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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*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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."). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review of claims 1, 2, 6, 7, 15, and 16 as discussed below.

Our findings of fact and conclusions of law are based on the record developed thus far. This is not a final decision as to the patentability of any challenged claim. Any final decision will be based on the full record developed during trial.

II. BACKGROUND

A. Related Proceedings

The parties identify the petition for *inter partes* review of related U.S. Patent No. 9,272,280 B2 (IPR2017-00852). Pet. 1; Paper 3, 1. The parties indicate that U.S. Patent Application No. 15/202,059 may be affected by the requested review (Pet. 1; Paper 3, 1), and Petitioner indicates that U.S. Patent Application No. 15/357,492 may also be affected by the requested 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. 1001, [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; and

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. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

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

Petitioner also relies on the declaration of Patrick Mize, Ph.D. ("Mize Declaration," Ex. 1003).

III. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).

Petitioner offers a proposed construction for several terms (Pet. 7–9), and Patent Owner offers proposed constructions for two of the terms Petitioner construes as well as two additional terms, including "configured for use with a single test sample" (Prelim. Resp. 6–12).

Upon review of the parties' arguments and supporting information, we determine that it is necessary to address only the construction of "configured for use with a single test sample" for purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

Patent Owner proposes that "configured for use with a single test sample" means "designed such that a single sample is introduced into the device for testing." Prelim. Resp. 9–12. In support of its construction, Patent Owner directs us to different examples, embodiments, and figures in the '971 patent wherein a sample "is introduced using a single inlet and then separated and provided to the different chambers from that inlet." *Id.* at 12.

Petitioner does not specifically address this term in its section on claim construction, but does generally assert that the broadest reasonable interpretation standard applies. Pet. 9.

Although not expressly included in its construction, Patent Owner appears to argue that a device "configured for use with a single test sample" must have a single inlet for the introduction of a sample, which sample is then separated and distributed from that inlet. *See* Prelim. Resp. 9–12 (all evidence and arguments directed towards designs that use a single sample inlet). We are not persuaded, however, that the phrase "configured for use with a single test sample" requires limiting the number of entry or inlet ports on a measuring device. Adopting such a construction would require importing limitations from the specification into the claim, which is improper. *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) ("[L]imitations from the specification are not to be read into the claims."). Accordingly, we are not persuaded that Patent Owner's proposed construction is the broadest reasonable interpretation of the phrase "configured for use with a single test sample."

We, therefore, decline to adopt Patent Owner's proposed construction or modify the language of the claim itself. We note, however, that Patent Owner considers a sample that is separated and provided to different chambers of a device to constitute a "single test sample." Prelim. Resp. 12. Therefore, 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.

B. 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 – Anticipation by Baugh

Petitioner argues that Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971 patent. Pet. 9–15.

According to Petitioner, Baugh teaches "measuring and determining the effectiveness of antiplatelet reagents or platelet function inhibitors in the coagulation of blood" using a cartridge that includes a "plurality of test cells," wherein "(a)n aliquot of a blood sample is added to each cell." *Id.* at 10–11 (quoting Ex. 1005, 1:14–20, 2:2–7. 4:7–8).[1] Petitioner thus contends

[1] Petitioner acknowledges that original citations to Baugh in the Petition were incorrect, and provides a chart listing the original incorrect citations in the Petition and corresponding corrected citations. Ex. 1020. For purposes

Baugh discloses "[a] device for evaluation of hemostasis, comprising: a plurality of test chambers each configured to receive blood of a test sample" as required by claim 1.

Petitioner further notes that each of the test cells in Baugh includes "a reagent chamber which contains a reagent or reagents," and a plunger assembly used to measure coagulation properties. Pet. 11 (citing Ex. 1005, 2:2–25). Petitioner thus indicates Baugh discloses "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" as required by claim 1.

Claim 1 recites "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." Petitioner contends Baugh discloses this limitation by teaching the use of "an activation reagent to activate coagulation of the blood." *Id.* at 11–12 (citing Ex. 1005, 2:7–9, 6:1–17).

Petitioner also contends that Baugh discloses using abciximab in addition to an activator of coagulation in certain test cells, and therefore satisfies the claim 1 requirement of having "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." *Id.* at 12 (citing Ex. 1005, 5:33–43).

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of this Decision, we refer only to Petitioner's corrected citations provided in Exhibit 1020.

Claim 1 further requires "an interrogation device that measures at least one viscoelastic property of the test sample." Petitioner asserts that Baugh discloses a plunger assembly that can measure changes in a property of a fluid in a reaction chamber, such as viscosity, "as a result of the onset or occurrence of a coagulation-related activity." Pet. 12–13 (citing Ex. 1005, 2:10–25).

