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Paper 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

B.R.A.H.M.S. GMBH,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

Case PGR2016-00018
Patent 9,091,698 B2

Before TONI R. SCHEINER, LORA M. GREEN, and BRIAN P. MURPHY, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

DECISION
Institution of Post Grant Review
37 C.F.R. § 42.208

I. INTRODUCTION

B.R.A.H.M.S. GmbH ("Petitioner") filed a Petition requesting post grant review of claims 1–12 of U.S. Patent No. 9,091,698 (Ex. 1001, "the '698 patent"). Paper 1 ("Pet."). Becton, Dickinson and Company ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 324.

To institute a post grant review, we must determine whether the information presented in the Petition, "if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). Upon consideration of the Petition and the Preliminary Response, for the reasons set forth below, we determine that the evidence and arguments presented in the Petition are sufficient to satisfy the "more likely than not" standard regarding the asserted unpatentability of claims 1–12 in the '698 patent. Therefore, we authorize a post grant review to be instituted as to those claims.

Our determinations at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to patentability of claims for which post grant review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Proceedings

Petitioner and Patent Owner do not identify any related matters. Pet. 1; Paper 5, 1.

B. The '698 Patent

The '698 patent, titled "Advanced Detection of Sepsis," issued July 28, 2015, from U.S. application Ser. No. 14/203,367 ("the '367 application"), filed March 10, 2014. Ex. 1001. The '367 application is a continuation of U.S. application Ser. No. 12/935,727 ("the '727 application"), filed January 26, 2011 (now U.S. Patent No. 8,669,113 ("the '113 patent")), which is a national stage application of International Application No. PCT/US2009/002065, filed April 2, 2009. *Id.* at 1:5–13; Ex. 1008. The international application claims benefit of U.S. Provisional Application No. 61/123,071, filed April 3, 2008. *Id.* Because it was filed after March 16, 2013, the '367 application is an AIA (first-inventor-to-file) application; the '727 application, filed before that date, is a pre-AIA (first-to-invent) application.[1]

For the reasons given in Section II C. and D. below, we determine that claims 1-12 are not entitled to an effective filing date earlier than March 10, 2014 and, therefore, are eligible for post-grant review under 35 U.S.C. § 321 *et seq.*

The '698 patent is directed to a method for the early detection of sepsis, a disease condition that results from "an interaction between a pathogenic microorganism and the host's defense system that triggers an excessive and dysregulated inflammatory response in the host." *Id.* at 1:23–35. Sepsis follows a well-described progression from systemic inflammatory response syndrome ("SIRS")-negative, to SIRS-positive, to sepsis, which may progress to severe sepsis, septic shock, multiple organ

[1] *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA").

dysfunction, and death. *Id.* at 1:41–45. The '698 patent describes several embodiments for early detection of sepsis, i.e., prior to overt symptoms indicating a clinically significant infection, to permit timely prophylactic treatment. *Id.* at 2:33–39.

One embodiment disclosed by the '698 patent comprises the steps of measuring i) an amount of lysophosphatidylcholine ("LPC") in fluid or tissue of an SIRS-positive subject and ii) clinical markers of the subject, at a plurality of time points, for use in combination to detect sepsis. *Id.* at 2:47–3:5. Figure 1 depicts that embodiment of the invention and is reproduced below.

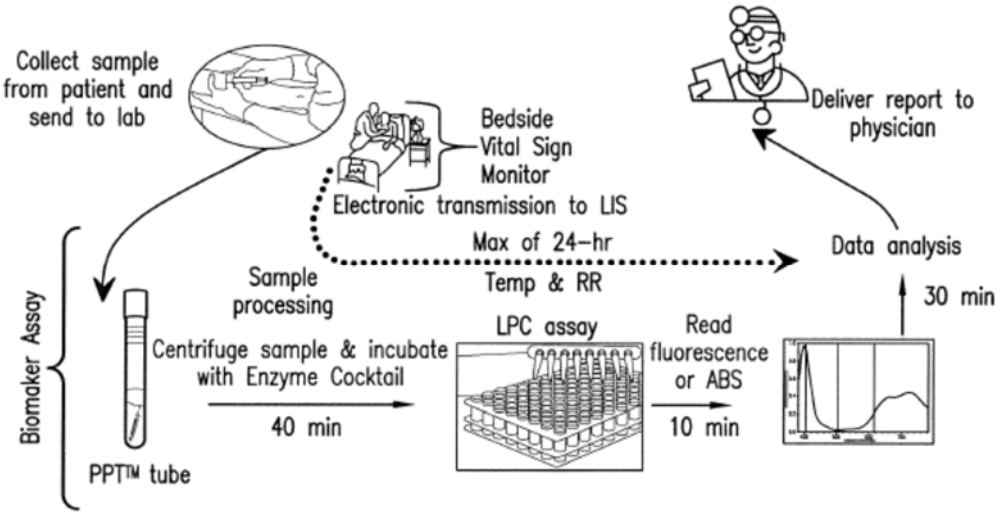

Figure 1, above, depicts a blood sample from a patient being assayed for LPC amount, and clinical markers, such as the patient's temperature and respiratory rate, being measured using a vial sign monitor. *Id.* at 7:56–64, 14:34–43, 52:7–9, 52:25–30. The marker values for LPC, temperature, and respiratory rate are analyzed and used to detect sepsis in the patient, for example, by determining the probability of sepsis. *Id.* at 39:15–19. The combination of LPC, temperature, and respiratory rate marker values

provides greater accuracy in predicting sepsis compared to the use of LPC values alone. *Id.* at 53:7–32. The '113 patent claims LPC-based methods for detecting sepsis. Ex. 1008, 67:37–68:63.

