

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANALYTICS FOR LIFE, INC.,
Petitioner,

v.

8825319 CANADA LIMITED,
Patent Owner.

Case IPR2017-01742
Patent 9,131,864 B2

Before JOSIAH C. COCKS, SCOTT A. DANIELS, and
BARRY L. GROSSMAN, *Administrative Patent Judges*.

DANIELS, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Analytics For Life, Inc. (“Petitioner” or “Analytics”) filed a request for an *inter partes* review of claims 1–20 of U.S. Patent No. 9,131,864 B2 (“the ’864 patent”). Paper 1 (“Pet.”). 8825319 Canada Limited (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). We instituted an *inter partes* review of claims 1–20 of the ’864 patent on all of the grounds asserted by Petitioner. Paper 9 (“Dec. Inst.”). Patent Owner filed a Patent Owner Response (Paper 13, “PO Resp.”) and Contingent Motion to Amend (Paper 14, “Mot. Amend”). Petitioner subsequently filed a Reply (Paper 17, “Pet. Reply”), and an Opposition to Patent Owner’s Contingent Motion to Amend (Paper 16, “Opp. Mot. Amend”). Patent Owner timely filed a Reply to Petitioner’s Opposition (Paper 18, “PO Reply Opp.”).

Oral argument was held on October 24, 2018 in Alexandria, Virginia. Paper 23.

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that each of challenged claims, 1–5, 9–11, 13, and 16–20 of the ’864 patent, is unpatentable. Petitioner has not demonstrated that claims 6–8, 12, 14, and 15 of the ’864 patent, are unpatentable.

In addition, we deny Patent Owner’s Contingent Motion to Amend to replace claims 1–5 and 19 with substitute claims 21–25 and 27. We grant Patent Owner’s Contingent Motion to Amend to replace claim 9 with substitute claim 26.

B. Related Proceedings

Neither party indicates that there are any other pending judicial or administrative matters related to the '864 patent. Pet. 2, Paper 3.¹

C. The '864 Patent

The '864 patent (Ex. 1001), titled “System and Method for Evaluating an Electrophysiological Signal,” relates generally to computer implemented signal analysis, namely, a method of reconstructing an electrophysiological signal from a medical patient, such as an electrocardiogram, i.e. an “ECG,” by performing a model-derived reconstruction of the signal, and evaluating the reconstructed signal over a cycle to identify portions of the signal representing certain pathological events. Ex. 1001, 4:16–19, 36–42.

Black’s Medical Dictionary explains that an electrocardiogram is “[a] record of the variations in electric potential which occur in the heart as it contracts and relaxes.” https://search.credoreference.com/content/entry/blackmed/electrocardiogram_ecg/0 (last visited Jan. 21, 2019). Besides ECG applications, the '864 patent explains that electrophysiological signals can include, *inter alia*, “voiced speech signals, electrooculogram (EOG) and electromyogram (EMG) signals, vestibuloocular response signals, blood

¹ Patent Owner initially requested that we stay this proceeding in light of the United States Supreme Court’s consideration of, among other things, whether *inter partes* review violates the U.S. Constitution, as argued in *Oil States vs. Greene’s Energy Group, LLC, et al.* Paper 3. The request for a stay was *not* granted. Dec. Inst. n. 1. *Oil States* was decided by the U.S. Supreme Court on April 24, 2018 and determined that “[p]atents thus remain ‘subject to [the Board’s] authority’ to cancel outside of an Article III court.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1374 citing *Crowell*, 52 S.Ct. 28.

pressure gamma synchrony signals (based on electroencephalogram (EEG) measurements), a respiratory function signal, a pulse oximetry signal (measuring the oxygenation of a patient's blood).” *Id.* at 1:25–30.

Figure 6 reproduced below illustrates, in the time domain, a patient's ECG signal data by dashed line in comparison to a model derived reconstruction of the signal, shown in darker, more solid line, as accomplished by a fast orthogonal search (FOS) transformation. *Id.* at 5:20–23.

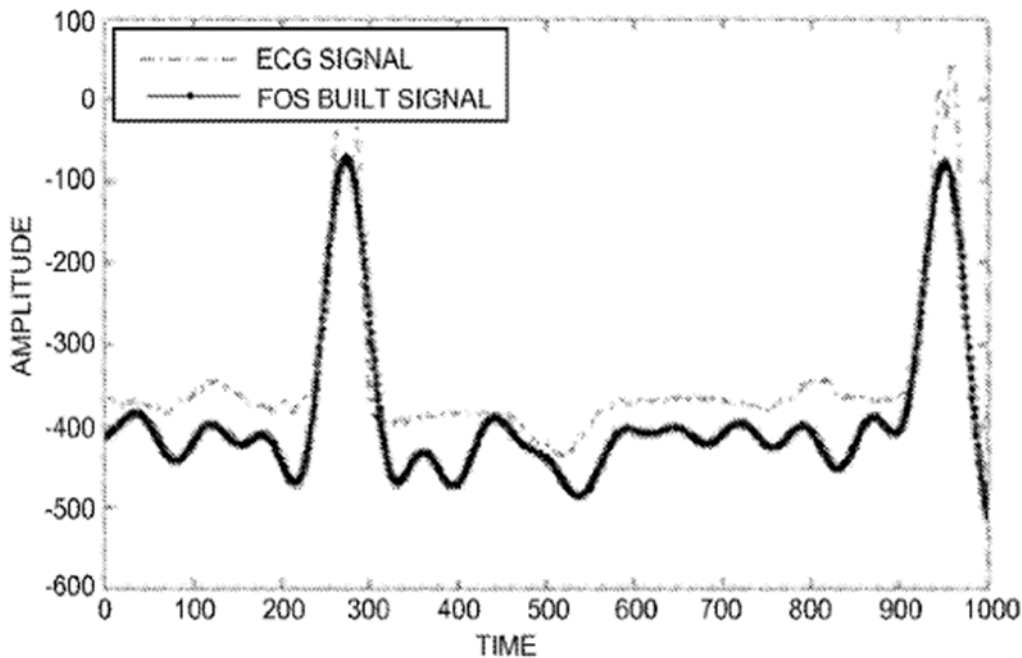


FIG. 6

Figure 6 of the '864 patent, above, shows a FOS reconstruction of the patient's ECG signal data in the time domain using “twenty sine/cosine pairs of basis function terms producing a compression ratio of 33:1 and Mean square error of 4.39.” *Id.* at 10:20–23.