Petitioner provides similar explanations regarding Baugh's disclosure of each limitation in dependent claims 2, 6, 7, 15, and 16. Pet. 13–15. For example, claim 7 ultimately depends from claim 1, and further requires that "the device is configured for use with a single test sample." Petitioner asserts that Baugh discloses using a single sample in its multi-chamber cartridge and analyzer in view of its teaching that "[a] dispensing subassembly 104 of the apparatus 62 automatically supplies a sample of blood to each test cell 66 of the cartridge 64 or 65." *Id.* at 14 (citing Ex. 1005, 8:17–20). Petitioner also indicates that Baugh teaches dividing a sample into portions and loading those portions into each test well. *Id.* (citing Ex. 1005, Abstract (stating that "[a]n aliquot of a blood sample is added to each cell")).

Based on the information and arguments presented, we find Petitioner explains sufficiently how and where Baugh discloses each claim limitation in claims 1, 2, 6, 7, 15, and 16.

Patent Owner argues that Petitioner has not shown that Baugh discloses all of the limitations of claim 1 because claim 1 requires an interrogation device that measures a viscoelastic property, and Baugh discloses only an apparatus that measures a viscosity change. Prelim. Resp. 21–23. According to Patent Owner,

> a "viscoelastic property" is a property of a material that exhibits behavior that incorporates both elastic and viscous responses. The word "viscosity," on the other hand, refers only to the degree to which a fluid can resist flow. . . . As such viscosity only relates to the measurement of a liquid and not measurement of a viscoelastic material – a material that exhibits behavior that incorporates both elastic and viscous responses.

Id. at 22–23 (internal citation omitted).

In discussing the meaning of the term "viscoelastic property," however, Patent Owner directs us to column 15 of the '971 patent, which states "[w]hen the blood sample is in a viscous fluid state, the application of the acoustic force generates large displacements. As coagulation is activated and fibrinogen is cross linked into fibrin strands, the sample behaves as viscoelastic solid and the induced displacement reduce as the stiffness of the sample increases." Ex. 1002, 15:50–55. This sentence suggests a correlation between the activation of coagulation in a fluid sample and the onset of viscoelastic properties.

As Petitioner points out, Baugh discloses that its device measures changes in sample properties *after* "the onset or occurrence of a coagulation-related activity." Pet. 12; Ex. 1005, 2:19–23. Thus, consistent with the teachings of the '971 patent, we agree with Petitioner, based on the present record, that Baugh teaches using its device to measure viscoelastic properties of the sample.

With regard to claim 7, Patent Owner argues that Petitioner has not explained how Baugh discloses that its device is "configured for use with a single test sample." Prelim. Resp. 23. Patent Owner's argument, however, is based on its proposed construction of the phrase "configured for use with a single test sample," which, as discussed above, improperly attempts to incorporate certain structural features from the specification into the claim.

Contrary to Patent Owner's arguments, we find Petitioner's explanation that Baugh teaches dividing a sample into aliquots that are loaded into the test wells to be sufficient, on this record, to demonstrate that Baugh discloses a device configured for use with a single test sample.

Patent Owner also contends that, to support its arguments, Petitioner improperly incorporates by reference into the Petition certain statements made in the Mize Declaration.[2] Pet. 12–17. We disagree. To support its anticipation argument, Petitioner includes a claim chart in the Petition with citations directly to Baugh. Accordingly, the Petitioner has directed us to sufficient evidentiary support in the Petition itself.

In view of the foregoing, we determine that the current record establishes a reasonable likelihood that Petitioner would prevail on its assertion that Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971 patent.

iii. Claims 3 and 4 – Obvious in view of Baugh and Viola

Petitioner contends that the subject matter of claims 3 and 4 would have been obvious in view of the combined teachings of Baugh and Viola. Pet. 24–25. Specifically, Petitioner argues that Baugh 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-

[2] Patent Owner also argues that the Petition and Mize Declaration are "rife with errors," including citation errors to Baugh, and therefore "Petitioner does not 'specify where each element of the claim is found in the prior art patents or printed publications relied upon' as set forth in 37 C.F.R. §§ 42.22(a)(2) and 42.104(b)(4)." Prelim. Resp. 52–53. In view of Petitioner's submission of a table of corrected citations, however, we consider this argument to be moot.

112." *Id.* at 24. Petitioner also provides a claim chart showing how the prior art "discloses and enables each and every limitation of claims 3 and 4 of the '971 patent." *Id.*

Patent Owner argues that Petitioner fails to explain why a person of ordinary skill in the art would have had a reason to modify Baugh in view of Viola, and why a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. Prelim. Resp. 34–36.

