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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.

PGR2019-00047
Patent 10,031,144 B2

Before JO-ANNE M. KOKOSKI, KRISTINA M. KALAN, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

Instrumentation Laboratory Company ("Petitioner") filed a Petition requesting post-grant review of claims 1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63 of US Patent No. 10,031,144 B2 ("the '144 patent," Ex. 1001). Paper 2 ("Pet."). HemoSonics LLC ("Patent Owner") filed a Patent Owner Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

Under 35 U.S.C. § 324, a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Moreover, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), §§ 3(n)(1), 6(f)(2)(A), 125 Stat. 284, 293, 311 (2011), available at https://go.usa.gov/xQA4b; 35 U.S.C. § 100(i). After considering the Petition and the Preliminary Response, as well as the supporting evidence, we determine that the Petition fails to demonstrate that it is more likely than not that the '144 patent is eligible for post-grant review. Accordingly, we deny the Petition.

II. BACKGROUND

A. Related Proceedings

The parties identify the petition for post-grant review of related US Patent No. 9,977,039 B2 (PGR2019-00033) as a related proceeding.[1] Pet. 4; Paper 5, 1.[2] Additionally, the parties identify the Final Written Decisions in IPR2017-00852 (addressing related US Patent No. 9,727,280 B2) and IPR2017-00855 (addressing related US Patent No. 9,410,971 B2) as related proceedings. Pet. 4; Paper 5, 1.

B. The '144 Patent

The '144 patent, titled "Devices, Systems and Methods for Evaluation of Hemostasis," issued on July 24, 2018, from US Application No. 15/202,059 ("the '059 application"). Ex. 1001, at code (54), (45), (21). The '059 application is a continuation of a series of patent applications, and claims priority to US Application No. 13/397,398 ("the '398 application," Ex. 2012), filed February 15, 2012, now issued as US Patent No. 9,272,280 B2, as well as US Provisional Application No. 61/443,088 ("the '088 provisional application"), filed February 15, 2011. Ex. 1001, at code (63), (60).

The '144 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

[1] On August 23, 2019, the Board issued a decision denying institution of post-grant review of the '039 patent. PGR2019-00033, Paper 8. Petitioner filed a Request for Rehearing of that decision on September 22, 2019. PGR2019-00033, Paper 9.

[2] Although Patent Owner identifies PGR2019-00033 as a related matter, it incorrectly lists US Pat. No. 9,410,971 B2 as the subject of that proceeding.

coagulation inhibitors." *Id.* at 1:20–23. The '144 patent states 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 1:23–28.

Accordingly, the '144 patent is directed to devices, systems, and methods for evaluating hemostasis, including "sonorheometric devices for evaluation of hemostasis in a subject by in vitro evaluation of a test sample from the subject." Ex. 1001, 2:14–17. The '144 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 2:17–21. In one example, the test chambers are configured to be "interrogated with sound to determine a hemostatic parameter of the test samples." *Id.* at 2:27–29. The sound can be generated by a transducer and focused within the biological sample (*id.* at 12:30–33), and, thereafter, "[s]ound reflected from the blood reagent mixture in the test chamber is received and processed to generate a hemostasis parameter" (*id.* at 2:62–65).

C. Challenged Claims

Petitioner challenges claims 1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63 ("the challenged claims") of the '144 patent. Independent claim 1 is illustrative, and is reproduced below:

> 1. An apparatus for evaluation of hemostasis, comprising:
>
> a housing that is configured to couple to a system, wherein the system comprises one or more transducers for each of a plurality of test chambers, wherein the system comprises at

least one processor and memory having instructions stored thereon, wherein the instructions when executed by the at least one processor cause the at least one processor to direct the one or more transducers associated with each of the plurality of test chambers in the interrogation of the test sample to determine at least one viscoelastic property of the test sample;

the plurality of test chambers, including a first test chamber, a second test chamber, and a third test chamber, that are each at least partially defined by the housing; and

a fluid pathway having an inlet, defined by the housing, and from which an external vessel establishes fluid communication, to receive a test sample, wherein the fluid pathway is in fluid communication with the first test chamber, the second test chamber, and the third test chamber to deliver the test sample, or a portion thereof, to the first test chamber, the second test chamber, and the third test chamber

wherein each of the plurality of test chambers comprises a reagent or combination of reagents, and wherein each of the plurality of test chambers, including the first, second, and third test chambers, is configured to receive, via the fluid pathway, blood of a test sample to be interrogated to determine a plurality of hemostatic parameters;

wherein the first test chamber comprises 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 configured to activate coagulation via extrinsic or intrinsic pathway;

wherein the second test chamber comprises a second combination of reagents that interact with blood of the test sample received therein, wherein the second combination of reagents includes i) a reagent, or a combination of reagents, configured to activate coagulation via the extrinsic or intrinsic pathway and ii) a reagent, or a combination of reagents, configured to inhibit platelet contraction; and

> wherein the third test chambers comprises a third reagent or a third combination of reagents that interact with the blood received therein, wherein the third reagent, or a reagent included in the third combination of reagents, is configured to activate coagulation via the extrinsic or intrinsic pathway.

