 3 and 4 that are not present in Baugh, Petitioner directs us to portions of Viola, and relies on the same claim chart and arguments from the Petition here as it did for its argument that the subject matter of claims 3 and 4 would have been obvious in view of Schubert and Viola. *Id.* For the reasons discussed above, we find that Petitioner does not identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in the claims of the '971 patent. Nor does Petitioner address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed limitation.

Independent claim 17 contains limitations similar to those in independent claim 1, and further requires that the first and second chambers be "configured to be interrogated with ultrasound for a hemostatic parameter of the blood received therein to be determined." Ex. 1002, 20:29–34. Petitioner contends that Baugh, in combination with Viola, "renders obvious IPR claims 17, 18, 19[,] and 20, by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 135-142." Pet. 33–34. Petitioner also presents a claim chart, and contends that this chart "further evidences how [Baugh] in combination with [Viola] discloses and enables each and every limitation of claims 17, 18[,] 19[,] and 20 of the '971 Patent." *Id.* at 34.

In the Petition, Petitioner asserts that Viola is directed to "a novel ultrasound-based technology, named sonorheometry," and that Viola "[e]ssentially . . . teaches all the principles and techniques necessary to implement sono[r]heometry to test a test chamber and detect viscoelasticity through the coagulation process." *Id.* at 36–37 (citing Ex. 1012, Abstract, Section 2.2, and Section 2.3). Petitioner concludes that it would have been obvious to a person of ordinary skill in the art "to interrogate each of the chambers in [Baugh] using the techniques described in [Viola]." *Id.* at 37.

Although Petitioner contends that Viola discloses configuring a chamber to be interrogated with ultrasound, as required in claim 17, Petitioner does not identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in the claims of the '971 patent. *KSR*, 550 U.S. at 418 ("[A] a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Baugh and Viola disclose and enable every element of the claims. As noted in our Institution Decision, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons discussed above, we decline to consider information that Petitioner simply incorporates by reference to cited portions of the Mize Declaration.

In view of the foregoing, we find that Petitioner has not established by a preponderance of evidence that claims 3, 4, and 17 are obvious. Because claims 18–20 depend from claim 17, we reach the same conclusion regarding these claims.

Furthermore, even if we were to consider substantively the cited paragraphs in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, we are not persuaded Petitioner has established, by a preponderance of evidence, that claims 3, 4, and 17–20 are unpatentable. For example, Petitioner directs us to Dr. Mize's discussion of column 7, lines 35 through 41 of Baugh, and his assertion that Baugh anticipates "the assays and apparatus described therein being interrogated using other known techniques." Suppl. Reply 6–7 (citing Ex. 1003 ¶ 111).

The cited portion of Baugh reads as follows:

> [M]any of the details of functionality will be generalized herein with the understanding that the assignee's prior patents and applications disclose many of these details to a greater extent. It is anticipated that similar results and effects as those obtained from using the assignee's plunger sensor technique will also be obtainable by practicing the present invention using other well known methods and devices.

Ex. 1005, 7:35–41. Dr. Mize relies on this language as evidence to support the conclusion that it would have been obvious for a person of ordinary skill in the art to have combined the teachings of Viola with Baugh. Neither Petitioner nor Dr. Mize, however, directs us to evidence that Viola's acoustic interrogation device (disclosed in a 2009 publication) was well known as of January 1999, the filing date of the application leading to Baugh.

Furthermore, we do not find persuasive Petitioner and Dr. Mize's conclusion that Viola "[e]ssentially . . . teaches all the principles and techniques necessary to implement sono[r]heometry to test a test chamber and detect viscoelasticity through the coagulation process." Pet. 37; Ex. 1003 ¶ 141. First, these types of conclusory statements are insufficient to support a finding of obviousness. *Kahn*, 441 F.3d at 988. Second, the qualification "essentially" raises some uncertainty about whether a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving the claimed invention based on the combined teachings of Viola and Baugh. For example, it is not clear what additional information, if any, would be necessary to "implement[] sonorheometry" according to Viola, which conducted its studies on a "prototype" bench-top instrument. Ex. 1012, 107.

In view of this, and the absence of any additional analysis and evidence presented by Petitioner or Dr. Mize regarding a motivation to combine the teachings of the cited references and an expectation of success, we are not persuaded that Petitioner has established, by a preponderance of evidence, that claims 3, 4, and 17–20 are unpatentable as obvious in view of Baugh and Viola. *See Tech. Licensing*, 545 F.3d at 1327 ("[I]f the fact trier of the issue is left uncertain, the party with the burden loses.").

iv. Claim 5

Petitioner contends that the subject matter of claim 5 would have been obvious in view of the combined teachings of Baugh and Gavin. Pet. 25–26. Petitioner relies on the same arguments and claim charts here as it did for its argument that the subject matter of claim 5 would have been obvious in view of Schubert and Gavin. These arguments, however, are no more persuasive

here than they were when considered above. For the same reasons discussed above, we find Petitioner fails to establish, by a preponderance of evidence, that claim 5 is unpatentable as obvious in view of Baugh and Gavin.