A petition for *inter partes* review must identify how the challenged claims are unpatentable under the statutory grounds asserted by the petitioner, and must specify where each element of the claims is found in the relied-upon prior art. 37 C.F.R. § 42.104(b)(4). A petition must include "a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent." *Id.* § 42.22(a)(2).

"[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." *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.* Further, "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).

In the Petition, Petitioner provides a claim chart demonstrating that the combined teachings of Baugh and Viola disclose or suggest each and

every limitation of claims 3 and 4. Petitioner, however, does not identify 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. Absent any such evidence or arguments in the Petition, we determine that Petitioner has failed to establish a reasonable likelihood of prevailing on its contention that claims 3 and 4 would have been obvious over the combined teachings of Baugh and Viola.

We note that Petitioner cites several paragraphs of the Mize Declaration in support of its broad assertion that Baugh and Viola disclose each and every element of the claims. As pointed out by Patent Owner, these types of citations to the Mize Declaration constitute attempts to incorporate arguments and evidence into the Petition by reference to the Mize Declaration. *See* Prelim. Resp. 13–17. 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 is not identified sufficiently in the Petition, but instead is incorporated by reference to the cited portions of the Mize Declaration.

For all of the foregoing reasons, we determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that claims 3 and 4 are unpatentable as obvious in view of the combined teachings of Baugh and Viola.

iv. Claim 5 – Obvious in view of Baugh and Garvin

Petitioner contends that the subject matter of claim 5 would have been obvious in view of the combined teachings of Baugh and Garvin because the references "disclos[e] 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. Petitioner also provides a claim chart showing how Garvin "discloses and enables each and every limitation of claim 5 of the '971 patent." *Id.*

Patent Owner argues that Petitioner fails to explain why a person of ordinary skill in the art would have had a reason to modify Baugh in view of Garvin, and why a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. Prelim. Resp. 36–37.

For the same reasons discussed above with regard to claims 3 and 4, we find Petitioner's arguments and evidence insufficient to establish a reason why a person having 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. We, therefore, determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that claim 5 is unpatentable as obvious in view of the combined teachings of Baugh and Garvin.

v. Claims 8–13 – Obvious in view of Baugh and Braun alone or further in view of Ostgaard, Jina, and Miller

Petitioner contends that the subject matter of claims 8–13 would have been obvious in view of the combined teachings of Baugh and Braun (claims 8, 12, 13), or in view of the combined teaching of Baugh, Braun, Ostgaard, Jina, and Miller (claims 9–11). Pet. 27–31. Petitioner contends that the references "disclos[e] 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, ¶¶ 118-12[9]." Pet. 27, 30. Petitioner also provides claim charts showing how these references disclose and enable each and every limitation of claims 8–13 of the '971 patent. *Id.* at 27–31 (noting that the claim charts are "reproduced in an abbreviated form from Dr. Mize's Declaration").

Patent Owner argues that Petitioner fails to explain why a person of ordinary skill in the art would have (1) had a reason to modify Baugh in view of Braun, Ostgaard, Jina, and/or Miller, or (2) had a reasonable expectation of success in achieving the claimed invention. Prelim. Resp. 37–42. For example, Patent Owner notes "the Petition only states what [Braun] discloses with regard to claim 8," and argues that Petitioner fails to explain why a person of ordinary skill in the art "would have a reasonable expectation of success in using the fluid pathway allegedly provided in [Braun] in the devices of [Baugh]." *Id.* at 39. Patent Owner also argues that Petitioner's reproduction of an "abbreviated form" of claim charts from the Mize Declaration and other general references to the Mize Declaration constitute improper incorporation by reference. *Id.* at 37–38, 40.

As was the case with Petitioner's obviousness arguments for claims 3–5 above, 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 Baugh and Braun to arrive at the subject matter recited in claim 8, or why a person of ordinary skill in the art would have had a reasonable expectation of successfully doing so. Additionally, we agree that Petitioner improperly incorporates arguments and evidence into the Petition by reference to the Mize Declaration. As discussed above, we decline to consider information that is not identified sufficiently in the Petition, but instead is incorporated by reference to the cited portions of the Mize Declaration. In view of this, Petitioner has failed to establish a reasonable likelihood of demonstrating that claim 8 would have been obvious over the asserted prior art.