Ex. 1001, 19:23–20:6.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63 would have been unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63	§ 112(b) (indefiniteness)	
1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63	§ 112(a) (written description and enablement)	
1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63	§102	Schubert[3]
1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63	§103	Schubert in view of the State of the Art on TEM/TEG
1–4, 9, 11–14, 16–21, 30, 39, 42, 50, 58, 61, and 63	§103	Schubert in view of the State of the Art for acoustic-echo based interrogation and data analysis

Petitioner also relies on the declaration of Frank M. LaDuca, Ph.D. ("the LaDuca Declaration," Ex. 1002). Patent Owner relies on the Declaration of James P. Landers, Ph.D. ("the Landers Declaration," Ex. 2001).

[3] US 2010/0154520 A1, published June 24, 2010 (Ex. 1005).

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art for the '144 patent would have "a bachelor degree in a relevant science discipline (such as biology, chemistry, natural sciences, engineering or a biomedical engineering discipline) and at least 4 years of practical experience designing or creating devices/systems for evaluating hemostasis." Pet. 28 (citing Ex. 1002 ¶ 95). Patent Owner, relying on the Landers Declaration, offers a similar definition. Prelim. Resp. 11–12 (citing Ex. 2001 ¶¶ 47–48).

Based on the general agreement between the parties, we find that a person of ordinary skill in the art would have had a bachelor's degree in a science discipline such as biology, chemistry, natural sciences, engineering, or a biomedical engineering discipline, and 4 years of practical experience designing or creating devices for evaluating hemostasis. Pet. 28; Prelim. Resp. 11–12. This level of ordinary skill is reflected by the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

B. Post-Grant Review Eligibility

As a threshold matter, we must determine whether the '144 patent is eligible for post-grant review. There are two specific requirements that must be met in order for post-grant review to be available. First, post-grant review is available only if the petition is filed within nine months of issuance of the challenged patent. 35 U.S.C. § 321(c). Here, the Petition was filed April 24, 2019, which is within nine months of the '144 patent's July 24,

2018, issue date, and, therefore, the first requirement is met. Ex. 1001, at code (45).

Second, as noted above, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See* AIA §§ 3(n)(1), 6(f)(2)(A). The "effective filing date" for a claim is either the application's actual filing date or the filing date of the earliest application that supports the claim. 35 U.S.C. § 100(i).

Petitioner has the burden of demonstrating eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016). To show that the '144 patent is eligible for post-grant review, Petitioner bears the burden of proving that the challenged claims lack the benefit of the filing date of the earliest application that supports the claims. In particular, Petitioner must prove that at least one of the challenged claims of the '144 patent was "not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought." *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at 11 (PTAB Dec. 22, 2015).

Petitioner contends that the '144 patent is eligible for post-grant review because the challenged claims of the '144 patent "lack enablement and written description support by any pre-AIA disclosure." Pet. 1. As discussed in more detail below, Petitioner argues that the '144 patent[4] fails

[4] Section VII of the Petition is the portion of the Petition directed to enablement and written description, and forms the basis for Petitioner's argument that the challenged claims are eligible for post-grant review.

to satisfy the written description and enablement requirements under 35 U.S.C. § 112(a) because the challenged claims are directed to a broad genus whereas the '144 patent specification discloses only one species within that genus. Pet. 48–49. In particular, Petitioner argues that the independent claims of the '144 patent recite "generic structure[s] . . . using functional modifiers . . . followed by generic functions . . . relative to imprecise and arbitrary values," but the '144 patent discloses only a structure specific for acoustic-echo interrogation and data analysis. Pet. 48. Petitioner further argues that "the Challenged Claims fail under 35 U.S.C. § 112 since the generalization of interrogation and data analysis beyond the acoustic-echo implementations of the '144 patent . . . exceeds the scope of the original disclosure." Pet. 50–51 (citing *LizardTech, Inc. v. Earth Resource Mapping, Inc.* 424 F.3d 1336, 1344 (Fed. Cir. 2005)).

