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Paper No. 55
Entered: February 13, 2019

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).

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