Because claims 9–13 depend, either directly or indirectly, from claim 8, we reach the same conclusion regarding claims 9–13. In addition, Petitioner's arguments and analysis regarding the unpatentability of claims 9–13 suffer from the same deficiencies discussed above, namely, a failure to explain adequately (1) the significance of the evidence cited in the claim charts, (2) why a person of ordinary skill in the art would have combined the teachings of the cited art, or (3) why a person of ordinary skill in the art would have had a reasonable expectation of successfully doing so.

For these reasons, we determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that claims 8–13 of the '971 patent are unpatentable as obvious in view of the combined teachings of Baugh and Braun (claims 8, 12, 13), or the combined teachings of Baugh, Braun, Ostgaard, Jina, and Miller (claims 9–11).

vi. Claims 17–20 – Obvious in view of Baugh and Viola

Petitioner contends that the subject matter of claims 17–20 would have been obvious in view of the combined teachings of Baugh and Viola. Pet. 33–40. Specifically, Petitioner argues 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." *Id.* at 34. 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").

Patent Owner argues that Petitioner fails to explain why a person of ordinary skill in the art would have had a reason to modify Baugh in view of Viola, and why a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. Prelim. Resp. 44–45. For example, with regard to the limitation in claim 17 regarding the use of ultrasound, Patent Owner asserts that "Petitioner has provided no particular justification as to why Viola['s] mere disclosure of an ultrasound method is in itself a motivation to combine Viola . . . with the device of [Baugh], which entirely lacks any reference to sound-based measurements." *Id.* at 45. Patent Owner also argues that Petitioner's reproduction of an "abbreviated form" of the claim chart from the Mize Declaration and other general references to the Mize Declaration constitute improper incorporation by reference. *Id.* at 44.

As was the case with Petitioner's obviousness arguments discussed above, 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 Baugh and Viola to arrive at the subject matter recited in claims 17–20, or why a person of ordinary skill in the art would have had a reasonable expectation of successfully doing so. Instead, Petitioner identifies certain parts of Viola that disclose limitations in claims 17–20, and concludes, based on these disclosures, that "[i]t would have therefore been obvious to interrogate each of the chambers in [Baugh] using the techniques described in Viola." Pet. 37. These types of conclusory statements are insufficient to establish a reasonable likelihood of demonstrating that claims 17–20 would have been obvious over the combined teachings of Baugh and Viola. *See KSR*, 550 U.S. at 418–419; *In re Kahn*, 441 F.3d at 988.

Additionally, we agree that Petitioner improperly incorporates arguments and evidence into the Petition by reference to the Mize Declaration. As discussed above, we decline to consider information that is not identified sufficiently in the Petition, but instead is incorporated by reference to the cited portions of the Mize Declaration.

For these reasons, we determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that claims 17–20 of the '971 patent are unpatentable as obvious in view of the combined teachings of Baugh and Viola.

C. 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, 7, 8, 15, and 16 – Anticipated by Schubert

Petitioner argues that Schubert anticipates claims 1, 2, 6, 7, 8, 15, and 16 of the ’971 patent. Pet. 15–23. To support its argument, Petitioner provides a claim chart “reproduced in abbreviated form from Dr. Mize’s Declaration” that allegedly demonstrates how Schubert discloses all the limitations of claims 1, 2, 6, 7, 15, and 16 of the ’971 patent. *Id.* at 16.

Claim 1 requires, *inter alia*, “a first chamber . . . 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.” Petitioner notes 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.” *Id.* at 18 (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.* at 19.

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 (stating that "a second measurement cavity can include an extrinsic activator in combination with cytochalasin D reagents (as would be used in the FIBTEM™ assay"). Petitioner therefore argues that Schubert discloses the claim 1 requirement of having "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." *Id.* (citing Ex. 1006 ¶ 83).

Patent Owner argues that Petitioner fails to demonstrate how Schubert discloses using an activator of coagulants as "the first reagent" or as part of the first or second "combination of reagents" required in claim 1. Prelim. Resp. 24–27. Patent Owner acknowledges that paragraph 83 of Schubert "mentions" the EXTEM, INTEM, and FIBTEM tests "as tests for intrinsic and extrinsic activation of a blood sample," but argues that Schubert does

not explicitly disclose that these tests include an activator of coagulation as a reagent. *Id.* at 24–25. Patent Owner further argues that although Schubert "mentions reagents" in the same paragraph as its discussion of these tests, Schubert explicitly discloses only cytochalasin D, which is not an activator of coagulation. *Id.* at 25. Patent Owner also argues that Petitioner cannot rely on what would have been "apparent to a person of ordinary skill in the art" regarding the aforementioned tests to satisfy its burden of proving Schubert anticipates claim 1. *Id.* (citing *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017)). Additionally, Patent Owner urges us to disregard Dr. Mize's testimony because it is improperly incorporated by reference into the Petition, and notes that Dr. Mize's statements that the INTEM, EXTEM, and FIBTEM tests include an activator of coagulation as a reagent are unsupported and conclusory.