Patent Owner contends that the '144 patent is not eligible for post-grant review because Petitioner fails to meet its burden of proving that any of the challenged claims of the '144 patent have an effective filing date on or after March 16, 2013. Prelim. Resp. 1. In particular, Patent Owner argues that Petitioner fails to prove that the priority applications upon which the '144 patent relies do not provide sufficient written description support and enabling disclosure for the challenged claims, because Petitioner ignores

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Pet. 48–55. In Section VII, Petitioner refers only to "the '144 patent," as opposed to the priority applications (the '088 provisional application and the '398 application). Pet. 48–55. Petitioner, however, acknowledges that the specification of the '144 patent is identical to the specification of US Patent Number 9,272,280 B2, which issued from the '398 application. Pet. 1.

teachings within the Specification that demonstrate the inventors described and enabled more than just a single species. Prelim. Resp. 2.

1. Written Description

To satisfy the written description requirement under 35 U.S.C. § 112(a), the specification must "reasonably convey[] to those skilled in the art that the inventor had possession" of the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An adequate description does not require any particular form of disclosure or that the specification recite the claimed invention *in haec verba*, but must do more than render the claimed invention obvious. *Id.* at 1352. In evaluating the adequacy of the disclosure, a court may consider "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Capon v. Eshhar,* 418 F.3d 1349, 1359 (Fed. Cir. 2005) (cited with approval in *Ariad*, 598 F.3d at 1352); *see also Boston Sci. Corp. v. Johnson & Johnson,* 647 F.3d 1353, 1366 (Fed. Cir. 2011) (holding that because the assessment for written description is made from the perspective of a person of ordinary skill in the art, in some instances, a patentee can rely on information that is "well-known in the art" to satisfy written description).

a. Independent Claims 1, 20, 42, and 61

Petitioner contends that there is no written description support for independent claims 1, 20, 42, and 61, because the claims encompass "any type of interrogation using unspecified transducers and unspecified data processing to determine a viscoelastic property" (Pet. 39 (claim 1)), and "any type of signal analysis using unspecified transducers and unspecified

data processing to determine the hemostatic parameters" (Pet. 41 (claims 20, 42, and 61)), whereas the '144 patent specification "focuses extensively on implementing acoustic-echo interrogation," and does not "mention or suggest implementing any other technique for evaluating hemostasis and there is no invitation to adapt the apparatus and systems to any other technique" (Pet. 52). Thus, according to Petitioner, the "original disclosure of the '144 patent fails to demonstrate possession by Patent Owner of any implementation other than with respect to acoustic-echo interrogation, which are the only embodiments disclosed in the '144 patent for evaluating hemostasis." Pet. 51; *see also* Pet. 45 (arguing "[t]he only corresponding structure in the embodiments of the '144 patent for the function of the test chamber being configured for interrogation is a sound focusing assembly for dry ultrasonic coupling," and "[t]he specification of the '144 patent does not establish or suggest using different test chamber configurations for arbitrary interrogation techniques").

Patent Owner contends that "Petitioner ignores that the patent discloses alternative methods for interrogating a blood sample during hemostasis to determine a viscoelastic property, and Petitioner discounts the knowledge of a" person of ordinary skill in the art. Prelim. Resp. 15 (citing Ex. 2001 ¶¶ 59–70). Patent Owner argues that, in addition to acoustic interrogation, the '144 patent specification[5] discloses other well-known

[5] In the Preliminary Response, when presenting its arguments regarding written description and enablement in the context of eligibility for post-grant review, Patent Owner mainly refers to "the '144 patent" or "patent specification" as opposed to referring to the priority applications (the '088 provisional application and the '398 application). Patent Owner's declarant Dr. Landers, however, states that the disclosure of the '059 application

interrogation techniques for evaluating viscoelastic properties of blood, including thromboelastography (TEG) and rotational thromboelastometry (ROTEM or TEM). Prelim. Resp. 19 (citing Ex. 1001, 1:62–2:10); Pet. 30; *see also* Prelim. Resp. 5, n.3 (noting the parties agree that TEM and ROTEM refer to the same thromboelastometry). In view of this, Patent Owner argues that a person of ordinary skill in the art would have understood that the test chambers described in the '144 patent were not limited to a single interrogation method. Prelim. Resp. 23–25.