v. Claims 8, 12, and 13

Petitioner contends that the subject matter of claims 8, 12, and 13 would have been obvious in view of the combined teachings of Baugh and Braun. Pet. 26–27. Petitioner states that Baugh in combination with Braun "renders obvious IPR claims 8, 12, and 13 by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 118-123." Pet. 27. Petitioner also provides a claim chart describing where Braun allegedly discloses the limitations in claims 8, 12, and 13. *Id.* at 27–28. According to Petitioner, this claim chart shows how the prior art "discloses and enables each and every limitation of claims 8, 12, and 13 of the '971 Patent." *Id.* at 27.

With regard to claim 8, Petitioner argues that Braun teaches a cartridge that includes a fluid receiving/dispensing reservoir, one or more fluid-receiving chambers and one or more conduits that permit fluid communication between the reservoir and chambers. Pet. 27–28. Petitioner, however, fails to identify in the Petition a reason why a person of ordinary skill in the art would have combined the disclosed elements in the art in the same fashion as recited in claim 8 of the '971 patent.

In the Supplemental Reply, Petitioner argues that the Petition itself provides a motivation to combine elements from Braun and Baugh. Suppl. Reply 9. In particular, Petitioner directs us to the statement that a person of ordinary skill in the art "would have been motivated [to] implement fluid

flow into receiving chambers as well as tangential flow into the receiving chambers both of which promotes mixing of a sample and reagent." *Id.* (citing Pet. 28 (claim chart)). First, we note that this statement regarding a reason to combine was made in reference to the specific limitations disclosed in claim 12, not claim 8. Petitioner does not explain how this alleged motivation applies to claim 8. Second, as discussed above in Section II.B.v, it is clear from Braun that its purported improvements in fluid flow and mixing are relative to a specific prior art device. Pet. 28; Ex. 1014, 4:16–5:48 (reciting physical differences between Braun's device and the device disclosed in the '209 patent). For example, Braun states that "applicants have found that their use has a very significant effect on the reliability of test results produced by use of the cartridges of this patent disclosure vis-a-vis the results produced by the cartridges described in the '209 patent." Ex. 1014, 4:11–15; *see also id.* at 4:53–57 (stating that "the increase in liquid velocity in the restricted passage serves to mix the reagent with the liquid much more thoroughly than the system taught in the '209 patent").

Although Braun's teachings appear to be directed to making specific physical changes to one particular prior art test cartridge/device, in the Petition, Petitioner concludes that a person of ordinary skill in the art would have been motivated to apply these changes to any test cartridge/device, including the ones disclosed in Baugh. Petitioner, however, fails to address any similarities or differences between the two devices, or direct us to evidence or argument addressing whether a person of ordinary skill in the art would have considered these improvements applicable to Baugh's cartridges/devices.

Petitioner also fails to address sufficiently the question of whether a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. To the extent Petitioner contends its statement that the claim chart shows how Braun, in combination with Baugh, "enables each and every limitation of claim 8" addresses likelihood of success, we note that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Kahn*, 441 F.3d at 988.

In view of the foregoing, we find Petitioner fails to establish, by a preponderance of evidence, that claim 8 is unpatentable as obvious in view of Baugh and Braun. Because claims 12 and 13 depend from claim 8, we reach the same conclusion regarding claims 12 and 13.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Baugh and Braun disclose and enable each and every element of the claims. As noted in our Institution Decision, and as discussed above, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition, constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons discussed above, we decline to consider information that Petitioner incorporates by reference to cited portions of the Mize Declaration.

The outcome here would not change even if we were to consider substantively the cited paragraphs in the Mize Declaration. In its Supplemental Reply, Petitioner directs us to paragraph 122 of the Mize

Declaration, stating that Dr. Mize explains that Braun "is intended to be a general construct that can be adapted for any number of different types of tests/assays that involve mixing a sample with a reagent in a receiving chamber." Suppl. Reply 8–9; Ex. 1003 ¶ 122.

As discussed above in Section II.B.v, the cited language in Braun that Dr. Mize relies upon appears to indicate that the "improvements" achieved by Braun's cartridges are not limited to use of the cartridge with a particular test *sample* (i.e., blood). In particular, the cited language indicates that Braun's cartridges can be used with other biological (e.g., urine) and non-biological (e.g., industrial chemical compositions) fluids, and provide similar results. We are not persuaded that this language supports Petitioner's "general construct" argument, namely, that Braun's teachings lead to improvements when implemented in any existing *cartridge* used for tests that involve mixing a sample with a reagent. Further, Dr. Mize does not explain adequately why a person of ordinary skill in the art would have had a reasonable expectation of successfully arriving at the claimed invention, based on the combined teachings of Braun and Baugh. *Kinetic Concepts*, 688 F.3d at 1360.