The '698 patent claims an alternate embodiment that relies on measurements of the biomarker procalcitonin ("PCT"). Ex. 1001, 7:18–20. The method claimed in the '698 patent includes the steps of measuring i) an amount of PCT in fluid or tissue of an SIRS-positive subject and ii) one or more clinical markers of the subject to detect sepsis, at a plurality of time points. *Id.* at 67:28–68:3. Measuring an increased amount of PCT over a 24-hour interval is used to detect sepsis in the subject. *Id.*

C. Illustrative Claims

Petitioner challenges claims 1–12 of the '698 patent. Independent claim 1 and dependent claims 2 and 8 are illustrative and reproduced below:

> 1. A method for the advanced detection of sepsis in a SIRS-positive subject, comprising the steps of:
>
> (a) measuring at a plurality of time points, prior to laboratory confirmation of a clinically significant infection causative of sepsis, an amount of procalcitonin in fluid or tissue of the subject; and
>
> (b) measuring at a plurality of time points, prior to laboratory confirmation of a clinically significant infection causative of sepsis, one or more clinical markers of the subject, to detect sepsis in the subject;
>
> wherein an increase in the amount of procalcitonin from a previous amount over a 24 hour interval detects sepsis in the subject.
>
> 2. The method of claim 1, wherein the one or more clinical marker(s) are selected from the group consisting of respiratory rate, body temperature, heart rate, systolic blood pressure, diastolic blood pressure, mean artery pressure, white blood cell count, monocyte count, lymphocyte count, granulocyte count,

> neutrophil count, immature neutrophil to total neutrophil ratio, platelet count, serum creatinine concentration, urea concentration, lactate concentration, glucose concentration, base excess, pO_1 and HCO_3^- concentration.
>
> 8. The method of claim 2, wherein a body temperature greater than 38°C. detects sepsis.

D. Asserted Grounds of Unpatentability

Petitioner advances nine grounds of unpatentability in relation to the challenged claims in the '698 patent. Pet. 11–12.

Reference[s]	Statutory Basis	Challenged Claims
n/a	§ 112(a), lack of written description	1–12
n/a	§ 112(a), lack of enablement	1–12
'113 Patent (Ex. 1008)[2]	§ 102(a)(1)	1–12
'113 Patent alone, or '113 Patent and the U-G Reference (Ex. 1005)[3] or Harbarth (Ex. 1006)[4]	§ 103	1–12

[2] U.S. Patent No. 8,669,113, issued March 11, 2014, from the '727 application filed January 26, 2011 ("'113 Patent"). Ex. 1008.
[3] Uettwiller-Geiger, Denise L., *Clinical Applications of Procalcitonin (PCT)*, Journal of Clinical Ligand Assay, 30(1-2):20–28 (Spring-Summer 2007) ("U-G Reference"). Ex. 1005.
[4] Harbarth, Stephan et. al., *Diagnostic Value of Procalcitonin, Interleukin-6, and Interleukin-8 in Critically Ill Patients Admitted with Suspected Sepsis*, Amer. J. Resp. and Critical Care Medicine, 164:396–402 (2001) ("Harbarth"). Ex. 1006.

Reference[s]	Statutory Basis	Challenged Claims
U-G Reference	§ 102(a)(1)	1–12
Harbarth	§ 102(a)(1)	1–12
Balci (Ex. 1007)[5]	§ 102(a)(1)	1–12
Bohuon (Ex. 1004)[6] alone, or Bohuon and the U-G reference or Harbarth	§ 103	1–12
n/a	§ 112(b), indefiniteness	1–12

Petitioner supports its challenge with the Declaration of Dr. Philipp Schuetz. Ex. 1002.

II. ANALYSIS

A. Claim Construction

In a post grant review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 200(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary

[5] Balci, Canan, et. al., *Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit*, Critical Care, 7 (1):85–90 (2003) ("Balci"). Ex. 1007.
[6] U.S. Patent No. 5,639,617 to Bohuon, issued June 17, 1997 ("Bohuon"). Ex. 1004.

skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner offers explicit constructions of several claim terms. Pet. 12–18. Patent Owner does not propose any explicit constructions, but includes arguments bearing on claim construction in its substantive response to Petitioner's asserted grounds of unpatentability. Prelim. Resp. 24 n.3. On the present record, we determine that only the following claim terms require explicit construction for purposes of this Decision. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (citation omitted).

1. "advanced detection of sepsis"

Petitioner acknowledges that the preamble phrase "advanced detection of sepsis" is defined by lexicography in the '698 patent. Pet. 12 (citing Ex. 1001, 14:1–6). Petitioner then argues that "advanced detection of sepsis" equates with "early detection of sepsis" for purposes of this proceeding. *Id.* Patent Owner does not address the argument.

The quoted claim phrase appears in the preamble of claim 1: "A method for the advanced detection of sepsis in a SIRS-positive subject, comprising the steps of." The portion of the preamble reciting "a SIRS-positive subject" provides antecedent basis for the recitation in step 1(a) of measuring an amount of PCT "in fluid or tissue of the subject" and for the recitation in step 1(b) of measuring "one or more clinical markers of the subject." In contrast, the phrase "advanced detection of sepsis" does not

provide antecedent basis for any aspect of the method steps recited in claim 1. Therefore, we determine the preamble phrase "advanced detection of sepsis" is not a substantive limitation of the method recited in claim 1. *See TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323–24 (Fed. Cir. 2015) (portion of preamble that "provides a necessary structure for claim 1 does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention").

Claim 7 depends from claim 1 and recites "wherein the advanced detection is at least 12 hours prior to the onset of sepsis." To the extent the preamble phrase "advanced detection of sepsis" provides antecedent basis for the "wherein" clause in claim 7, we adopt the definition provided by lexicography in the '698 patent: "detection of sepsis, or likelihood of development of clinical manifestations sufficient to support a clinical suspicion of sepsis, that is, prior to the onset of overt signs indicative of a clinically significant infection, prior to the development of such clinical manifestations." Ex. 1001, 14:1-6.