With regard to the use of transducers and data processors associated with interrogation techniques to determine viscoelastic properties, Patent Owner notes that the '144 patent provides details regarding a preferred embodiment involving the "ultrasonic method." Prelim. Resp. 20–21. According to Patent Owner, the '144 patent discloses information regarding a transducer that transmits ultrasound into the test chamber and receives reflected sound, and a processor that can use the received data to determine a viscoelastic property or hemostatic parameter. Prelim. Resp. 20–21 (citing Ex. 1001, 12:16–13:44, 15:17–18:47). Patent Owner asserts similar details regarding ROTEM and TEG do not need to be included in the '144 patent because "implementation of those techniques with a processor falls within the knowledge of a [person of ordinary skill in the art]." Prelim. Resp. 21.

(which issued as the '144 patent) is "essentially the same as" the disclosure of the '398 application. Ex. 2001 ¶ 27. Accordingly, we do not perceive any shortcoming in Patent Owner's references to the specification of the '144 patent in making its arguments, as we credit Dr. Landers's testimony regarding the similarity of the '059 application specification and the '398 application specification. Additionally, in footnote 10 on page 19, Patent Owner argues that the invention disclosed in the '088 provisional application is compatible with different interrogation techniques. Prelim. Resp. 19 n.10.

Patent Owner also directs us to the portion of the ’144 patent that discusses constructing test chambers to work in conjunction with a light-emitting diode and an optical detector to measure sample volume, and magnetic beads and an electromagnetic field to mix the blood sample in the test chamber. Prelim. Resp. 24. According to Patent Owner, a person of ordinary skill in the art would understand from this information that the chamber of the ’144 patent could accommodate different interrogation techniques. Prelim. Resp. 24.

We agree with Patent Owner, and are not persuaded by Petitioner’s argument that the ’144 patent specification[6] fails to demonstrate possession by Patent Owner of any implementation other than acoustic-echo interrogation of a sample to determine a hemostatic parameter or viscoelastic property. *See* Pet. 51. Although the specific embodiment described in the ’144 patent is directed to acoustic interrogation, the ’144 patent specification uses broad language when discussing interrogation methods and identifies other interrogation methods, namely TEG and ROTEM, which do not use acoustics to determine hemostatic parameters or viscoelastic properties of a sample. Ex. 1001, 1:62–2:10, 3:65–4:4; Ex. 2015 ¶¶ 6, 28.

[6] For purposes of this Decision, we follow the parties’ convention of referring to the specification of the ’144 patent for our discussion of written description and enablement. Our analysis, however, applies equally to the ’398 application, in view of Dr. Landers’ statement that the disclosure of the ’398 application and the ’059 application are essentially the same, and absent evidence or argument to the contrary from Petitioner. Furthermore, even though the parties do not cite to the priority applications, we include cites to the ’398 application in addition to the ’144 patent specification, where applicable.

It is undisputed that TEG and ROTEM were well known to a person of ordinary skill in the art, and these techniques used transducers and processors to determine hemostatic properties. *E.g.* Pet. 30–31; Prelim. Resp. 7, 21. For example, Petitioner states that "[b]oth TEG and TEM measure clot firmness using force-response testing." Pet. 30 (citing Ex. 1002 ¶ 47). According to Petitioner's own description of TEG and TEM, both methods involve a cup and pin assembly, wherein the rotational amplitude of the pin is recorded as a curve reflecting clot firmness over time, and various parameters are derived from the curve to evaluate hemostasis. Pet. 30–31.

Petitioner further states that "as with any force-response type testing, TEM includes transducers which transmit energy into the test chamber and receive energy out of the chamber" (Pet. 67), and the "transducers in TEM can include the pin to sample interface which both imparts a force and receives a counter-force from the sample" (Pet. 68). Petitioner also states that "TEG and TEM curves necessarily (and do) involve computer processing to track and store the many data points of observed maximum rotation." Pet. 31.

Petitioner's own characterization of what a person of ordinary skill in the art would have known about TEG and TEM, including the use of transducers and processors associated with TEG and TEM, undermines its argument that the disclosure of the '144 patent fails to demonstrate possession by Patent Owner of any implementation other than with respect to acoustic-echo interrogation. *See In re Fisher*, 427 F.2d 833, 839 (CCPA 1969); *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001) ("The law is clear that patent documents need not include subject matter that is

known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention."). To the contrary, the discussion of TEM and TEG in the '144 patent (Ex. 1001, 1:62–2:10; Ex. 2012 ¶ 6) reasonably conveys to a person of ordinary skill in the art that the inventors had possession of more than simply an apparatus and system designed for acoustic interrogation of a sample to determine a hemostatic parameter or viscoelastic property.

In view of this, we disagree with Petitioner's assertions that the '144 patent "claim[s] a genus for which only one species was disclosed," and "claim[s] functional elements untethered to any discernable definite structure." Pet. 49. Accordingly, we are not persuaded by Petitioner's "policy" arguments, which are based on those assertions. *See* Pet. 48–50.