The '864 patent explains that known signal processing techniques, such as fast Fourier transforms, to transform signal data from time domain to frequency domain, “are incapable of quantifying certain fluctuation characteristics of a number of pathologies related to the electrophysiological signal.” *Id.* at 3:52–54. To obtain a more accurate reconstruction, the '864 patent teaches that FOS and MFOS (“modified fast orthogonal search”) transforms, performed on the underlying signal data “creates models with terms that are highly correlated with the targeted ECG signals.” *Id.* at 7:31–32.

In one embodiment, shown below in Figure 21A, the '864 patent describes an analysis that generates a phase space plot of certain ratios of derivatives and visually color codes the ratios, which “can be useful as a diagnostic tool, or to predict clinical outcome, and to view in X, Y, Z space.” *Id.* at 23:14–16.

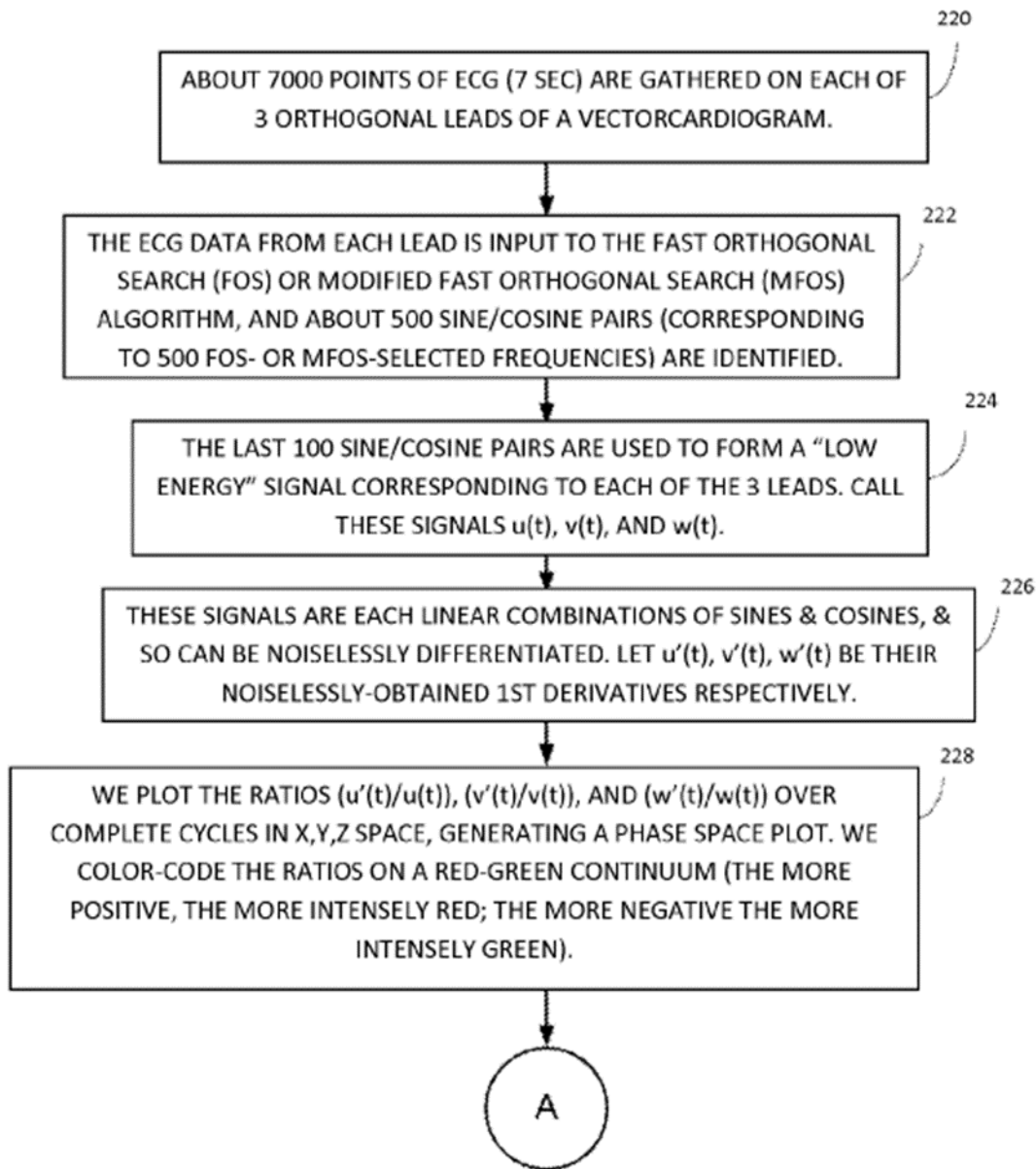


FIG. 21A

Figure 21A, above, is a flow diagram illustrating steps for detecting an abnormality in the heart including performing a FOS or MFOS transform on ECG data at step 222, and then selecting and differentiating the linear combination of certain sine/cosine pairs corresponding to particular FOS, or MFOS, frequencies at steps 224, 226. *Id.* at 22:58–64. The '864 patent

explains further that the ratio of certain signals to their respective derivatives, is “useful as a diagnostic tool, or to predict clinical outcome, and to view in X, Y, Z space.” *Id.* at 23:15–16.

D. Illustrative Claims

Of the challenged claims, claims 1, 9, and 19 are independent. Each of dependent claims 2–8 and 13–18 depend from claim 1, claims 10–12 depend from claim 9, and claim 20 depends directly from independent claim 19. Claim 1 illustrates the claimed subject matter and is reproduced below:

1. A method of detecting an abnormality in a patient from an electrophysiological signal, comprising:
 - (a) obtaining an electrophysiological signal corresponding to the patient;
 - (b) finding, using a processor of a computing device, a model corresponding to the electrophysiological signal wherein at least one term in the model is differentiable;
 - (c) obtaining the derivative of the at least one term; and
 - (d) using the derivative over at least one cycle of the electrophysiological signal in order to detect the abnormality.

Ex. 1001, 29:61–30:4.

E. The Alleged Grounds of Unpatentability

In support of their respective positions, Petitioner relies upon the declaration, supplemental declaration, and declaration in support of opposition to motion to amend of David Anderson, Ph.D. (Exs. 1002, 1020, 1022), and Patent Owner relies on the declarations of Paul Zalesky, Ph.D. (Exs. 2026, 2031).

Petitioner contends that the challenged claims are unpatentable on the following grounds.

References	Basis	Claims Challenged
Jay ² and Scharf ³	§ 102/103	1, 2–6, and 13
Jay, Scharf and Ahlström ⁴	§ 103	7–8, 14–15, and 17–18
Korenberg ⁵	§ 102/103	9–12 and 16
Adeney ⁶	§ 102	19–20
Adeney and Mao ⁷	§ 103	19–20

II. CLAIM CONSTRUCTION

A. Legal Standard

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2017); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).⁸

² Ex. 1006, U.S. Patent No. 6,325,761 B1 (Dec. 4, 2001).