Thus, even considering substantively the cited paragraph in the Mize Declaration, and Petitioner's corresponding arguments in the Supplemental Reply, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Kahn*, 441 F.3d at 988. As a result, we find Petitioner fails to establish, by a preponderance of evidence, that claims 8, 12, and 13 are unpatentable as obvious in view of Baugh and Braun.

vi. Claims 9–11

Petitioner contends that the subject matter of claims 9–11 would have been obvious in view of the combined teachings of Baugh, Ostgaard, Jina, and Miller. Pet. 29–31.

Claims 9, 10 (through claim 9), and 11 (through claims 9 and 10) depend from claim 8. For the reasons discussed above, we find Petitioner fails to establish, by a preponderance of evidence, that claim 8 is unpatentable as obvious in view of Baugh and Braun. Petitioner does not rely on Ostgaard, Jina, or Miller to cure the aforementioned deficiencies with regard to its arguments and evidence with respect to claim 8.

As a result, we find that Petitioner has failed to establish, by a preponderance of evidence, that claims 9–11 are unpatentable as obvious in view of Baugh, Ostgaard, Jina, and Miller.

vii. Claim 14

Petitioner contends that the subject matter of claim 14 would have been obvious in view of the combined teachings of Baugh and Warden. Pet. 32–33.

Petitioner relies on the same arguments and claim charts here as it did for its argument that the subject matter of claim 14 would have been obvious in view of Schubert and Warden. These arguments, however, are no more persuasive here than they were when considered above. For the same reasons discussed above, we find Petitioner fails to establish, by a preponderance of evidence, that claim 14 is unpatentable as obvious in view of Baugh and Warden.

D. Challenges Based on Warden

Petitioner contends that the subject matter of claims 17–20 would have been obvious in view of the combined teachings of Warden, Lang, and Viola. Pet. 40–45. Specifically, Petitioner argues that Warden in combination with Viola and Lang "renders obvious IPR claims 17, 18, 19[,] and 20, by disclosing each and every element of the claims, arranged as claimed in a manner enabling to a [person of ordinary skill in the art], as discussed by Dr. Mize in Ex. 1003, ¶¶ 142–147." Pet. 40. Petitioner also provides a claim chart showing how the prior art "discloses and enables each and every limitation of claims 17, 18[,] 19[,] and 20 of the '971 patent." *Id.* (noting that the claim chart is "reproduced in an abbreviated form from Dr. Mize's Declaration").

Although Petitioner identifies certain parts of Warden, Viola, and Lang that it asserts disclose or suggest limitations in claims 17–20, Petitioner fails to present arguments or evidence in the Petition explaining why a person of ordinary skill in the art would have combined the teachings of Warden, Lang, and Viola to arrive at the subject matter recited in claims 17–20, or whether a person of ordinary skill in the art would have had a reasonable expectation of successfully doing so. Petitioner's arguments and information are insufficient to establish a prima facie case of obviousness. *KSR*, 550 U.S. at 418–419; *Kahn*, 441 F.3d at 988.

Petitioner cites several paragraphs of the Mize Declaration in support of its broad and conclusory assertion that Warden, Lang, and Viola disclose and enable each and every element of the claims. As noted in our Institution Decision, and discussed above, these types of citations to the Mize Declaration, without adequate substantive discussion in the Petition,

constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Inst. Dec. 14; 37 C.F.R. § 42.6(a)(3). For the reasons discussed above, we decline to consider information that Petitioner incorporates by reference to cited portions of the Mize Declaration.[4]

In view of the foregoing, we find that Petitioner has not established by a preponderance of evidence that claims 17–20 are unpatentable as obvious in view of Warden, Lang, and Viola.

IV. CONCLUSION

For all of the foregoing reasons, we conclude that Petitioner has demonstrated by a preponderance of evidence that claims 1, 2, 6–8, 15, and 16 of the '971 patent are unpatentable. Petitioner has not demonstrated by a preponderance of evidence that claims 3–5, 9–14, and 17–20 are unpatentable.

V. ORDER

For the reasons given, it is hereby

ORDERED that claims 1, 2, 6–8, 15, and 16 of the '971 patent are held unpatentable;

FURTHER ORDERED that Petitioner has not shown by a preponderance of the evidence that claims 3–5, 9–14, and 17–20 of the '971 patent are unpatentable; and

[4] Petitioner does not address this ground in its Supplemental Response. Nevertheless, even if we were to consider substantively the cited paragraphs in the Mize Declaration, the present record remains devoid of any articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. For example, Petitioner does not address sufficiently the question of why a person of ordinary skill in the art would have been motivated to combine the teachings of Lang and Warden.

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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