These disclosures also distinguish the present facts from those in *LizardTech,* cited by Petitioner in support of its arguments. *See* Pet. 57. Unlike the '144 patent specification, the specification in *LizardTech* described only one specific method for solving one particular problem—creating "seamless" discrete wavelet transforms (DWTs) for use in electronic image data compression. *LizardTech,* 424 F.3d at 1345. Furthermore, the prior art described in the *LizardTech* specification created only "non-seamless" DWTs, and there was no indication that a person of ordinary skill in the art would have known how to create a seamless DWT using any method other than that taught in the specification. *Id.* at 1343, 1345.

Accordingly, we determine that Petitioner fails to show sufficiently that the challenged independent claims lack support in the '144 patent

specification (or the ’398 application), and therefore, fails to show the claims are not entitled to the February 15, 2012 filing date of the ’398 application.

b. Dependent claims 16, 39, 58, and 63

Claims 16, 39, 58, and 63 depend from claims 1, 20, 42, and 61, respectively, and require that “a first transducer of the one or more transducers comprises a light emitting diode (LED) emitter and a second transducer of the one or more transducers comprises a detector.” Ex. 1001, 20:62–65 (claim 16), 22:57–60 (claim 39), 24:37–40 (claim 58), 25:24–27 (claim 63). Petitioner argues that these claims require an LED emitter and detector serving as transducers for interrogating a sample as part of determining a viscoelastic property or hemostatic parameter. Pet. 46, 54–55. According to Petitioner, however, “the ‘144 patent only discloses an LED emitter and an [optical] detector for monitoring chamber fluid level,” and there is no basis or support in the ’144 patent “that an LED emitter and a detector would be used in interrogating a viscoelastic property or determining hemostatic parameters and how this could be achieved.” Pet. 46 (citing Ex. 1002 ¶ 117).

Patent Owner asserts that Petitioner’s argument “relies upon the misperception that each transducer recited in the claims must assist in determining a viscoelastic property or a hemostatic parameter.” Prelim. Resp. 35–36. According to Patent Owner, the independent claims require only “at least one transducer exists that can determine either a viscoelastic property or a hemostatic parameter.” Prelim. Resp. 35–36 n.19.

In a post grant review filed after November 13, 2018, we construe claim terms according to the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.200(b)

(2019) ("In a post-grant review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)."). Under *Phillips*, claim terms are afforded "their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* It is also important to consider the prosecution history, as it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention." *Id.* at 1317.

To properly construe dependent claims 16, 39, 58, and 63, we begin by addressing the ordinary and customary meaning of the words in the independent claims from which these claims depend. Claim 1 recites an apparatus comprising "one or more transducers for each of a plurality of test chambers." Ex. 1001, 19:25–26. Based on the ordinary and customary meaning of this claim language, a person of ordinary skill in the art would understand that the claim requires at least one transducer to be present in the claimed apparatus and systems. This is consistent with the '144 patent specification, which describes embodiments having at least one transducer. *E.g.*, Ex. 1001, 1:62–2:10, 12:3–33.

Claim 1 further recites a processor that "direct[s] the one or more transducers . . . in the interrogation of the test sample to determine at least one viscoelastic property of the test sample." Ex. 1001, 19:26–34. When

read in the context of the claim language addressed above, and based on the ordinary and customary meaning of the terms, we determine that a person of ordinary skill in the art would understand that the claim requires not only the presence of at least one transducer in the claimed apparatus, but also that the processor directs at least one transducer to interrogate the test sample to determine a viscoelastic property of the test sample. This is consistent with the '144 patent specification, which describes, as one example, a processor causing the "transmission of ultrasound" to evaluate hemostasis indices of a sample. *E.g.*, Ex. 1001, 13:56–60.

We reach a similar conclusion regarding claims 20, 42, and 61, which recite systems comprising "one or more transducers for transmitting energy into one or more test chamber and for receiving reflected energy from the chamber and the sample therein," and a processor that "is configured to determine the hemostatic parameters from signals transmitted to the processor from the one or more transducers." Ex. 1001, 21:22–29 (claim 20), 23:14–21 (claim 42), 24:60–67 (claim 61). We determine that a person of ordinary skill in the art would understand that these claims require a system having at least one transducer, and a processor configured to determine hemostatic parameters from signals transmitted from at least one transducer. This is consistent with the '144 patent specification, which describes information received by a transducer and transmitted to a processor to determine hemostatic parameters. *E.g.,* Ex. 1001, 13:27–14:3.