³ Ex. 1005, U.S. Patent Appl’n. No. 2006/0211930 A1 (Pub. Sept. 21, 2006).

⁴ Ex. 1011, Christer Ahlström, *Nonlinear Phonocardiographic Signal Processing*, (April 2008) (unpublished multidisciplinary doctoral thesis, Dep’t of Biomedical Eng’g Linköping University, (on file with author).

⁵ Ex. 1007, M.J. Korenberg, *A Robust Orthogonal Algorithm for System Identification and Time-Series Analysis*, 60 Biol. Cybern., Springer-Verlag, 4, 267-276 (1989).

⁶ Ex. 1008, M.J. Korenberg, K.M. Adeney, *Iterative Fast Orthogonal Search for Modeling by a Sum of Exponentials or Sinusoids*, 26 Annals of Biomedical Eng’g, 315–327 (1998).

⁷ Ex. 1010, K.Z. Mao, *Orthogonal Forward Selection and Backward Elimination Algorithms for Feature Subset Selection*, 34 IEEE Transactions on Systems, Man, and Cybernetics—Part B: Cybernetics, 1, 629–634 (2004).

⁸ On October 11, 2018, the USPTO revised its rules to harmonize the Board’s claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial And Appeal Board, 83 Fed. Reg. 51,340

Claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007), *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996 (“Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.”)). We apply this standard to the claims of the ’864 patent.

B. Claim Terms

1. Modified fast orthogonal search (MFOS)

Petitioner contends that the term “modified fast orthogonal search,” as recited in claim 12, should be understood as set forth in the specification of the ’864 patent, as

a variant of the fast orthogonal search algorithm in which a search through candidate terms is performed that selects two or more distinct candidate terms to add to the model at successive stages where one of the selected terms causes, out of the candidate terms searched, the greatest reduction in the measure of approximating the signal, and another of the selected terms is, out of the candidate terms searched, at a relative maximum of the reduction of the measure of approximating the signal.

(Oct. 11, 2018).) (to be codified at 37 C.F.R. pt. 42). This rule change, however, applies to petitions filed on or after November 13, 2018, and therefore does not apply to this proceeding. *Id.*

Pet. 19 (citing Ex. 1001, 9:47–55). Petitioner asserts also that “[a] transform (of MFOS) would be understood by a POSITA to be an application of the (MFOS) algorithm to input signals.” *Id.* (citing Ex.1002 ¶ 61).

In our Decision to Institute, because there was no objection from Patent Owner in its Preliminary Response, we noted that “[t]here is no substantive dispute over the term ‘modified fast orthogonal search.’” Inst. Dec. 13. Now, in its Response, Patent Owner argues that application of MFOS transform to an electrophysiological signal means “select[ing] terms to add to the model at successive stages, and wherein at least two distinct candidate terms are selected *in one stage*.” PO Resp. 12 (citing Ex. 2026 ¶¶ 32–33). Patent Owner asserts that MFOS, as described in the specification and claimed, is a hybrid approach of the alternatives described in Korenberg. *See id.* at 14 (Patent Owner explains that “[i]n [Ex.]1007, Korenberg only selects one term from each stage, *or* selects all terms in one stage.”) *see also id.* (Patent Owner states that Korenberg teaches “[e]ither using multiple (successive) stages to detect one term in each stage, or detecting multiple terms in one stage.”).

What the ’864 patent states specifically is:

The MFOS method involves a search through candidate terms to select terms to add to the model at successive stages, wherein at least two distinct candidate terms are selected at the same stage at least once.

Ex. 1001, 9:47–50.

In its Reply, Petitioner asserts that Patent Owner’s construction of MFOS is too narrow because it “requires ‘at least two distinct candidate terms are selected at the same stage and at multiple stages.’” Pet. Reply 20 (emphasis added by Petitioner (citing PO Resp. 13, 33)). This is not entirely

accurate. Patent Owner's construction is that terms are selected in multiple stages and, in "at least one stage," multiple terms are selected. We do not read Patent Owner's construction to *require* selecting multiple terms in each of the multiple stages, as Petitioner's argument implies. We understand Patent Owner's construction, including the phrase "at least two distinct candidate terms are selected *in one stage*," as encompassing multiple terms being selected in one, or more stages. See PO Resp. 14–15 ("[T]he broadest reasonable interpretation *consistent with the specification* (9:47–50) is that at least two distinct candidate terms are selected at the same stage at least once.").

Patent Owner's position is the most persuasive because it is the most consistent with the specification of the '864 patent. A plain reading of the specification indicates that MFOS requires "successive stages." See Ex. 1001, 9:47–48. ("The MFOS method involves a search through candidate terms to select terms to add to the model at successive stages. . . ."). This is also consistent with Petitioner's original proposed construction. See Pet. 19. Indeed, nothing in Petitioner's original proposed construction implies that the claim encompasses anything besides "successive stages." See *id.* (Petitioner proposed that "[a]s defined in the patent specification, this term should be found to mean 'a variant of the fast orthogonal search algorithm in which a search through candidate terms is performed that selects two or more distinct candidate terms to add to the model at successive stages.'").

Petitioner's objections based on Dr. Zalesky's deposition testimony under cross-examination are not compelling because the relevant queries by Petitioner's counsel, although they state "one stage," never convey to Dr. Zalesky that this means the absence of successive stages. See Pet. Reply 20

(citing Ex. 1021, 73:2–23). Thus, it is not clear that Dr. Zalesky’s deposition testimony contradicts his direct testimony that MFOS requires “successive stages” and that “a POSITA would understand claim 12 to mean wherein at least two distinct candidate terms are selected *in one stage*.” Ex. 2026 ¶ 32.

Given that MFOS as explained in the ’864 patent requires multiple, i.e. successive, stages, it follows naturally that the specification language “at least two distinct candidate terms are selected *at the same stage at least once*” means that, in at least one of the successive stages, two distinct candidate terms are selected. Ex. 1001, 9:49–50. A reasonable reading of the specification indicates that an MFOS transform requires a candidate term, or terms, to be added to the model at successive stages, and that, at one or more of the successive stages, multiple candidate terms are selected. *Id.* at 9:47–59. We are persuaded that the correct construction of a MFOS transform includes selecting candidate “terms to add to the model at successive stages, wherein at least two distinct candidate terms are selected in at least one stage at least once,” as expressly described in the ’864 patent. *Id.* at 9:47–50.

