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Paper No. 47
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INSTRUMENTATION LABORATORY COMPANY,
Petitioner,

v.

HEMOSONICS LLC,
Patent Owner.

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Case IPR2017-00852
Patent 9,272,280 B2

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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 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."). On September 1, 2017, we instituted an *inter partes* review of claims 1 and 2. Paper 14 ("Inst. Dec.") (instituting trial on all claims but not all grounds raised in the Petition).

After institution, Patent Owner filed a Patent Owner Response (Paper 19, "PO Resp.") and Petitioner filed a Reply (Paper 22, "Reply"). On April 26, 2018, we issued an order modifying our institution decision to include all grounds raised in the Petition. Paper 26. After receiving authorization from the Board, Petitioner filed a Supplemental Reply (Paper 27, "Suppl. Reply") addressing the grounds not addressed in its 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 37 ("Hearing Tr."); Paper 46 ("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 44. On the same day, we issued an order extending the time of pendency in this proceeding by up to six months. Paper 45.

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 and 2 are unpatentable.

## 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) as a related proceeding. 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 '280 Patent*

The '280 patent, titled "Device, Systems and Methods for Evaluation of Hemostasis," issued on March 1, 2016. Ex. 1001, at [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. Illustrative Claim*

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. Reviewed Grounds*

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

*F. Level of Ordinary Skill in the Art*

Petitioner contends that a person of ordinary skill in the art 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. 7–8; 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. 13. Patent Owner also contends that a person of ordinary skill would have had "experience in and an understanding of multiple areas, including hemostasis, 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

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