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Paper No. 8
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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 IPR2018-00264
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
Denying Institution of *Inter Partes* Review
35 U.S.C. § *314(a)*

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 1 ("Pet."). HemoSonics LLC ("Patent Owner") filed a Patent Owner Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). Under the circumstances of this case, for the reasons explained below, we exercise our discretion under 35 U.S.C. § 314(a) to not institute *inter partes* review of the challenged claims.

II. BACKGROUND

A. Related Proceedings

Petitioner previously challenged claims 1–20 of the '971 patent in IPR2017-00855 ("the 855 IPR"). Pet. 6–7; IPR2017-00855, Paper 14. On September 1, 2017, we instituted an *inter partes* review of claims 1, 2, 6, 7, 15, and 16, but not claims 3–5, 8–14, and 17–20. Pet. 6–7; IPR2017-00855, Paper 14. On April 26, 2018, in response to the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, No. 16-969, 2018 WL 1914661 (U.S. April 24, 2018), we modified our institution decision in the 855 IPR to include review of all challenged claims and all grounds raised in the Petition. Paper 28, 2.

The parties also identify IPR2017-00852, involving related U.S. Patent No. 9,272,280 B2. Pet. 6; Paper 5, 1.

B. The '971 Patent

The '971 patent, titled "Devices, Systems and Methods for Evaluation of Hemostasis," issued on August 9, 2016. Ex. 1001, 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 3–5, 8–14, and 17–20 of the '971 patent. Independent claim 1, and claim 3 that depends therefrom, are illustrative, and are 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.

3. The device of claim 1**,** wherein the interrogation device is configured to use acoustic radiation force.

Id. at 18:62–19:13, 19:24–25. 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).

F. 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).

E. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Reference(s)	Statutory Basis	Claim(s) Challenged
Schubert	§ 102	8
Schubert and Braun	§ 103	12 and 13
Baugh and Braun	§ 103	8, 12, and 13
Schubert and Ostgaard	§ 103	9–11
Baugh, Braun, and Ostgaard	§ 103	9–11
Schubert and Gavin	§ 103	5
Baugh and Gavin	§ 103	5
Schubert and Warden	§ 103	14
Baugh and Warden	§ 103	14
Schubert and Viola	§ 103	3, 4, and 17–20
Baugh and Viola	§ 103	3, 4, and 17–20

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

III. ANALYSIS

A. Procedural History

On February 4, 2017, Petitioner filed a petition in the 855 IPR requesting an *inter partes* review of claims 1–20 of the '971 patent based on the following 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,[1] and Miller[2]	§ 103	9–11
Schubert, Gavin, Braun, Ostgaard, Jina, and Miller	§ 103	9–11
Baugh and Warden	§ 103	14

[1] Jina, U.S. Patent No. 6,046,051, issued Apr. 4, 2000 ("Jina," Ex. 1016).
[2] Miller et al., U.S. Pub. No. 2003/0199082 A1, published Oct. 23, 2003 ("Miller," Ex. 1017).

Schubert and Warden	§ 103	14
Baugh and Viola	§ 103	17–20
Warden, Lang,[3] and Viola	§103	17–20

IPR2017-00855, Paper 14, 5. On September 1, 2017, we instituted an *inter partes* review with respect to the question of whether Baugh anticipates claims 1, 2, 6, 7, 15, and 16 of the '971 patent. We were not persuaded by Petitioner's arguments that Schubert anticipated claims 1, 2, 6, 7, 8, 15, and 16. *Id.* at 20–23. Nor were we persuaded by Petitioner's arguments that the subject matter of claims 3–5, 8–14, and 17–20 would have been obvious to a person of ordinary skill in the art in view of the combined teachings of several prior art references, including Baugh, Schubert, Braun, Ostgaard, Viola, and Gavin. *Id.* at 12–25. For example, for several challenges, we determined that Petitioner failed to "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." *Id.* at 13–19, 25. We, therefore, did not institute an *inter partes* review of claims 3–5, 8–14, and 17–20.