"[A] claim is anticipated 'if each and every limitation is found either expressly or inherently in a single prior art reference.'" *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010). Here, Petitioner fails to demonstrate sufficiently where the use of activators of coagulation as a reagent is found either expressly or inherently in Schubert. 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. Furthermore, we agree that Petitioner has improperly incorporated arguments and

evidence into the Petition by reference to the Mize Declaration. As discussed above, we decline to consider information that is not identified sufficiently in the Petition, but instead is incorporated by reference to the cited portions of the Mize Declaration.

For all of the foregoing reasons, we find that Petitioner has failed to demonstrate adequately that Schubert discloses each and every limitation of independent claim 1. Because claims 2, 6, 7, 8, 15, and 16 depend, either directly or indirectly, from claim 1, we reach the same conclusion regarding these claims as well. We, therefore, determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that Schubert anticipates claims 1, 2, 6, 7, 8, 15, and 16 of the '971 patent.

iii. Claims 3–5 and 8–14 – Obvious in view of Schubert

Petitioner contends that the subject matter of claims 3–5 and 8–14 is obvious in view of the combined teachings of Schubert and one or more of Viola, Braun, Garvin, Ostgaard, Jina, and Miller. Pet. 25–27, 29, 31–33. Claims 3–5 and 8–14 depend, either directly or indirectly, from claim 1, and Petitioner's arguments that the combined teachings of Schubert and the other prior art references render these claims unpatentable as obvious are based on Petitioner's contention that Schubert discloses each and every limitation of claim 1. Petitioner does not rely on any of Viola, Braun, Garvin, Ostgaard, Jina, or Miller to remedy the deficiencies in Schubert with respect to claim 1 as described above. In view of our determination that Petitioner has failed to demonstrate adequately that Schubert discloses each and every limitation of independent claim 1, we find that Petitioner has failed to demonstrate that the combined teachings of Schubert and one or more of Viola, Braun, Garvin, Ostgaard, Jina, and Miller disclose or suggest each and every

limitation of claims 3–5 and 8–14.

We, therefore, determine the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that the subject matter of claims 3–5 and 8–14 would have been obvious in view of the combined teachings of Schubert and one or more of Viola, Braun, Garvin, Ostgaard, Jina, and Miller.

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 Warren, Lang, and Viola. Pet. 40–45. Specifically, Petitioner argues that Warren 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").

Patent Owner argues that Petitioner fails to explain why a person of ordinary skill in the art would have had a reason to modify Warden in view of Viola, and why a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. Prelim. Resp. 46. Patent Owner also argues that Petitioner's reproduction of an "abbreviated form" of the claim chart from the Mize Declaration and other general references to the Mize Declaration constitute improper incorporation by reference. *Id.* at 44.

We agree that 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 why a person of ordinary skill in the art would have had a reasonable expectation of successfully doing so. Instead, Petitioner simply identifies certain parts of Warden, Viola, and Lang that disclose limitations in claims 17–20. Petitioner's arguments and information are insufficient to establish a prima facie case of obviousness. *KSR*, 550 U.S. at 418–419; *In re Kahn*, 441 F.3d at 988; *see also ActiveVideo Networks, Inc. v. Verizon Comm'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (requiring an explanation as to "why a person of ordinary skill in the art would have combined elements from specific references *in the way the claimed invention does*.")

Additionally, we agree that Petitioner improperly incorporates arguments and evidence into the Petition by reference to the Mize Declaration. As discussed above, we decline to consider information that is not identified sufficiently in the Petition, but instead is incorporated by reference to the cited portions of the Mize Declaration.

For these reasons, we determine that the current record fails to establish a reasonable likelihood that Petitioner would prevail on its assertion that claims 17–20 of the '971 patent are unpatentable as obvious in view of the combined teachings of Warden, Lang, and Viola.

IV. CONCLUSION

Based on the information presented, we conclude that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge that Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971

patent. Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to any other challenges raised in the Petition.

The Board has not made a final determination as to the patentability of any challenged claim.

V. ORDER

For the reasons given, it is hereby

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1, 2, 6, 7, 15, and 16 of the '971 patent with respect to the question of whether Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971 patent;

FURTHER ORDERED that no ground other than the one specifically granted above is authorized for *inter partes* review as to the claims of the '971 patent; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial commencing on the entry date of this Decision.

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