2. "an increase in the amount of procalcitonin from a previous amount over a 24-hour interval"

Claim 1 of the '698 patent concludes with a "wherein" clause that recites "an increase in the amount of procalcitonin from a previous amount over a 24-hour interval." Petitioner asserts that, due to a lack of guidance in the '698 patent, the quoted phrase should be construed to mean "any increase in the amount of PCT over any previous measurement of PCT within a 24 hour interval." Pet. 18. Patent Owner responds that a person of

ordinary skill in the art ("POSA")[7] would have understood the recited "increase" in PCT does not encompass a statistically irrelevant increase in PCT, for example an increase in PCT that falls within the expected variability of the method used to measure PCT. Prelim. Resp. 25.

Petitioner is correct that the '698 patent does not describe or quantify the increase in PCT levels over a 24-hour interval to detect sepsis, even in view of the knowledge of a POSA. Therefore, based on the present record, and considering the "wherein" clause in the context of claim 1 as a whole, we construe the phrase "an increase in the amount of procalcitonin from a previous amount over a 24-hour interval" as "a measured increase in the amount of procalcitonin in fluid or tissue of the subject over a 24-hour interval."

B. Post Grant Review Eligibility

Post-grant reviews are available only for patents "described in section 3(n)(1)" of the AIA. AIA § 6(f)(2)(A); *see also Arkema Inc. v. Honeywell Int'l Inc.*, Case PGR2016-00011, slip op. at 15 (PTAB Sept. 2, 2016). These patents are those that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or

[7] Petitioner argues that a POSA at the time of the claimed invention would have been a medical clinician with an M.D., or equivalent, and at least two years of experience diagnosing and treating infectious diseases, particularly in an emergency room setting, so as to understand the issues and complications in the use of diagnostic markers related to systemic inflammation and sepsis. Pet. 20–21 (citing Ex. 1002 ¶ 18). Patent Owner adopts Petitioner's definition of a POSA only for purposes of its Preliminary Response. Prelim. Resp. 17 n.2. We adopt and apply Petitioner's definition of a POSA, where appropriate, for purposes of this Decision.

after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. AIA § 3(n)(1). Because the AIA was enacted on September 16, 2011, post-grant reviews are available only for patents that issue from applications that at one point contained at least one claim with an effective filing date on or after March 16, 2013, with "effective filing date" having the definition given to it by 35 U.S.C. § 100(i). Our rules require that each petitioner for post-grant review certify that the challenged patent has an effective filing date that renders the patent available for post-grant review. 37 C.F.R. § 42.204(a) ("The petitioner must certify that the patent for which review is sought is available for post-grant review . . . .").

The effective filing date of an application for a patent on an invention is "the filing date of the earliest application for which the . . . application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c)." 35 U.S.C. § 100(i)(1)(B). In the event that the application is not entitled to any earlier filing date or right of priority, the effective filing date is "the actual filing date of the . . . application for the patent containing a claim to the invention." 35 U.S.C. § 100(i)(1)(A).

Petitioner contends that the '698 patent is available for post-grant review because at least one of claims 1–12 is not entitled to an effective filing date earlier than the March 10, 2014 filing date of the '367 application. Pet. 9, 18. According to Petitioner, Patent Owner's earlier-filed priority applications do not describe or enable the claimed subject matter of an "increase" in PCT "over a 24-hour interval," as recited in the "wherein" clause of claim 1. Pet. 19–20, 21–48. Patent Owner disagrees with

Petitioner's analysis and states that the earlier-filed '727 application, which issued as the '113 patent, is sufficient to establish an effective filing date of April 2, 2009. Prelim. Resp. 2–4.

Based on the present record, for the reasons given below, we determine that Petitioner has established sufficiently that claims 1-12 are not entitled to an effective filing date earlier than March 10, 2014 and, therefore, are eligible for post-grant review under 35 U.S.C. § 321 *et seq.*

C. Asserted Lack of Written Description

1. The Parties' Arguments

Petitioner argues that the '698 patent specification does not describe an "increase" in PCT "over a 24-hour interval," as recited in the "wherein" clause of claim 1. Pet. 19–20, 47–48 (citing Ex. 1002 ¶¶ 81–85). Petitioner notes, in particular, that the '698 patent describes only that "a difference in the amount of one or more biomarkers measured at a plurality of time points detects sepsis," and that "one or more biomarkers measured at a plurality of time points correlated directly with detection of sepsis." *Id.* at 47 (quoting Ex. 1001, 7:5–17). Petitioner argues, therefore, that the description of a "difference" in amount, or even a direct correlation, in an unspecified biomarker is insufficient to describe an "increase" in the amount of the specific biomarker PCT "over a 24-hour interval" to detect sepsis. *Id.* at 48.

Patent Owner responds by citing Petitioner's argument that the '113 patent, which shares the same specification as the '698 patent, anticipates claims 1–12. Prelim. Resp. 51–52 (citing Pet. 50–51). Patent Owner emphasizes that Petitioner, in support of Ground 3, expressly acknowledges that the '113 patent ('727 application) "'discloses that PCT, a biomarker, increases with detection of sepsis.'" *Id.* (quoting Pet. 51). Patent Owner

argues, therefore, that Petitioner effectively has admitted the '698 patent specification describes all claim limitations in the '698 patent, including the "wherein" clause in claim 1. *Id.* at 52. Patent Owner also argues that a POSA would have recognized that PCT correlates directly with sepsis, and that Example 1 in the '698 patent discloses PCT was measured at 24-hour intervals to detect sepsis. *Id.* at 54–56.

2. Analysis

The test for written description support is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). When examining the written description support for a claimed invention, the exact terms appearing in the claim "need not be used *in haec verba*." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). With the above principles in mind, we analyze whether the '698 patent specification provides sufficient written description support for the "wherein" clause in claim 1 of the '698 patent.

Based on the present record at this stage of the proceeding, we are persuaded by Petitioner's argument. First, we view Petitioner's anticipation contention based on the '113 patent (Ground 3) as a separate argument, rather than a binding "admission" of the sufficiency of written description support for the "wherein" clause. Second, the portions of the '698 patent cited by the parties do not describe measuring an increase in the amount of PCT over a 24-hour interval to detect sepsis. The description of a "difference" in amount, or even a direct correlation, in an unspecified biomarker is insufficient to describe an "increase" in the amount of the

specific biomarker PCT within the specified time frame to detect sepsis. Ex. 1001, 7:1–55. A comparison to the '698 patent's description regarding the use of LPC to detect sepsis is instructive.