2. *Abnormality in a patient*

Patent Owner proposes that “abnormality in a patient” as it is recited in the preamble of claim 1 means “[a] physical, physiological, or electrophysiological abnormality in a patient, distinct from noise in a signal.” PO Resp. 11–13 (citing Ex. 1001, 9:24–35, 30:60–31:2, 17:31–38; Ex. 2026 ¶¶ 28–29). Petitioner does not expressly contradict this construction, but contends that this claim construction is a “red herring.” Pet. Reply 5. We do not understand any particular dispute over the term

“abnormality” based on these arguments, which seem to pass one another as two ships in the night, but, to the extent necessary, we determine that “abnormality” is, as Patent Owner contends, a “physical, physiological, or electrophysiological abnormality in a patient.” *See, e.g.*, Ex. 1001, 24:52–54 (The ’864 patent explains that “[t]iming in the cardiac (heart beat) cycle when the red alarming regions occur enables locating the corresponding regions of the heart where the abnormality is located.”).

What is essentially a non-dispute does, however, highlight an underlying issue in this proceeding, which should be addressed directly—the fundamental nature of what the technology, systems, devices, and methods described in the ’864 patent and the prior art references, such as Scharf, in fact, actually “detect.” We understand that medical devices, such as an ECG machine and signal conditioning analyses, *detect an electrophysiological signal* of a patient. *See* Ex. 1001, 4:51–53 (“The electrophysiological signal is transformed to detect a plurality of non-linear terms corresponding to the electrophysiological signal.”). An ECG machine, for example, measures the electrical activity of a patient’s heart so that “important physiological information can be captured as electrophysiological signals.” *Id.* at 1:22–23.

We have been apprised of no analytical mathematical transform, construct, or method, which itself specifically detects an *abnormality in a patient*. More accurately, the electrophysiological signal is detected as described in the ’864 patent, and transformed mathematically to “a model derived reconstruction . . . used to identify a pathological event.” *Id.* at 4:17–19. The reconstructed signal, and the pathological event it represents, contains representations of all parts of the pathological event, both normal and abnormal. Detecting an “abnormality *in a patient*” in the

representations, as opposed to normal heart function, as understood from the '864 patent including the preamble to claim 1 and as confirmed by both parties' declarants in this proceeding, is ultimately accomplished by a human being, for instance a physician. *See id.* at 13:38–39 (“It is always helpful *for a doctor to detect* the early damage in the heart.”) (emphasis added); *see also* Ex. 1021, 42:6–8 (From Zalesky’s deposition, “Q. An[] abnormality is assessed by who? A. The physician; typically, the cardiologist in this case.”), *see also* Ex. 1022 ¶ 29 (Dr. Anderson states that “utilizing FOS (as disclosed in Jay) to substitute for the initial reconstruction process in Scharf (which uses FFT) would result in an even cleaner signal to be further analyzed and assessed by a physician.”). We determine, therefore, that “detecting an abnormality in a patient” is ultimately accomplished by a human being, for instance a physician.

3. Order of the derivative

Patent Owner argues that “order,” for example as recited in claim 3, “order of the derivative,” means “order used to detect the abnormality,” and is the only way that claims 2–5 make sense. PO Resp. 11, 13–14. Petitioner does not address construction of “order of the derivative” directly, but argues that this proposed construction is part of Patent Owner’s subterfuge to convince the Board that the derivative *itself* is used to detect the abnormality. *See* Pet. Reply 2–8 (Petitioner contends that, “ultimately, the detection of an abnormality in the '864 Patent is performed by a skilled physician, such as a cardiologist.”).

Claim 2 recites, for example, “wherein the derivative has an order, and wherein the order is a real number.” Ex. 1001, 30:5–6. As a

fundamental principal of calculus, a plain reading of claim 2 indicates that the “order” of a derivative, used in the mathematical sense, for example

$$\frac{d}{dx} \left(\frac{df}{dx} \right)$$

is understood as the second order derivative of the function $f(x)$, and can also be denoted as

$$\frac{d^2 f}{dx^2}$$

See Schenk, *CALCULUS AND ANALYTIC GEOMETRY*, Higher Order Derivatives 134, 3d ed. 1984. In addition, real numbers are “positive numbers, the negative numbers, and zero.” *Id.* at 1. Considering the specification of the ’864 patent, we see the first derivative, $u'(t)$, $v'(t)$, $w'(t)$, of several functions, $u(t)$, $v(t)$, $w(t)$, explained consistently with the mathematical concept above. Ex. 1001, 23:16–19. We also note that the specification states “this derivative can be useful as a diagnostic tool, or to predict clinical outcome, and to view in X, Y, Z space.” *Id.* at 23:14–16. This evidence indicates that, if anything, it is the reconstructed model obtained from the derivative, not necessarily the “order” of the derivative itself, that is helpful in determining an ultimate diagnosis. The specification, therefore, does not persuasively support Patent Owner’s assertion that “order of the derivative” means “order used to detect the abnormality.” Dr. Zalesky’s deposition testimony also does not support Patent Owner’s construction. Dr. Zalesky testifies that the order of the derivative does not necessarily detect anything, but “leads to an underlying model.””:

Q. How does the ’864 Patent describe using an order to de[t]ect an abnormality?

A. His algorithm or his methodology incorporates a specific order of derivative computation and some mathematical

computations associated with those derivatives. The order in which he does those basically leads to an underlying model, which, in turn, can lead to identification abnormality.

Q. So the order doesn't detect the abnormality; is that correct?

A. Detect would not be the right word.

Q. Okay. What would be the right word?

A. The order leads to a model that reflects the abnormality.

Ex. 1021, 45:2–16. Dr. Zalesky's deposition testimony is essentially consistent with his declaration testimony that "[t]he 'order' specified in Claims 2–6 is essential to the production of an abnormality detection, resulting from the sequence of signal acquisition, finding a model with a differentiable component, producing the derivative, and reviewing one or more complete electrophysiological cycles." Ex. 2026 ¶ 31.⁹ We find Dr. Zalesky's deposition testimony that "detect is not the right word" to be particularly telling that Patent Owner's use of the noun "order" as the subject of the verb "to detect" is misplaced. The phrase "order of the derivative" is most reasonably understood by a person of ordinary skill in the art as Dr. Zalesky defined it during his deposition, "a specific order of derivative computation." Ex. 1021, 45:5

4. Lead signals

Patent Owner argues that "lead signals" as recited in claim 19 means "[s]ignals from ECG leads, not reconstructed or modeled functions or terms

⁹ Dr. Zalesky's declaration testimony (Ex. 2026 ¶ 30) that "order" means "[o]rder used to detect the abnormality" mirrors Patent Owner's construction in their Response. PO Resp. 11. Neither Dr. Zalesky's subsequent declaration nor deposition testimony, however, is compelling support for this conclusory claim construction, unsupported by facts, data, or persuasive analysis.

of such functions.” PO Resp. 12. Patent Owner points to the specification of the ’864 patent in support of this construction and asserts that “[c]learly the lead signals refer to the multiple leads, with each signal corresponding to a separate lead.” *Id.* at 15 (citing Ex. 1001, 26:46–27:36).

