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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 IPR2017-00852
Patent 9,272,280 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 and 2 of U.S. Patent No. 9,272,280 B2 (Ex. 1001, "the '280 patent"). Paper 2 ("Pet."). HemoSonics LLC ("Patent Owner") filed a Patent Owner Preliminary Response to the Petition. Paper 6 ("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 and 2 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. 9,410,971 B2 (IPR2017-00855). 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 '280 Patent

The '280 patent, titled "Device, Systems and Methods for Evaluation of Hemostasis," issued on March 1, 2016. Ex. 1001, [54], [45]. The '280 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 1:29–32. The '280 patent indicates that "[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 1:32–37.

Accordingly, the '280 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 2:22–25. The '280 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 2:25–34. The test chambers are also configured to be "interrogated with sound to determine a hemostatic parameter of the test samples" (*id.* at 2:35–37, 2:43–45), and "[s]ound reflected from the blood reagent mixture in the test chamber is received and processed to generate a hemostasis parameter" (*id.* at 3:3–5).

C. Challenged Claims

Petitioner challenges claims 1 and 2 of the '280 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 combination including an activator of coagulation and one or both of abciximab and cytochalasin D.

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).

E. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Reference	Statutory Basis	Claims Challenged
Baugh	§ 102	1 and 2
Schubert	§ 102	1 and 2

Petitioner also relies on the declaration of Patrick Mize, Ph.D. ("the 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. 8–11), and Patent Owner offers proposed constructions for two of the terms Petitioner construes (Prelim. Resp. 5–7). Upon review of the parties' arguments and supporting information, we determine that no express claim construction is necessary 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.").

B. References

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. Schubert (Ex. 1006)

Schubert is directed to "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. With regard to blood coagulation, Schubert teaches that

> 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.

C. Challenges Based on Baugh

Petitioner argues that Baugh anticipates claims 1 and 2 of the '280 patent. Pet. 12–17.

Claim 1 requires "[a] device for evaluation of hemostasis, comprising: a plurality of test chambers each configured to receive blood of a test sample." Petitioner presents a claim chart indicating that 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 13–14 (quoting Ex. 1005, 1:14–20, 2:2–7, 4:7–8, 4:42–47).[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. *Id.* at 14–15 (citing Ex. 1005, 2:2–25, 7:21–25). Petitioner thus indicates that 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 further 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." For this limitation, Petitioner directs us to the portion of Baugh that teaches using "an activation reagent to activate coagulation of the blood." *Id.* at 15–16 (citing Ex. 1005, 2:2–7).

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 combination including an

[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. 1012. For purposes of this Decision, we refer only to Petitioner's corrected citations provided in Exhibit 1012.

activator of coagulation and one or both of abciximab and cytochalasin D." *Id.* at 16–17 (citing Ex. 1005, 5:33–43, 6:34–36).

Claim 2 depends from claim 1 and further requires that the first and second chambers comprise a combination of reagents including one or more of kaolin, celite, glass, thrombin, ellagic acid, and tissue factor. Petitioner asserts that Baugh satisfies this limitation by teaching that suitable activators include kaolin, powdered glass, and silica. Pet. 17 (citing Ex. 1005, 6:1–17).

Based on the information and arguments presented, we find Petitioner explains sufficiently how and where Baugh discloses each claim limitation.

Patent Owner does not directly challenge Petitioner's assertions that Baugh discloses each and every limitation of claims 1 and 2. Instead, Patent Owner contends that Petitioner improperly incorporates by reference into the Petition certain statements made in the Mize Declaration to support its contentions.[2] Prelim. Resp. 13–18. Patent Owner also argues that Petitioner improperly relies on prior art that is not a patent or printed publication, including, for example, Petitioner's "Table of Prior Art Devices" (Ex. 1010). Prelim. Resp. 8. We disagree. To support its anticipation argument, Petitioner includes a claim chart in the Petition with citations directly to Baugh. Accordingly, Petitioner has directed us to sufficient evidentiary support in the Petition itself.

[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. 27. In view of Petitioner's submission of a table of corrected citations, however, we consider this argument to be moot. *See* Ex. 1012.

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 and 2 of the '280 patent.

D. Challenges Based on Schubert

Petitioner argues that Schubert anticipates claims 1 and 2 of the '280 patent. Pet. 18–24.

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 21–22 (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.* at 22 (citing Ex. 1006 ¶ 83). Petitioner asserts that these tests were well known in the art prior to the priority date of the '280 patent, and 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.* (citing Ex. 1003 ¶ 39).

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 22–23 (asserting "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 . . . 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).

Patent Owner argues that Petitioner fails to demonstrate how Shubert 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. 20–24. 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 21–23. 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.* 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.* at 22 (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 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. *Id.* at 23–24.

"[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.

Further, Petitioner does not provide any citation in the Petition to support the assertion that "the EXTEM™ assay includes an extrinsic activator (such as tissue factor) while the FIBTEM™ assay includes an extrinsic activator in combination with cytochalasin D." Pet. 18. Dr. Mize testifies that these assays use coagulation activators, but fails to disclose the underlying facts or data upon which this testimony is based. Ex. 1003 ¶ 39 n. xxiv (p. 61). We therefore find that such testimony is conclusory, and is entitled to little or no weight. *See* 37 C.F.R. § 42.65(a). We are also unpersuaded by Petitioner's contention that these tests were well known in the art, as we are not permitted to "fill in missing limitations simply because a skilled artisan would immediately envision them." *Nidec*, 851 F.3d at 1274–75.

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 claim 2 depends from claim 1, we reach the same conclusion regarding dependent claim 2. 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 and 2 of the ’280 patent.

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 and 2 of the ’280 patent, but not with respect to its challenge that Schubert anticipates claims 1 and 2 of the ’280 patent.

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 and 2 of the ’280 patent with respect to the question of whether Baugh anticipates claims 1 and 2 of the ’280 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 ’280 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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