The '698 patent describes how increasing and decreasing amounts of LPC are inversely correlated to detecting sepsis:

> In particular embodiments, one amount of lysophosphatidylcholine [LPC] measured is 0, 12, 24, 36 or 48 hours prior to the manifestation of overt clinical symptoms currently viewed as indicative of a clinically significant infection. In particular embodiments, increasing amounts of lysophosphatidylcholine indicate decreased likelihood of onset of sepsis, and *decreasing amounts of lysophosphatidylcholine detect sepsis or indicate increased likelihood of onset of sepsis*.

Ex. 1001, 3:55–63 (emphasis added). Similarly, the '698 patent describes how measuring a second amount of LPC "that is less than 95%, 90%, 80%, 75%, 50%, 33%, 25%, 20% or 10% of a previous amount," detects sepsis. *Id.* at 31:23–25. The '698 patent does not contain a comparable description that relates an increasing amount of PCT to an increased likelihood of detecting sepsis. Inferring that a POSA would have known there was a direct correlation between increasing PCT levels and detection of sepsis, as argued by Patent Owner, would be to supply the description of what Patent Owner asserts to be a novel element of the claimed invention. Prelim. Resp. 58–59 ("[T]he claimed method evaluates the *change* in the amount of PCT over a 24-hour interval, where an *increase* is indicative of sepsis. In this way the claimed method is fundamentally different than methods in the cited references.").

Patent Owner is correct that Example 1 of the ’698 patent describes taking blood samples for measuring the biomarkers, which include PCT, every 24 hours. Ex. 1001, 52:8–9. Example 1 and Table 1, however, do not describe an increase in PCT over a 24-hour interval as detecting sepsis. Example 1 states only that “Table 1 provides the performance of out-of-bag cross-validation of logistic regression results using . . . Procalcitonin (PCT).” *Id.* at 52:58–61. Patent Owner does not cite a description in the ’698 patent that relates the stated regression results to an increase in PCT levels over a 24-hour interval. The data in Table 1 indicates only the relative accuracy of the forecasting algorithm, as a percentage, when using PCT or PCT, Temperature, and Respiratory Rate to detect sepsis.

Based on the present record, we determine Petitioner has provided sufficient argument and evidence to establish it is more likely than not that the ’698 patent does not provide a sufficient written description of “an increase in the amount of PCT levels from a previous amount over a 24 hour interval detects sepsis in the subject,” as recited in the “wherein” clause of claim 1. 35 U.S.C. § 112(a).

D. Asserted Lack of Enablement of Claims 1–12

1. The Parties’ Arguments

Petitioner argues the ’698 patent specification would not have enabled a POSA to detect sepsis in the subject by measuring an increase in the amount of PCT over a 24-hour interval. Pet. 19, 21–46 (citing Ex. 1002 ¶¶ 47–55, 58–78). Petitioner argues, for example, that the ’698 patent does not enable a POSA to determine i) a PCT threshold level to distinguish sepsis from a non-sepsis systemic inflammatory response, particularly at PCT levels below conventional thresholds, ii) the amount of increase in PCT

levels needed to detect sepsis, iii) how to exclude non-sepsis factors that can cause an increase in PCT levels, such as trauma, surgery, and viral infection, and iv) how the recited "one or more clinical markers" are combined with the measurement of increased PCT levels over a 24-hour interval to detect sepsis in the subject. *Id.* at 19. Petitioner argues, therefore, that the '698 patent specification does not satisfy the enablement requirement of 35 U.S.C. § 112(a) as to claims 1–12. *Id.* at 20.

Patent Owner responds to each of Petitioner's arguments in detail, and emphasizes the description of Example 1 in support of the argument that claims 1–12 are fully enabled by the '698 patent specification. Prelim. Resp. 2–3, 8–50. Patent Owner argues that Example 1 "illustrates that PCT levels measured at 24-hour intervals can be used for the advanced detection of sepsis in SIRS-positive subjects, alone or in combination with clinical markers such as body temperature and respiratory rate." *Id.* at 3. Patent Owner also argues that Petitioner's arguments do not take account of the '698 patent specification and Example 1 in view of the knowledge of a POSA. *Id.* at 20–22. On the present record, we are persuaded by Petitioner's arguments and evidence.

2. Analysis

"Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). Undue experimentation 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." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors are merely illustrative; an individual case must turn on its own facts. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

We agree with Petitioner that Example 1 and Table 1do not provide an enabling description of how an *increase* in PCT levels over a 24-hour interval, either alone or in combination with clinical markers such as body temperature and respiratory rate, is used to detect sepsis. The measured PCT levels in the example are not reported or described. An increase in PCT levels over a 24-hour interval is not reported or described. The potential use of reference PCT levels to detect sepsis also is not described. Even if we were to credit Patent Owner's position that a threshold PCT value is not recited or required as part of the claimed method (Prelim. Resp. 9–20), we agree with Petitioner that there are insufficient guideposts in the '698 patent specification, including Example 1, to enable a POSA to use a measured increase in PCT levels over a 24-hour interval to detect sepsis in the subject.

The '698 patent specification, including Example 1, does not provide a quantifiable measure or description of the amount of increase in PCT levels measured over a 24-hour interval that would be used to detect sepsis. In comparison, the method of measuring a decrease in LPC levels to detect sepsis is described in the '698 patent as "a second amount that is less than 95%, 90%, 80%, 75%, 50%, 33%, 25%, 20% or 10% of a previous amount." Ex. 1001, 31:23–26. The corresponding "wherein" clause in claim 1 of the '113 patent recites that "a second amount is less than 75% of a previous amount over a 24 hour interval." Ex. 1008, 68:13–16.