We turn next to the language in claims 16, 39, 58, and 63, which recites that "a first transducer of the one or more transducers comprises a light emitting diode (LED) emitter and a second transducer of the one or

more transducers comprises a detector." *E.g.*, Ex. 1001, 20:62–65 (claim 16).

Petitioner construes these claims to require that both the LED and detector interrogate a test sample to determine a viscoelastic property or hemostatic parameter. Pet. 46, 54–55. Petitioner, however, does not demonstrate adequately that this is the proper construction. To the contrary, Petitioner acknowledges that the '144 patent specification does not disclose an LED used to determine a viscoelastic property or a hemostatic parameter. Pet. 55. Instead, the '144 patent specification discloses the use of an LED to optically monitor volume of sample. Ex. 1001, 6:40–53. In addition to the LED transducer, the specification discloses ROTEM and acoustic interrogation methods, which include a detector. *See* Ex. 1001, 1:62–2:10 (discussing ROTEM), 2:43–46 (discussing a transducer for "receiving reflected sound" from a sample chamber); Pet. 68 (discussing a detector in the context of TEM); Prelim. Resp. 37 (discussing transducers that include a detector in ROTEM and acoustic methods). The '144 patent specification thus supports a construction wherein not all transducers in an apparatus or system must interrogate a sample to determine a viscoelastic property or hemostatic parameter.

The prosecution history likewise supports a construction wherein it is not required that both the LED and detector be utilized in determining a viscoelastic property or hemostatic parameter. As support for the amended claim, Patent Owner pointed to paragraphs 46 and 47 of the '398 application. Ex. 1003, 213 (noting that paragraphs 46 and 47 of the originally filed specification provide support for amended claims 97, 116, and 133, which contain the disputed limitation). These paragraphs

correspond to column 6, lines 40–53 in the issued patent, which, as noted above, describe the use of an LED for optical monitoring of sample volume. Thus, the prosecution history provides evidence that the inventors did not consider dependent claims 16, 39, 58, and 63 to require that both the LED and detector be used for interrogating a sample to determine a viscoelastic property or hemostatic parameter. *See Phillips*, 415 F.3d at 1317.

For all of the foregoing reasons, we are not persuaded that claims 16, 39, 58, and 63 require that the claimed system or apparatus utilize both a transducer comprising a light emitting diode (LED) emitter and a transducer comprising a detector to interrogate a sample in determining a hemostatic parameter or viscoelastic property. Rather, we determine the claims require the presence of both a transducer comprising a light emitting diode (LED) emitter and a transducer comprising a detector, and further require that at least one transducer is used to interrogate a sample to determine a hemostatic parameter or viscoelastic property.

Having determined the proper construction of claims 16, 39, 58, and 63, we next address Petitioner's argument that these claims lack written description support in the '144 patent. We agree with Patent Owner that Petitioner's arguments are based on an incorrect construction of the claim. Prelim. Resp. 35–36; Pet. 46, 54–55. Because Petitioner offers no evidence regarding a lack of written description support under any other construction, we determine that Petitioner fails to show sufficiently that claims 16, 39, 58, and 63 lack written description support in the '144 patent specification. We, therefore, determine that Petitioner fails to show that these claims are not entitled to the February 15, 2012 filing date of the '398 application.

Although not necessary for purposes of this Decision, we note that both parties agree that the ’144 patent discusses the use of an LED in conjunction with other detectors, and both parties agree that an LED and a detector are transducers. Prelim. Resp. 37; Pet. 54–55, 68. Thus, the ’144 patent discloses the presence of both a transducer comprising an LED emitter and a transducer comprising a detector as recited in claims 16, 39, 58, and 63. This evidence supports a determination that the ’144 patent provides written description support for claims 16, 39, 58, and 63, under the construction adopted herein, and, therefore, the claims are entitled to the February 15, 2012 filing date of the ’398 application.

c. Dependent Claims 18, 30, and 50

Claims 18, 30, and 50 depend from claims 1, 20, and 42, respectively, and recite that “the first reagent or the first combination of reagents are mixed with the test sample in a portion of the fluid pathway prior to being delivered to the first test chamber” (Ex. 1001, 21:4–7 (claim 18), 22:20–23 (claim 30)), and “the test sample is mixed with the reagent or the combination of regents prior to being delivered into the test chamber” (Ex. 1001, 24:1–3 (claim 50)). Petitioner refers to these as the “pre-mix” claims, and contends that “there is no basis or support in the original disclosure for mixing of the reagents with the sample outside of the test chamber.” Pet. 55; *see also* Pet. 47 (stating “the ‘144 patent only teaches embodiments where the reagents are pre-loaded and mixed with the sample in the test chambers”).