On September 15, 2017, Petitioner filed a Request for Rehearing of the portion of our decision denying institution of *inter partes* review of claims 3–5, 8–14, and 17–20 with respect to the question of whether the subject matter of these claims would have been obvious to a person of ordinary skill in the art in view of the combined teachings of Baugh and

[3] 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).

various other references. IPR2017-00855, Paper 16. On November 3, 2017, we denied Petitioner's request. *Id.,* Paper 18. On April 26, 2018, pursuant to the Supreme Court's decision in *SAS Inst.*, we issued an order modifying our institution decision to institute on all of the challenged claims and all of the grounds presented in the 855 IPR petition. *Id.*, Paper 28.

B. Application of our Discretion Under 35 U.S.C. § 314

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a), "the PTO is permitted, but never compelled, to institute an IPR proceeding"). When determining whether to exercise our discretion under § 314(a), we consider the following non-exhaustive factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and

7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, Case IPR2016-01357, slip op. 15–16 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (hereinafter, "*General Plastic*") (citing *NVIDIA Corp. v. Samsung Elecs. Co.*, Case IPR2016-00134, slip op. 6–7 (PTAB May 4, 2016) (Paper 9)). We address each of these factors in turn, but note that not all the factors need to weigh against institution for us to exercise our discretion under § 314(a).

1. Whether the same petitioner previously filed a petition directed to the same claims of the same patent

It is undisputed that the Petitioner in the present proceeding previously filed the 855 IPR directed to the same claims of the same patent. Pet. 6–7. This factor weighs against institution.

2. Whether at the time of filing of the first petition the Petitioner knew of the prior art asserted in the second petition or should have known of it

As shown in Sections II.E and III.A, Petitioner utilizes the same references in the first petition (for the 855 IPR) and the present Petition. *See* Prelim. Resp. 3–5 (chart comparing challenges and art in the 855 IPR and the present Petition), 10–11 (noting that Exhibits 1005–1019 in the present Petition are identical to those in the first petition). Patent Owner notes that Petitioner adds seven new exhibits, but argues that Petitioner "does not rely upon any of these exhibits in the asserted grounds for unpatentability," and that Petitioner "had these newly added exhibits available to it when it filed the '855 petition because these exhibits published between 1994 and 2009." *Id.* at 11.

Petitioner argues that "[m]uch of the [855] IPR was not considered substantively" due to our determination that Petitioner improperly incorporated arguments and evidence into the Petition by reference to the Mize Declaration. Pet. 7. Petitioner contends that "[a] decision to not consider evidence presented in the declaration due to improper incorporation by reference is not a decision on the merits of such evidence but rather is a decision based on formalistic requirements for how such evidence was presented." *Id.* at 8 n.2. Therefore, Petitioner argues that "[s]ubstantially new art and evidence are presented in this Petition [that are] different from such of the art and arguments that were substantively considered in the [855] IPR." *Id.* at 7.

We are not persuaded by Petitioner's arguments. As reflected in our Decision on Institution in the 855 IPR, we considered the substance of Petitioner's petition in the 855 IPR, including, but not limited to, the claim charts provided in the Petition and the references Petitioner cited therein. *See generally* IPR2017-00855, Paper 14.

Accordingly, this factor weighs against institution.

3. Whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition

There is no dispute that at the time of filing the present Petition (November 30, 2017), Petitioner had received Patent Owner's preliminary response (filed June 7, 2017) and our decision on whether to institute review in the first petition (entered September 1, 2017). Petitioner had also received our decision denying its request for rehearing (entered November 3, 2017). Pet. 7–9; Prelim. Resp. 13.