Patent Owner has not cited a comparable enabling description of the amount of PCT increase, measured over a 24-hour interval, to be used to detect sepsis in the subject. It is not a question of a POSA being "confounded" by the difference between a directly correlated biomarker, such as PCT, and a biomarker with levels bearing an inverse correlation to sepsis, i.e. measuring a decrease in LPC levels over 24 hours. Prelim. Resp. 21–22. Rather, the question is whether the '698 patent provides an enabling description, with sufficient guideposts to enable a POSA to use a measured increase in PCT levels over a 24-hour interval to detect sepsis in the subject. In the absence of a description of any relevant PCT threshold levels, quantifiable increases in PCT levels over a 24 hour interval, or exclusions of non-sepsis causes of increased PCT levels (Pet. 34–39), on the present record we are persuaded by Petitioner's non-enablement argument.

Based on the present record, we determine Petitioner has provided sufficient argument and evidence to establish it is more likely than not that the '698 patent does not enable a POSA to use "an increase in the amount of PCT levels from a previous amount over a 24 hour interval [to] detect[] sepsis in the subject," as recited in the "wherein" clause of independent claim 1. 35 U.S.C. § 112(a).

For the reasons given in Section II C. and D. above, we further determine that claims 1–12 are not entitled to an effective filing date earlier than March 10, 2014, and, therefore, are eligible for post-grant review under 35 U.S.C. § 321 *et seq.*

E. Asserted Anticipation of Claims 1–12 by the '113 Patent

Petitioner argues that the '113 patent anticipates claims 1–12 of the '698 patent. Pet. 49-53. Petitioner argues that the '113 patent, which shares

the same specification as the '698 patent apart from claims of priority, discloses all the limitations in claims 1–12, including the "wherein" clause in claim 1. *Id.* 51–52 (citing Ex. 1008, 7:5–8 ("a difference in the amount of one or more biomarkers measured at a plurality of time points detects sepsis")). Petitioner argues that its anticipation argument is not inconsistent with its insufficient written description and non-enablement arguments, because a prior art reference under 35 U.S.C. § 102 does not need to demonstrate utility, i.e. teach a POSA how to "use" an invention. *Id.* at 49–50 (citing *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005)). Patent Owner responds that Petitioner has failed to carry its burden because Petitioner has allegedly "admitted" that the '698 patent contains an enabling written description of the "wherein" clause in claim 1. PO Resp. 51-52, 57-58. We disagree with both parties.

For the reasons given in Sections II.C. and II.D., above, the '698 patent is not entitled to an effective filing date earlier than the March 10, 2014 filing date of the '367 application. Therefore, the '113 patent is available as prior art under 35 U.S.C. § 102(a)(1), because it qualifies as a printed publication as of its October 8, 2009 Patent Cooperation Treaty publication date. Ex. 1008, (87). The '113 patent does not anticipate claims 1–12 of the '698 patent, however, because the '113 patent does not disclose the "wherein" clause in independent claim 1 of the '698 patent. *See* Sections II.C. and II.D. above; *see also* Pet. 56 ("the '113 patent does not specifically disclose that PCT levels increase with the detection of sepsis"). In short, Petitioner cannot have it both ways.

Therefore, we determine Petitioner has not provided sufficient argument and evidence to establish it is more likely than not that claims 1–12 of the ’698 patent are anticipated by the ’113 patent.

F. Asserted Obviousness of Claims 1–12 over the ’113 Patent alone, the ’113 Patent and the U-G Reference, or the ’113 Patent and Harbarth

Petitioner argues that the subject matter of claims 1–12 of the ’698 patent would have been obvious to a POSA over the ’113 patent alone, the ’113 patent and the U-G reference, or the ’113 patent and Harbarth. Pet. 53–59. Petitioner argues in the alternative, without clearly defining the differences among the three alternative grounds. As stated in Section II.E., above, Petitioner acknowledges the ’113 patent does not disclose the “wherein” clause in claim 1 of the ’698 patent. Therefore, we reject Petitioner’s undeveloped and conclusory assertion that the ’113 patent alone would have rendered the subject matter of claims 1–12 obvious to a POSA. We turn our attention to Petitioner’s two alternative obviousness grounds involving the combinations of the ’113 patent and the U-G Reference or the ’113 patent and Harbarth.

1. The U-G Reference

The U-G Reference is a review article that provides an overview of the clinical use of PCT, including the use of PCT in the diagnosis and treatment of sepsis. Ex. 1005, 20 Col. 1 ¶ 1. The U-G Reference discloses the “consensus” definitions of SIRS and sepsis in a manner consistent with the definitions used in the ’698 patent. *Id.* at 20 Col. 1 ¶ 2, 21 Table 1. The U-G Reference posits that the ideal biomarker for sepsis “would have a high degree of sensitivity allowing for early diagnosis.” *Id.* at 20 Col. 2 ¶ 4.

The U-G Reference recognizes that PCT levels increase dramatically in sepsis patients, such that the "rate of increase of PCT, when bacterial infection is not yet controlled, is generally much higher than the rate of elimination when infection is under control." *Id.* at 21 Col. 1 ¶ 4. The U-G Reference further discloses that measurement of PCT is a valuable marker for identifying sepsis because it differentiates between the presence or absence of bacterial infection and the severity and progression of the disease. *Id.* at 21 Col. 2 ¶ 1, Fig. 1. Figure 1 shows the rate of increase in PCT level over time in sepsis patients. *Id.* The U-G Reference uses several PCT concentration ranges to differentiate healthy people (<0.05 ng/ml), "sepsis uncertain" (0.5–2 ng/ml), and "sepsis confirmed." (≥ 2 ng/ml). *Id.* at 22 Col. 1 ¶ 3, Fig. 2. For the sepsis uncertain population, the U-G Reference recommends the need to take repeat measurements of PCT levels "after 6-24 hours, until a specific diagnosis is identified." *Id.*

2. Harbarth

Harbarth reports clinical data used to assess the diagnostic value of PCT and other markers "in identifying critically ill patients with sepsis." Ex. 1006, 396 Col. 1 ¶ 1. Harbarth reports performing prospective measurements of PCT levels within 12 hours after admission, and daily thereafter, in patients admitted with acute SIRS and suspected infection. *Id.*; *see also id.* at 397 Col. 1 ¶ 3. Harbarth reports that median PCT levels on admission – ng/ml (range) – were "0.6 (0 to 5.3) for SIRS; 3.5 (0.4 to 6.7) for sepsis[;] 6.2 (2.2 to 85) for severe sepsis; and 21.3 (1.2 to 654) for septic shock ($p < 0.001$)." *Id.* at 398 Col. 1 ¶ 2. As a result of the study, Harbarth concludes that "[e]levated PCT concentrations appear to be a promising indicator of sepsis in newly admitted, critically ill patients." *Id.* at 396, Col.