Petitioner argues (1) that Patent Owner’s interpretation, which excludes basis functions representing the actual lead signal, e.g., “reconstructed or modeled functions or terms of such functions,” improperly restricts the term “lead signals” to the actual lead signals themselves and (2) that this narrow interpretation is not supported by the specification or Dr. Zalesky’s testimony. Pet. Reply 21–24 (citing Ex. 1022 ¶¶ 51–55; Ex. 1021, 109:9–115:12).

Contrary to Patent Owner’s assertion, it is not clear how the description of how a subset of ECG leads are selected supports such a restrictive meaning of “lead signals.” *See, e.g.*, Ex. 1001, 26:46–27:36 (“A key idea here is that when data are available from multiple experiments, one may select the SAME basis functions (out of the candidates) to fit all the experimental data.”). Parts of the specification upon which Patent Owner relies discuss the use of basis functions and signal reconstruction transforms for selecting leads, and state, “[o]f course other model-building techniques besides FOS and MFOS can be used with this strategy of treating the lead signals as if they form multiple sets of observation.” *Id.* at 27:32–36.

It is a fundamental feature of the ’864 patent that ECG lead signals can be represented by basis functions. *See id.* at 10:120–22 (“The FOS reconstructed ECG using twenty sine/ cosine pairs of basis function terms producing a compression ratio of 33:1 and Mean square error of 4.39 is shown in FIG. 6.”). According to the ’864 patent, for example, “fast

orthogonal search (FOS) transform is applied to the electrophysiological signal to generate a plurality of terms corresponding to the electrophysiological signal.” *Id.* at 17:31–34. As to claims 19 and 20 we can find no explanation, express or implied, in what Patent Owner points to in the specification, or any part of the specification, that limits the “lead signal” of claim 19 to an actual or original signal from an electrocardiogram (ECG) lead. *See id.* at 26:46–27:36. Apart from referring generally to, and copying a portion of, the specification into its Response, Patent Owner has failed to cogently explain how its conclusion that “lead signals refer to the multiple leads, with each signal corresponding to a separate lead” would have been understood by one of ordinary skill in the art as excluding “reconstructed or modeled functions or terms of such functions.” PO Resp. 15.

Dr. Zalesky’s testimony is also not definitive on this issue. *See Ex.* 1021, 106:2–115:12. Dr. Zalesky was asked how lead signal selection would be understood by one of ordinary skill in the art, as it is recited in claim 19, paragraphs (c), and in light of the specification of the ’864 patent. *Id.* at 107:21–108:24. Dr. Zalesky states that for paragraph (c),

So [the inventor’s] objective is to, let’s say that he starts with 12 lead EKG to knock that down to a smaller number of leads, and that the result of his modeling, using only those subselected leads gives him a good rendition at the end of the day of what the overall 12 lead would have done.

Id. at 108:1–6. Dr. Zalesky explains further that the inventor is “trying to identify one concise subset of model terms, [] *selected from the candidate functions* to fit the data from all the experiments.” *Id.* at 108:21–24 (emphasis added). If anything, Dr. Zalesky’s discussion of modeling and “model terms” with respect to claim 19 appears to contradict Patent Owner’s

assertion that “lead signals” from ECG leads cannot include “reconstructed or modeled functions or terms of such functions.” PO Resp. 12.

Dr. Zalesky’s explanation, in fact, appears somewhat consistent with Dr. Anderson’s testimony that “claim [19] specifically uses the terms ‘candidate signals’ and ‘lead signals.’ These terms are not synonymous with ECG leads; indeed, a lead signal is *used to define* a candidate signal but the candidate signal is not constrained to *be* a lead signal.” Ex. 1022 ¶ 52. Dr. Anderson explains further that the ’864 patent describes such candidate signals as actually “candidate functions,” where “[o]ne chooses one concise set out of the candidate functions to fit the data from ALL experiments (the coefficients will change from one experiment to the next, but this is allowed—use Eqs 17,18 in the above-referenced 1998 Korenberg and Adeney paper).” *Id.* ¶ 53 (citing Ex. 1001, 27:11–15).

We also point out that in the context of selecting lead signals, Dr. Anderson’s testimony appears to be consistent with the ’864 patent where it states that “other model-building techniques besides FOS and MFOS can be used with this strategy of treating the lead signals as if they form multiple sets of observation, while the lead signals also form the candidate functions.” Ex. 1001, 27:32–36. Overall, the evidence does not weigh in favor of Patent Owner’s proposed construction, which eliminates basis functions representing the lead signals in claims 19 and 20. Accordingly, we decline to interpret “[s]ignals from ECG leads” as excluding “reconstructed or modeled functions or terms of such functions.” We understand the term “lead signals” to have its ordinary meaning as understood from a reasonable reading of the specification and does not exclude basis functions representing the lead signals.

5. *Whether the Phrase “using the derivative . . . in order to detect the abnormality” as Recited in claim 1 is a Statement of Intended Use*

Claim 1 is “[a] method of detecting an abnormality” and recites the step of “using the derivative over at least one cycle of the electrophysiological signal in order to detect the abnormality.” Ex. 1001, 29:61–30:4. Petitioner argues that the phrase “using the derivative . . . in order to detect an abnormality” is a statement of intended use because it does not restrict the manner in which the abnormality is detected, and is therefore not limiting. Pet. Reply 3–4. Patent Owner does not specifically counter Petitioner’s contentions of intended use. PO Resp. 11–15. Patent Owner does argue, however, that the claim language means “using a derivative itself to indicate an abnormality in the physiological changes.” *Id.* at 19.

Read naturally, the language of claim 1, including the preamble “[a] method of detecting an abnormality” and the phrase “in order to detect the abnormality,” tells us a purpose or potential result of the claimed method including the steps of “obtaining the derivative” and “using the derivative.” Ex. 1001, 29:61–30:4. This result, as recited in the preamble, and the body of the claim at paragraph (d), does not, however, impose any functional or structural constraints on the method itself, or even the step of “using the derivative.” The method, including all the steps of “obtaining an electrophysiological signal,” “finding . . . a model,” “obtaining the derivative,” and “using the derivative,” may, for example, also result in the detection of no abnormality. In the preamble, “detecting an abnormality” is a stated purpose or potential result of the method. With respect to “using the derivative . . . in order to detect the abnormality,” the claim does not explain *how, or by whom or by what*, the derivative itself is being used (even over one cycle) to actually detect the abnormality.