As noted above, Petitioner bears the burden of demonstrating these claims lack adequate written description support in the ’144 patent. Other than citing to one paragraph in the LaDuca Declaration, which recites the

language in the Petition verbatim and provides no additional citation or support, Petitioner offers nothing to support its contentions that there is inadequate written description support for claims 18, 30, and 50. Pet. 47, 55; Ex. 1002 ¶ 118. Unsupported attorney arguments and conclusions are not sufficient to meet Petitioner's burden. Accordingly, we determine that Petitioner fails to show sufficiently that claims 18, 30, and 50 lack written description support in the '144 patent, and therefore, fails to show that those claims are not entitled to the February 15, 2012 filing date of the '398 application.

Although not necessary for purposes of this Decision, we note that Patent Owner directs us to portions of the '144 patent that discuss delivering the reagent or combination of reagents to the test chamber with the sample, and mixing the reagent and biological sample before delivery to the test chamber. Prelim. Resp. 38–39 (citing Ex. 1001, 10:19–21, 10:25–29). These portions of the '144 patent support Patent Owner's argument that the '144 patent provides adequate written description support for the pre-mix claims, and, therefore, that that those claims are entitled to the February 15, 2012 filing date of the '398 application.

d. Conclusion

After considering the Petition and the Preliminary Response, as well as all supporting evidence, we determine that the Petition fails to demonstrate that it is more likely than not that the challenged claims lack written description support in the '144 patent specification (or the '398 application), and therefore, are not entitled to the February 15, 2012 filing date of the '398 application.

2. Enablement

Under 35 U.S.C. § 112(a), enablement is separate and distinct from the written description requirement. *Ariad*, 598 F.3d at 1344. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). "[A] patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention." *Enzo Biochem, Inc. v. Calgene, Inc*., 188 F.3d 1362, 1371 (Fed. Cir. 1999). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors, referred to as the *Wands* factors, include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

Similar to its arguments regarding written description, Petitioner's arguments that the challenged claims are not enabled are based on its assertion that the claims are generally directed to a genus (arbitrary methods of interrogation), whereas the specification only discloses a single species (namely, the use of an acoustic-echo technique for interrogating a sample to determine viscoelastic properties or hemostatic parameters). *See* Pet. 40, 42, 44–45, 55; *see also* Pet. 54 (arguing that the breadth of the claims (*Wands*

factor 8) supports its position on enablement). In view of the purported lack of disclosure in the '144 patent, Petitioner argues that a person of ordinary skill in the art "would not have viewed the inventors of the '144 patent as having enabled or contemplated interrogation techniques for determining a viscoelastic property other than through the use of the disclosed acoustic-echo technique." *See* Pet. 40; *see also* Pet. 42, 44–45 (containing similar language).

Petitioner also argues that the challenged claims are not enabled because "[w]ithout specifying a particular technique for evaluating hemostasis, it is unknown what quantity of experimentation is necessary." Pet. 53. After reproducing several paragraphs from the LaDuca Declaration in the Petition, Petitioner argues that the '144 patent provides "no guidance" regarding how to make or use the invention (*Wands* factor 2), and no working examples (*Wands* factor 3). *Id.* at 53–54.

Patent Owner contends "the teachings concerning TEG, ROTEM, and acoustic methods, along with the knowledge of a [person of ordinary skill in the art] show that the inventors described and enabled more than just interrogation by a single method." Prelim. Resp. 2. Patent Owner further argues that Petitioner's arguments and Dr. LaDuca's opinions are flawed because they are based on the idea that "the patent specification must enable any interrogation system imaginable over the lifetime of the patent." Prelim. Resp. 30–31. According to Patent Owner, such assertions "disregard well-settled precedent that rejects that standard." Prelim. Resp. 30 (citing *Epistar Corp. v. International Trade Com'n*, 566 F.3d 1321, 1336 (Fed. Cir. 2009)).

Patent Owner also argues that Dr. LaDuca never testifies that any particular interrogation technique would require undue experimentation, and

never provides evidence that the experimentation required would be anything other than routine. Prelim. Resp. 33. Patent Owner notes that Dr. LaDuca acknowledges that "some technical features of evaluating hemostasis may be straightforward," and argues that, at most, Dr. LaDuca states that "a particular technique **may require experimentation** and creativity beyond" the ability of a person of ordinary skill in the art. Prelim. Resp. 33 (quoting Ex. 1002 ¶ 121). According to Patent Owner, however, "the potential that some technique may exist that requires undue experimentation does not render a claim invalid." Prelim. Resp. 33–34 (citing *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569 1576 (Fed. Cir. 1984)).