1 ¶ 1. The "elevated" PCT levels are determined based on comparison to a threshold PCT level: "a cutoff point of 1.1 ng/ml detected virtually all septic patients." *Id.* at 400, Col. 2 ¶ 1. Harbarth also reported that increased PCT levels 2 to 4 hours after a bacterial challenge test "may give valuable information long before blood culture results are back." *Id.*

3. Analysis

Petitioner argues that the U-G reference teaches an increased level of PCT as indicative of sepsis, based on repeated PCT measurements after 6-24 hours. Pet. 57. Petitioner concludes, therefore, that the U-G Reference discloses the "wherein" clause in claim 1. *Id.* (citing Ex. 1005, 22 Col. 1 ¶ 3). Petitioner makes a similar argument with respect to Harbarth's disclosure of a threshold cutoff of 1.1 ng/ml PCT as indicating sepsis. *Id.* at 57–58 (citing Ex. 1006, 399–400). Petitioner then provides a claim chart with citations to alleged disclosures of the claim 1 limitations in the '113 patent, the U-G Reference, and Harbarth. *Id.* at 58–59. Petitioner ends the argument with a boilerplate conclusion that "claim 1 is unpatentable as obvious over the '113 patent in combination with Uettwiller-Geiger [U-G Reference] or Harbarth." *Id.* at 59. No further analysis is included.

The Petition is silent with respect to the crucial consideration of whether a POSA would have been motivated to combine the '113 patent and either the U-G or Harbarth references, with a reasonable expectation of success, to achieve the claimed invention. The Petition cites to paragraphs 108–112 of Dr. Schuetz's Declaration in support, but Dr. Schuetz's Declaration merely repeats the statements in the Petition without further analysis. Pet. 55 (citing Ex. 1002 ¶¶ 108–112); Prelim. Resp. 6–7. As the Federal Circuit has explained, "obviousness concerns whether a skilled

artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk–Tek LLC,* 805 F.3d 1064, 1073 (Fed. Cir. 2015); *see also KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007) (stating that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"). In the absence of any such analysis in the Petition and supporting Declaration of Dr. Schuetz, we determine Petitioner has not provided sufficient argument and evidence to establish it is more likely than not that the subject matter of claims 1–12 of the '698 patent would have been obvious to a POSA over the '113 patent and either the U-G Reference or Harbarth.

G. Asserted Anticipation of Claims 1–12 by the U-G Reference

Petitioner contends the U-G Reference anticipates claims 1–12 of the '698 patent. Pet. 59–65. Petitioner explains how each limitation of claim 1 is asserted to be disclosed in the U-G Reference, relying on support in Dr. Schuetz's Declaration. *Id.* (citing Ex. 1002 ¶¶ 113–125). Petitioner includes a claim chart with citations to the U-G Reference disclosures corresponding to each limitation of claim 1. *Id.* at 64. Petitioner also identifies corresponding disclosures for each of dependent claims 2–12. *Id.* at 64–65. As noted in Section II.F.1., above, the U-G Reference discloses the "consensus" definitions of SIRS and sepsis in a manner consistent with those definitions used in the '698 patent. *Compare* Ex. 1005, 20 (Col. 1 ¶ 2), 21 (Table 1), *with* Ex. 1001, 13:7–20, 13:44–47.

Dr. Schuetz points out the U-G Reference's disclosure of using PCT for early diagnosis of sepsis, and the inclusion of PCT in the clinical

assessment of sepsis to "compliment [complement] clinical signs and routine laboratory parameters suggestive of severe infection." Ex. 1002 ¶ 119 (quoting Ex. 1005, 24 (Col. 1 ¶ 1)). Dr. Schuetz goes on to highlight reference to the clinical markers measured using the Acute Physiology and Chronic Health Evaluation (APACHE) II protocol, and the U-G Reference's disclosure that combining the PCT and APACHE indicators "resulted in a predictive level with higher sensitivity and specificity that can aid in determining adequate treatment strategies." *Id.* (citing Ex. 1005, 25 (Col. 1 ¶ 4–Col. 2 ¶ 1)). He opines that the measurement of PCT coupled with such clinical assessments would include the "one or more clinical markers" recited in claim 1. *Id.*

Petitioner further argues that the "wherein" clause of claim 1 is satisfied because the U-G Reference discloses that PCT levels indicative of sepsis can increase over time, with instructions "to repeat the measurement after 6-24 hours, until a specific diagnosis is identified." Pet. 63 (citing Ex. 1005, 22 (Col. 1 ¶ 3)). The U-G Reference discloses that "PCT concentrations can increase up to 1000 ng/ml in patients with sepsis" (Ex. 1005, 22 (Col. 1 ¶ 3)) and that the rate of increase of PCT is much higher when a bacterial infection is not under control (Ex. 1005, 21 (Col. 1 ¶ 4)). Dr. Schuetz opines that the U-G Reference discloses the "wherein" clause limitation in claim 1. Ex. 1002 ¶ 120. Dr. Schuetz further identifies the disclosure of the limitations recited in dependent claims 2–12. *Id.* at ¶¶ 121–125.

Patent Owner argues that the U-G Reference does not anticipate the challenged claims of the '698 patent. Patent Owner provides three reasons in support: the U-G Reference does not disclose 1) using an increase in PCT

levels over a 24-hour interval to detect sepsis, 2) measuring PCT levels at a plurality of time points in a SIRS-positive subject, and 3) the limitations of dependent claims 2–12 arranged as in those claims. Prelim. Resp. 59–63. Based on the present record at this stage of the proceeding, we are persuaded by Petitioner's arguments.