Reading the claim in light of the specification, the derivative of non-linear terms corresponding to the electrophysiological signal (an ECG signal) produces a model of the signal, and subsequent analysis of the reconstructed model may be used to detect, i.e. identify, an abnormality and the absence of an abnormality. *See* Ex. 1001, Fig. 12 (Step 116 states for example “[i]dentification of the pathological event is based on: at least one stability ratio produced from the model-derived reconstruction of the electrophysiological signal.”). Paragraph (d) of claim 1, therefore, specifies an intended use for the derivative—an intent to use the derivative over at least one cycle of the electrophysiological signal to provide a reconstructed model of the signal, from which a physiological abnormality may, or may not, be detected. Accordingly, we decline to read into claim 1 the requirement that the derivative itself is actually detecting an abnormality.

As discussed in greater detail below with respect to patentability, the meaning of this claim language is important in this proceeding because Patent Owner argues, albeit without expressly construing the phrase, that claim 1 is patentable, for instance, over Scharf, because Scharf does not disclose “using the derivative . . . to detect the abnormality.” PO Resp. 18. Patent Owner argues specifically that Scharf’s identification of motion artifacts that create noise in PPG signal measurements “is not an ‘abnormality in a patient’ as required by claim 1.” *Id.* Patent Owner argues that “[a]t best, Scharf shows a different method from the ’864 Patent of removing the noise from a signal. Scharf does not show then analyzing the reduced noise signal to detect an abnormality.” *Id.*

In any event, whether or not the phrase, “using the derivative . . . in order to detect the abnormality,” is a limitation of claim 1, or is a statement

of intended use, the specification of the '864 patent does not support Patent Owner's contention that the derivative is itself detecting the abnormality. PO Resp. 18. The specification of the '864 patent describes a "model-derived reconstruction," for instance as determined by a FOS or MFOS transformation, over at least one cycle of the electrophysiological signal, and in one embodiment "*a processor configured to identify a pathological event from [the] model-derived reconstruction of the electrophysiological signal.*" Ex. 1001, 4:29–31 (emphasis added). Dr. Zalesky, when deposed, also could not support Patent Owner's position that the claim or the specification described the derivative actually detecting anything. Ex. 1021, 76:9–19.

Q. And Claim 1, if you look specifically at Claim 1 of the '864 Patent, we've discussed this in some respect but not with regard to the claim. The Claim 1 doesn't require detecting the abnormality with the derivative, correct?

A. Correct.

Q. And indeed the '864 Patent doesn't describe detecting the abnormality with the derivative, correct?

A. It uses a derivative; it does not base it strictly on the derivative.

Id.

Claim 1 does not expressly recite who, or what, is "detect[ing] the abnormality," but it is clear from both the specification and Dr. Zalesky's testimony that differentiating basis functions, including a plurality of non-linear terms corresponding to the electrophysiological signal, produces a reconstructed model of the ECG signal, and does not specifically identify or detect a normal or abnormal signal. Ex. 1001, 6:52–58; Ex. 1021, 33:14–34:18. The evidence indicates that the reconstructed model of the ECG signal can then be evaluated by some further steps and comparative analysis,

and, for example, by a doctor as normal or abnormal. *See* Ex. 1001, 17:51–54 (“The system 132 has a processor 134 which is configured to identify a pathological event from a model-derived reconstruction of the electrophysiological signal.”), 23:5–23, Fig. 21A (describing, at step 228, using ratio of $(u'(t)/u(t))$, $(v'[t]/v(t))$, and $(w'(t)/w(t))$ to indicate instability when positive, and respectively color coding a visual 3D space plot output); Ex. 1021, 47:20–23 (discussing the '864 patent, Dr. Zalesky states that “[u]ltimately, the physician is going to look at some representation, such as a graphic representation of the model over an outline of the heart.”).

Therefore, we determine that the step of “using the derivative” does not itself actually detect an abnormality, as proffered by Patent Owner, but is, ultimately, a limiting step in the claimed method that may enable “detecting an abnormality in a patient,” for example by a physician, as an intended use of the method recited in the preamble of claim 1.

III. ANALYSIS

Petitioner’s challenges include anticipation as well as obviousness contentions, which are addressed below. At the outset, we describe the requisite state of the law as a prelude to our analysis under 35 U.S.C. §§ 102–103.

A. The Law of Anticipation

“Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (internal quotation marks omitted). Accordingly, an anticipatory reference

must show all of the limitations of the claims “arranged or combined in the same way as recited in the claims.” *Id.* at 1370; *see Finisar Corp. v DirecTV Group, Inc.*, 523 F.3d 1323, 1334–37 (Fed. Cir. 2008); *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000).

In addition, to anticipate a patent claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation.” *Finisar*, 523 F.3d at 1334. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates, even though artisans of ordinary skill may not have recognized the inherent characteristics or functioning of the prior art. *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed.Cir.1999) (citation omitted); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed.Cir.2002).

B. The Law of Obviousness

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *Translogic*, 504 F.3d at 1262. A *prima facie* case of obviousness is established when the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976).

C. Level of Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. “The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991).

Patent Owner and its declarant, Dr. Zalesky, agree with Petitioner’s declarant, Dr. Anderson’s, assessment that

a person of ordinary skill in the art would be one who “would have (1) a four year college degree with technical training in electrical engineering, biomedical engineering, mathematics, physics, or another related technical field and (2) experience with advanced signal processing, non-linear systems, and advanced calculus.

PO Resp. 10–11 (citing Ex. 1002 ¶ 32; Ex. 2026 ¶ 22).

Having reviewed the subject and content of the ’864 patent and the prior art references asserted in this proceeding, our findings as to the level of skill in the art are commensurate with that asserted by the parties.

Therefore, in our obviousness analysis below, we accept and adopt the parties' agreed upon level of ordinary skill in the art as set forth above.

D. Claims 1–6 and 13 — Anticipation by Scharf

Petitioner asserts that claims 1–6 and 13 are anticipated by Scharf. Pet. 20–33.