Petitioner contends that the grounds presented in the present Petition "do not reflect a repackaging of previously considered grounds," and that it is "not modifying its positions/arguments in view of a substantive decision by the Board." Pet. 9. Petitioner again relies on its position that the Board did not previously consider the substantive merits of the petition in the 855 IPR. *Id.*

Patent Owner disagrees, arguing that Petitioner's "access to the '855 IPR filings provide[d] a roadmap for [Petitioner] to correct its earlier failings." Prelim. Resp. 13. For example, Patent Owner notes that, in the 855 IPR, we rejected Petitioner's argument that Schubert anticipates claim 8 "because [Petitioner] failed to show that Schubert disclosed the reagent composition required by the claims." *Id.* at 14. Patent Owner asserts that because we identified this deficiency, Petitioner provided additional arguments and expert testimony in the present Petition to support its position that Schubert anticipates claim 8. *Id.* Patent Owner also contends that Petitioner supplemented its obviousness arguments based on our determination that the 855 IPR petition "failed to present persuasive arguments as to why a person of ordinary skill in the art would be motivated to combine the references and the evidence showing that the skilled artisan would have a reasonable expectation of success." *Id.* at 15. Patent Owner further contends that Petitioner included additional arguments in the present Petition based on Patent Owner's Preliminary Response in the 855 IPR. *Id.* at 17.

After reviewing the Petition and Preliminary Response, we observe that Petitioner, in the present Petition, relies on evidence and arguments that were not included in the 855 IPR petition. These additions to the present

Petition appear to address deficiencies we identified in the 855 IPR petition with regard to Petitioner's challenges of claims 3–5, 8–14, and 17–20. For example, in the 855 IPR, we determined that Petitioner failed to support adequately its assertion that the particular assays identified in Schubert included intrinsic or extrinsic activators. IPR2017-00855, Paper 14, 22–23. In the present Petition, Petitioner includes a new reference in an attempt to corroborate its assertion that the assays identified in Schubert include a coagulation activator, as required by claim 8 (which depends from claim 1). Pet. 23–24 (discussing Gorlinger,[4] Ex. 1020), 34 n.10.

Furthermore, in the 855 IPR, we determined that Petitioner failed to "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." IPR2017-00855, Paper 14, 14. In the present Petition, Petitioner presents several arguments directed to the question of whether a person of ordinary skill in the art would have been motivated to combine the teachings of various prior art references and/or modify the references. *See, e.g.*, Pet. 37, 40, 44–45, 48–50, 52–55, 57–58, 63.

Petitioner's inclusion of arguments and evidence in the present Petition that address deficiencies we identified in the 855 IPR petition demonstrates that Petitioner took advantage of having received our decision on institution for the 855 IPR at the time it filed the present Petition. Accordingly, this factor weighs against institution.

[4] Gorlinger et al., "*Perioperative Coagulation Management and Control of Platelet Transfusion by Point-of-Care Platelet Function Analysis*," TRANSFUS MED HEMOTHER 34:396-411 (2007)

4. The length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition

Petitioner filed the 855 IPR petition on February 4, 2017, and filed the present Petition on November 30, 2017. As discussed above, Petitioner relies on the same art in both petitions. Therefore, over nine months elapsed between the time Petitioner learned of the prior art asserted in the present Petition and the filing of the Petition. Because Petitioner was aware of the art asserted in the present Petition at the time it filed the 855 IPR petition, and waited over nine months before filing the present Petition, this weighs against institution.

5. Whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent

Petitioner contends that it timely filed the present Petition within one month of receiving our decision denying its rehearing request in the 855 IPR. Pet. 7–8. In that regard, Petitioner argues that it would have been "improper" to file the present Petition before we rendered a decision on its request for rehearing in the 855 IPR. *Id.*

Patent Owner asserts Petitioner's explanation "lacks merit" because only five out of the 11 grounds raised in the present Petition were addressed in Petitioner's rehearing request in the 855 IPR. Prelim. Resp. 20–21.

We conclude that under the present circumstances, this factor does not weigh significantly for or against exercising our discretion.

6. The finite resources of the Board

7. The requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after

the date on which the Director notices institution of review

We conclude that these factors do not weigh significantly for or against exercising our discretion.

C. Conclusion

In view of the considerations noted above, we determine a majority of the *General Plastic* factors weigh strongly against institution in this case. Accordingly, we exercise our discretion to deny institution under 35 U.S.C. § 314(a).

IV. ORDER

For the reasons given, it is hereby

ORDERED that *inter partes* review is not instituted.

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