First, Dr. Schuetz's Declaration testimony is unrebutted on the present record. Second, Patent Owner argues that even if a second measurement of PCT is taken within a 24-hour interval according to the protocol disclosed in the U-G Reference, "only the absolute value of the second measure[ment] is used" to detect sepsis by comparison against a particular threshold PCT level. *Id.* at 59–60. Based on the present record, we are persuaded Petitioner has provided adequate evidentiary support for the argument that the U-G Reference discloses a direct correlation between an increase in a patient's PCT level measured over a 24-hour interval and the early detection of sepsis. We are not persuaded that the reference to threshold ranges of PCT blood concentrations necessarily precludes a determination that the "wherein" clause of claim 1 is disclosed in the U-G Reference.

Similarly, the asserted disclosure of taking the PCT and clinical marker measurements on an SIRS-positive subject is sufficiently supported, on the present record, with reference to Table 1 in the U-G Reference. The limitations recited in dependent claims 2–12 also are sufficiently identified and supported by reference to specific portions of the U-G Reference and the Declaration of Dr. Schuetz. The parties will have an opportunity to further develop the record regarding the disputed disclosures during the trial of this case.

For the reasons given above, we determine Petitioner has provided sufficient argument and evidence to establish it is more likely than not that claims 1–12 of the '698 patent are anticipated by the U-G Reference.

H. Asserted Anticipation of Claims 1–12 by Harbarth

Petitioner asserts that Harbarth anticipates claims 1–12 of the '698 patent. Pet. 65–68. With regard to the "wherein" clause of claim 1, Petitioner asserts that "the clear implication is that an increase in PCT amounts above the cut-off value indicates sepsis." *Id.* at 67 (citing Ex. 1006, 399 (Col. 2 ¶ 3), 400 (Col. 2 ¶ 1)). We agree with Patent Owner that Petitioner has not provided sufficient evidence to establish that Harbarth discloses the claimed increase in the amount of PCT over a 24–hour interval. Prelim. Resp. 65–66.

Harbarth emphasizes decreasing "elevated" PCT levels below a threshold cut-off of 1.1 ng/ml as an indicator of a positive clinical outcome, rather than disclosing an increase in PCT levels as an early predictor of sepsis. Ex. 1006, 399 (Col. 2 ¶ 3) ("PCT levels decreased under the cutoff of 1.1 ng/ml within 8 d in all survivors except for one (Fig. 3, *panel A*)"), 400 (Col. 2 ¶ 1) ("[A] cutoff point of 1.1 ng/ml detected virtually all septic patients. . . . [A] greatly decreased PCT level indicates a favorable clinical evolution."). As Patent Owner notes, the Harbarth study was a follow-up study of patients with severe sepsis and septic shock, rather than a clinical study for early detection of sepsis prior to clinical confirmation. Prelim. Resp. 65 (citing Ex. 1006, 399 (Col. 2 ¶ 3)). Patent Owner also correctly notes that Petitioner does not explain how Harbarth's disclosure of a bacterial challenge test over a 2-to-4 hour time interval satisfies the recited "wherein" clause increase in the PCT amount over a "24 hour interval." *Id.*

at 66. We further agree that the Declaration of Dr. Schuetz does not provide additional insight, because it repeats the Petition arguments without additional explanation or evidence. *Id.* (citing Ex. 1002 ¶ 128).

For the reasons given above, we determine Petitioner has not provided sufficient argument and evidence to establish it is more likely than not that claim 1 of the '698 patent is anticipated by Harbarth. By virtue of their dependency, claims 2–12 include the same limitations as independent claim 1. Therefore, for the same reasons discussed above with respect to independent claim 1, we conclude Petitioner has not established it is more likely than not that dependent claims 2–12 are anticipated by Harbarth.

I. Asserted Anticipation by Balci

Petitioner asserts that Balci anticipates claims 1–12 of the '698 patent. Pet. 68–71. With regard to the "wherein" clause of claim 1, Petitioner asserts that Balci's discussion of another PCT study, reported by Al-Nawas, "clearly indicat[es] that an increase in the amount of PCT 'detects sepsis,' as the claimed method recites." *Id.* at 70 (citing Ex. 1007, 88 Col. 2 ¶ 2–89 Col. 1 ¶ 1). Balci states that "Al-Nawas and coworkers [ ] reported higher PCT levels in patients with clinically documented infection than in those fulfilling the criteria for SIRS." Petitioner does not provide any further explanation of the quoted material or illuminate how it would satisfy the "wherein" clause of claim 1.

Balci discloses a method of determining whether a patient is likely to have sepsis based on whether a single measurement of PCT level is above a threshold cutoff of 2.415 ng/ml. Ex. 1007, 87 Col. 2 ¶ 3, 88 Table 3. As Patent Owner correctly notes, Petitioner asserts only that Balci discloses a method for early detection of sepsis based on the amount of PCT measured,

rather than any change or increase in the amount of PCT measured. Prelim. Resp. 68 (citing Pet. 69). We further agree with Patent Owner that Petitioner does not demonstrate how Balci "clearly indicat[es]" an increase in the amount of PCT detects sepsis as recited in the "wherein" clause of claim 1. *Id.* at 68–69. Balci is silent regarding whether more than one PCT measurement is made over a given time period.

For the reasons given above, we determine Petitioner has not provided sufficient argument and evidence to establish it is more likely than not that claim 1 of the '698 patent is anticipated by Balci. By virtue of their dependency, claims 2–12 include the same limitations as independent claim 1. Therefore, for the same reasons discussed above with respect to independent claim 1, we conclude Petitioner has not established it is more likely than not that dependent claims 2–12 are anticipated by Balci.