We agree with Patent Owner that Petitioner fails to demonstrate sufficiently that the challenged claims are not enabled. First, for the reasons discussed above, we determine that the '144 patent discloses more than just a single method of interrogating a sample to determine a viscoelastic property or hemostatic parameter. Thus, Petitioner's enablement arguments, which are based on the opposite assertion, are unavailing. Moreover, to the extent Petitioner's enablement arguments are based on a lack of written description support for certain claim elements (e.g., Pet. 54–55), those arguments are not persuasive in view of our determination that there is written description support for the challenged claims in the '144 patent specification.

Next, Petitioner presents only a cursory discussion of the *Wands* factors, and relies on conclusory testimony from Dr. LaDuca that the claims would require "experimentation that typically goes beyond routine experimentation," such as "multiple iterations, prototypes, and refinements."

Pet. 52–53 (citing Ex. 1002 ¶¶ 119–123). Given the conclusory nature of Dr. LaDuca's testimony regarding the enablement of the challenged claims, and the lack of analysis underlying his opinions, we give it little weight. *See* 37 C.F.R. § 42.65 (2019) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Even if we were to accept Dr. LaDuca's opinions, his statements do not allow us to determine exactly what kind of experimentation would be necessary, whether it would be routine, or whether it would be extensive, and if so, how extensive. *See*, *e.g.*, Ex. 1002 ¶ 123 (referring to the "possibility of undue experimentation"); *see also* Pet. 53 (arguing that the amount of experimentation is "unknown"). Moreover, the need for "multiple iterations, prototypes, and refinements," alone does not constitute undue experimentation, as even "a considerable amount of experimentation is permissible, if it is merely routine." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *see also* Ex. 1002 ¶ 121.

Further, statements in the Petition and Dr. LaDuca's Declaration about the knowledge of a person of ordinary skill in the art and the overall state of the art are inconsistent with, and rebut, Petitioner's arguments and Dr. LaDuca's conclusions regarding enablement. For example, with regard to the relative skill in the art (*Wands* factor 6), Dr. LaDuca states that a person of ordinary skill in the art would have, among other things, "a skill set to contribute to the design of tests and systems for hemostasis diagnostics including helping define requirements for new products, including specification of new structure, including computer processor functional requirements" and "an ability to critically assess existing technology and

appreciate basic modifications to, or extensions of, such technology." Ex. 1002 ¶ 96.

Regarding the state of the art, Petitioner states that "the [state of the art] would provide context to a [person of ordinary skill in the art] to better understand the operation of the interrogation and detection systems in TEM as well as data processing and analysis aspects of TEM." Pet. 66. Petitioner also states that a person of ordinary skill in the art would "understand TEM . . . to include a processor for interrogation and data analysis (including for performing measurements in parallel and generating clot-firmness curves) based on context provided by the [state of the art]." Pet. 73; *see also* Pet. 71 (arguing that a person of ordinary skill in the art "would recognize that most any control apparatus that performs the stated functions of 'measurement' (including, 'controlling measurement' and 'collecting data'), 'data analysis,' and 'user interaction' would use a processor (e.g., a microprocessor, CPU etc.) to implement and/or control such functions").

These statements support Patent Owner's argument that "[t]he teachings of the '144 patent coupled with the knowledge of a [person of ordinary skill in the art] would allow a [person of ordinary skill in the art] to implement different testing techniques and associated processing of the data received therefrom without undue experimentation." Prelim. Resp. 22. Dr. LaDuca's statement that "some technical features of evaluating hemostasis may be straightforward," also supports Patent Owner's arguments. Ex. 1002 ¶ 121.

In view of the foregoing, we determine that Petitioner has not met its burden, even at this preliminary stage of the proceeding, of demonstrating

that the ’144 patent specification (or the ’398 application) lacks an enabling disclosure for the challenged claims.

IV. CONCLUSION

For all of the foregoing reasons, we are not persuaded Petitioner has satisfied its burden to prove that the ’144 patent specification (or the ’398 application) fails to provide sufficient written description support and enabling disclosure for the challenged claims. We, therefore, determine that the ’144 patent is entitled to the benefit of the filing date of the ’398 application (February 12, 2012) and, thus, the ’144 patent is not eligible for post-grant review.

V. ORDER

For the reasons given, it is hereby

ORDERED that the Petition for post-grant review is *denied.*

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