1. Scharf

Scharf discloses a method of removing motion artifacts from physiological signals including steps of acquiring patient photo-plethysmographic (PPG) data from a pulse oximeter, transforming that data into the frequency domain, analyzing the transformed data, and reconstructing the PPG data in the time domain.¹⁰ Ex. 1005, Abst., ¶ 20 Scharf also teaches computing the second order derivative of the reconstructed PPG data and “analyzing the candidate second order derivative photo-plethysmographic signal to determine the absence or presence of cardiac physiologic signal characteristics.” *Id.*

One problem with conventional pulse oximeters Scharf explains, is that they “are sensitive to corruption from external dynamics, causing motion artifacts that degrade the signal-to-noise ratio.” *Id.* ¶ 4. According to Scharf, motion artifacts such as patient movement and poor optical coupling can impact the accuracy of the signal measurement. *Id.* Figure 1c, of Scharf, reproduced below, illustrates particular steps for removing motion artifacts from PPG data.

¹⁰ “Plethysmograph : an instrument for determining and registering variations in the size of an organ, limb, or part resulting from changes in the amount of blood present or passing through it.” MERRIAM-WEBSTER ONLINE DICTIONARY, <https://www.merriam-webster.com/dictionary/plethysmograph> (last visited Jan. 19, 2019).

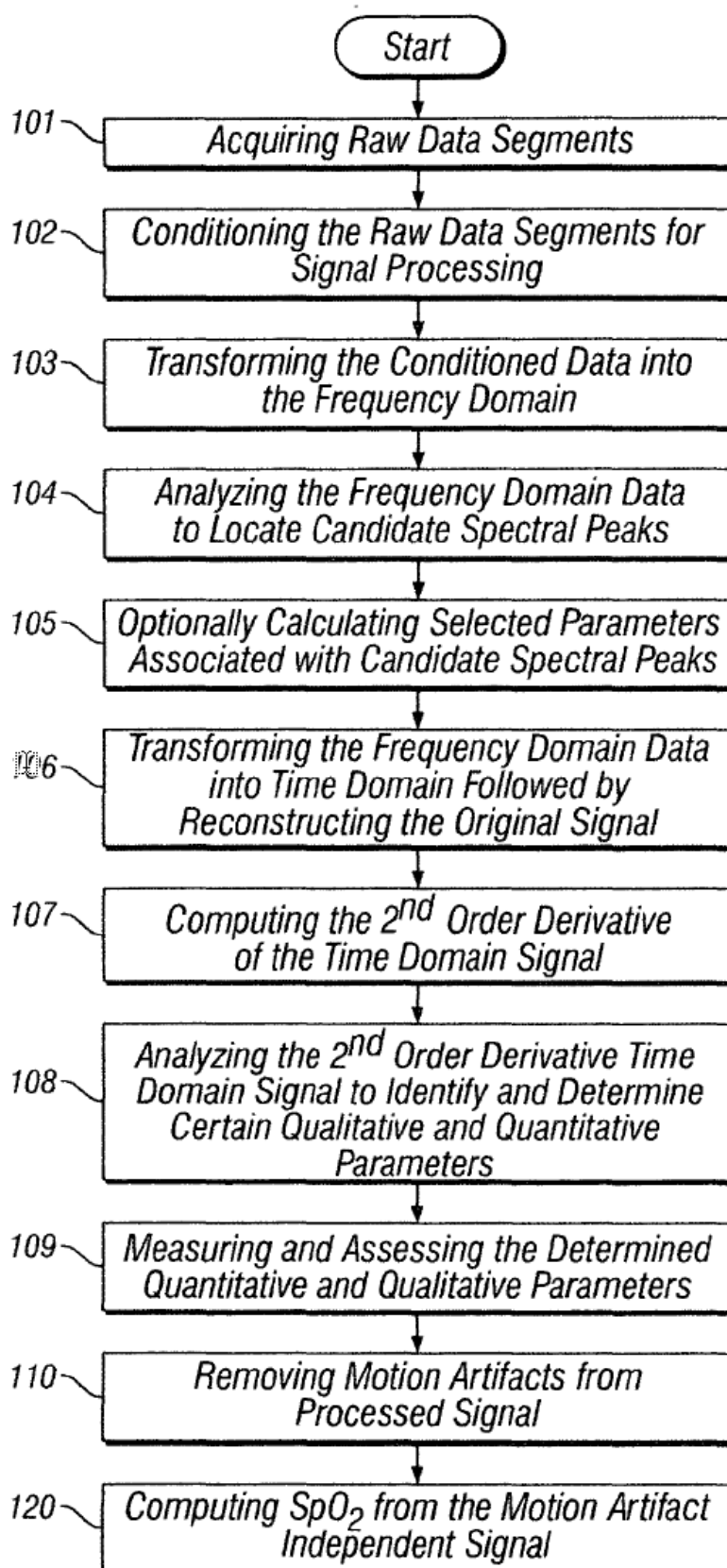


FIG. 1C

Figure 1C, above, from Scharf, is a flow-chart including step 107 for computing the second order derivative of the reconstructed time domain signal. Scharf describes that “[t]he numerical differentiation of digitized signals (or signal comprising discrete samples) is a well-known approach towards finding signal derivatives.” *Id.* at ¶ 66. Scharf goes on to explain that computing the second order derivative is helpful “since it visually represents physiological changes and other artifacts, better than that of normal waves.” *Id.* ¶ 67. Scharf explains that at steps 109 and 110 the motion artifacts are removed from the processed signal, and at step 120, SpO₂, the patients’ blood hemoglobin oxygen saturation level, is determined. *Id.* ¶ 41.

In one embodiment representative of the steps 108, 109, 110, and 120, in Figure 1C, Scharf calculates the second order derivative of the reconstructed time domain PPG to determine “a unique Cardiac morphology defined by four systolic waves and one diastolic wave.” *Id.* ¶ 81. The wave transitions and heights are then identified and measured against pre-defined criteria, and if acceptable, the wave is analyzed and assessed a score. *Id.* ¶ 83. Scharf explains that “[t]he primary/harmonic set with the highest score is classified as the most likely cardiac geometry while the primary/harmonic set with the lowest score is classified as the most likely motion geometry.” *Id.* ¶ 84. In this way, Scharf is able to separate out the motion artifacts and “provide the enhanced detection of physiological signals.” *Id.* ¶ 89. Scharf also states that, besides pulse oximeters, its method could be used with “other signal acquisition, measurement, and preconditioning systems, or signal transformation, and reconstruction methods” for evaluating various physiological signals. *Id.*

2. *Claim 1*

With respect to independent claim 1, Petitioner argues that Scharf discloses a method for obtaining more accurate reconstructed physiological signals of a patient by separating out motion artifacts to obtain an accurate signal of blood hemoglobin oxygen saturation for heart and respiration rate monitoring. Pet. 25. Although Scharf itself does not explicitly state that more accurate SpO2 measurements will better reveal an “abnormality,” Petitioner’s declarant, Dr. Anderson states that “by removing such inaccuracies in the SpO2 measurements, better oximeter measurements can be made. These more accurate reconstructed signals can then be used to assess for abnormalities.” Ex. 1002 ¶ 106 (citing Ex. 1005 ¶ 4).