J. Asserted Obviousness of Claims 1–12 over Bohuon (the '617 Patent) alone or with the U-G Reference or Harbarth

Petitioner asserts that the subject matter of claims 1–12 would have been obvious to a POSA over Bohuon alone or in combination with either the U-G Reference or Harbarth. Pet. 71–75 (citing Ex. 1004). Petitioner acknowledges that Bohuon does not disclose or teach a method for detecting sepsis in a SIRS-positive patient, but argues a POSA would have understood the method to include an SIRS-positive patient. *Id.* at 73. Alternatively, Petitioner relies on either the U-G Reference or Harbarth for this limitation. *Id.* Petitioner also acknowledges Bohuon's disclosure that PCT levels decrease as a result of successful treatment, but argues the inverse would have been true where increasing PCT levels indicate sepsis. *Id.* at 74 (citing

Ex. 1004, 8:1–8). No further analysis of the recited "wherein" clause is included.

We agree with Patent Owner that Petitioner's argument and evidence are insufficient to establish disclosure of the "wherein" clause of challenged claim 1 in Bohuon. Prelim. Resp. 71. Bohuon is not directed to a method that uses a measured increase in PCT levels over a 24-hour time interval to detect sepsis. Moreover, as in the case of Petitioner's obviousness assertion based on the '113 patent and the U-G Reference or Harbarth, the Petition is silent with respect to the crucial consideration of whether a POSA would have been motivated to combine Bohuon with either the U-G or Harbarth reference, with a reasonable expectation of success, to achieve the claimed invention. *Id.* at 71–72. In the absence of any such analysis in the Petition and supporting Declaration of Dr. Schuetz, we determine Petitioner has not provided sufficient argument and evidence to establish it is more likely than not that the subject matter of claims 1–12 of the '698 patent would have been obvious to a POSA over Bohuon and either the U-G Reference or Harbarth.

K. Asserted Indefiniteness of Claims 1–12 under § 112(b)

Petitioner asserts claim 1 is indefinite because there is no clear recitation of how clinical markers are used to detect sepsis. Pet. 76–77. Patent Owner responds that because the "wherein" clause recites only an increase in the amount PCT detects sepsis, the clinical markers are not required. PO Resp. 74–75. We address the merits of this argument below.

We are persuaded by Petitioner's argument and evidence that claim 1 is drafted in such a way as to be internally inconsistent and indefinite,

because it is unclear how the recited measurement of "one or more clinical markers" is used "to detect sepsis in the subject." Pet. 40–41. The first recitation of "to detect sepsis in the subject" is based on the measurement of "one or more clinical markers" in step 1(b) of claim 1. The second recitation of "to detect sepsis in the subject" appears in the "wherein" clause and is based on the measured increase in PCT levels over a 24-hour interval, a point on which Patent Owner agrees. Prelim. Resp. 32–33. We understand Patent Owner's position to be that the measuring step in claim 1(b) is unnecessary "to detect sepsis in the subject." *Id.* at 33–34 ("the use of the measured one or more clinical markers is not recited [in the wherein clause] and is not required."). We are not persuaded by Patent Owner's argument that the inclusion of measuring step 1(b) "to detect sepsis in the subject" is clear, but also unnecessary to detect sepsis in the subject. The fact that Example 1 discloses an example where PCT alone can be used to detect sepsis (Prelim. Resp. 34) does not explain why a measuring step for clinical markers, recited as a step "to detect sepsis in the subject," is supposedly unnecessary in a method for the advanced detection of sepsis.[8] If we were to read claim 1 as a method that requires only increased PCT levels over a

[8] On this record, we agree with Patent Owner's analysis that dependent claims 8–10 require the use of PCT and body temperature or respiratory rate to detect sepsis and are not internally inconsistent or indefinite. Prelim. Resp. 33, 47–50. We also agree with Patent Owner's analysis that "advanced detection" of sepsis in claim 7 would be understood by a POSA to mean making a sepsis determination at least 12 hours prior to conventional clinical manifestations sufficient to support a clinical suspicion of sepsis. *Compare* Pet. 43–44 ("it is unclear how a method to detect sepsis can be performed at least 12 hours prior to the onset of sepsis"), 77 (citing Ex. 1001, 52:7–17), *with* Prelim. Resp. 39–46.

24-hour interval to detect sepsis in the subject, then we would be reading out measuring step 1(b) for measuring one or more clinical markers "to detect sepsis in the subject."[9]

"A claim is indefinite when the boundaries of the protected subject matter are not clearly delineated and the scope is unclear." MPEP § 2173.04. For the reasons given above, we determine Petitioner has established it is more likely than not that claim 1 is indefinite under 35 U.S.C. § 112(b). By virtue of their dependency, claims 2–12 include the same limitations as independent claim 1. Therefore, for the same reasons discussed above with respect to independent claim 1, we determine Petitioner has established it is more likely than not that dependent claims 2–12 are indefinite under 35 U.S.C. § 112(b).

III. CONCLUSION

For the reasons given above, we are persuaded that the arguments and evidence presented in the Petition are sufficient to establish it is more likely than not that claims 1–12 of the '698 patent are unpatentable.

IV. ORDER

[9] By way of comparison, claim 1 of the '113 patent recites steps for measuring LPC levels, two or more clinical markers, and one or more biomarkers. Ex. 1008, 68:13–21. None of the recited measuring steps concludes with the phrase "to detect sepsis in the subject," or the like. The concluding "wherein" clause explicitly incorporates a decrease in LPC, a body temperature > 38°C or < 36°C, a respiratory rate > 20 breaths per minute, and a difference in the amount of one or more biomarkers over a 24-hour interval, to "detect sepsis in the subject."

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 324, a post grant review of the '698 patent is instituted on the following grounds:

Claims 1–12 for lack of written description under 35 U.S.C. § 112(a);

Claims 1–12 for lack of enablement under 35 U.S.C. § 112(a);

Claims 1–12 as anticipated by the U-G Reference under 35 U.S.C. § 102(a)(1); and

Claims 1–12 for indefiniteness under 35 U.S.C. § 112(b);

FURTHER ORDERED that a post grant review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the post grant review is limited to the grounds of unpatentability listed above, and no other grounds of unpatentability are authorized for post grant review.

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