Petitioner argues that Scharf’s method as applied to a pulse oximeter and measurement of blood hemoglobin oxygen saturation for heart and respiration rate monitoring includes “obtaining an electrophysiological signal” as recited in claim 1. Pet. 26. Dr. Anderson states further that Scharf utilizes a Fourier transform to model the signal, and that “[i]t is well known in the art that Fourier transform terms are differentiable and Scharf discloses taking the derivative of the signal comprised of linearly combined model terms.” Ex. 1002 ¶ 107 (citing Ex. 1005 ¶¶ 20, 46). Also according to Petitioner, in a preferred embodiment, Scharf discloses using the second order derivative of the transformed signal across 37 seconds of data, which encompasses multiple cycles and thus, “at least one cycle,” as called for in claim 1 in order to obtain an accurate signal and hence, assess for abnormalities. Pet. at 52.

Patent Owner’s main argument is that contrary to the claimed invention, “Sharf detects noise in a signal, not an abnormality (underlying

physical, physiological, or electrophysiological condition) in a patient.” PO Resp. 16. Specifically, Patent Owner contends that the claimed method “us[es] a derivative to identify a portion of a waveform indicating an abnormality.” *Id.* at 19. In other words, Patent Owner argues that rather than “detecting” or “identifying” an abnormality, Scharf’s “second order derivative is used to detect noise (e.g., motion artifacts), in order to distinguish the noise peaks from the pulse oximetry signal, and generate a cleaner reconstructed signal.” *Id.* at 17 (citing Ex 1005 ¶ 41).

As discussed above, we determined that the phrases “detecting an abnormality” and “in order to detect the abnormality” recite an intended use of the claimed method. If Scharf performs the same steps, and is capable of performing the intended use as recited, then it meets the claim. *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board’s factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant’s claim 1 (a dispensing top for dispensing popcorn in a specified manner)).

Turning to Patent Owner’s argument, even if we considered “detecting an abnormality” or “using the derivative . . . in order to detect the abnormality” as limiting, Scharf discloses more than detection and elimination of noise from a reconstructed signal as Patent Owner alleges. *See* PO Resp. 16–19. Scharf teaches that by taking a derivative of non-linear terms of a signal, a better more useful waveform, visually indicative of the patient’s cardiovascular behavior, is obtained. Ex. 1005 ¶ 67. Scharf states that “[t]he 2nd order derivative of PPG signals . . . facilitates efficient

qualitative and quantitative morphological analysis of physiological signals since it visually represents physiological changes and other artifacts, better than that of normal waves.” *Id.* Patent Owner’s declarant, Dr. Zalesky confirmed that obtaining the 2nd order derivative as described in Scharf would provide a better pulse oximetry waveform for assessment by a physician:

Q. Okay. But then the -- so let’s go to that example, then. In the Scharf publication, when you use SDPTG, that second order derivative, --

A. You’re getting really good at that.

Q. – you’re able to then relay a cleaner signal to the physician --

A. Yes.

Q. -- to assess an abnormality?

A. Yes. I would call it perhaps signal enhancement.

Q. Is that information visually represented to the physician?

A. Yes.

Q. In a one-dimensional plot?

A. Yes. It’s a one-dimensional waveform.

Ex. 1021 68:2–16. Therefore, to the extent it is necessary, we are persuaded that Scharf discloses “[a] method of detecting an abnormality in a patient” and the step of “using the derivative . . . in order to detect the abnormality” as called for in step d) of claim 1.

We are also persuaded that Scharf teaches step a) “obtaining an electrophysiological signal corresponding to the patient,” as recited in claim 1. For instance, Scharf describes a technique using “photoplethysmography (PPG) to measure SpO₂. Photoplethysmography (PPG) is the electro-optic

technique of measuring the cardiovascular pulse wave found throughout the human body.” Ex. 1005 ¶ 3. Dr. Zalesky confirmed that the ’864 patent included a pulse oximetry signal as one type of electrophysiological signal. *See* Ex. 1021 17:8–20, *and see* Ex. 1001, 1:29–31 (The ’864 patent provides examples of electrophysiological signals including “a pulse oximetry signal (measuring the oxygenation of a patient’s blood)”). Scharf also describes how a model of the electrophysiological signal is determined, and that the reconstructed model includes “at least one term that is differentiable” as recited in step b) of claim 1. Scharf states that its method includes “reconstructing a photo-plethysmographic signal in the time domain with only the candidate cardiac spectral peaks (primary plus harmonics), [and] computing the second order derivative of the reconstructed photo-plethysmographic signal.” Ex. 1005 ¶ 20.

Scharf also discloses “obtaining the derivative of the at least one term” as called for in step c) of claim 1. *See* Ex. 1005, ¶ 67 (“The SDPTG or an acceleration photo-plethysmogram (APG), as it is sometimes called, is obtained by computing the 2nd order derivative of a given photo-plethysmogram or PPG signals.”). Scharf explains further, as recited in step d) that the electrophysiological cardiac pulse signal is recorded “over a 37 second window.” *Id.* at ¶¶ 73, 76. Petitioner’s declarant, Dr. Anderson’s un rebutted testimony is, that “[s]ince Scharf discloses that the beats per minute ranges from 29 bpm to 252 bpm, 37 seconds must necessarily have multiple cycles.” Ex. 1002 ¶ 107.

We conclude, therefore, on the complete record before us in this case, that Petitioner has shown by a preponderance of the evidence that Scharf anticipates claim 1.

3. Dependent claims 2–4

Each of dependent claims 2–4 depend respectively from claim 1, and one another and require that the order of the derivative is, respectively, “a real number,” “a positive number,” and “a positive integer.” Ex. 1001, 30:5–11. Petitioner argues that Scharf discloses an analysis taking a second order derivative and thus, these limitations are met because, “[t]he number ‘2’ is a real number. The number ‘2’ is a positive number. The number ‘2’ is a positive integer.” Pet. 30. Patent Owner contends that these claims are allowable for the same reason as claim 1, because “there is absolutely no showing of using these particular characteristics . . . to indicate an abnormality.” PO Resp. 22.

As discussed above, we determined that the phrases “detecting an abnormality in a patient” and “in order to detect the abnormality” in claim 1 recite an intended use of the claimed method. Neither the order of the derivative, nor whether it is real, positive, and an integer, changes our fundamental analysis with respect to this determination. Also, we determined above that Scharf teaches a method of analyzing a pulse oximetry signal, and that Scharf’s method includes taking the second order derivative that provides a waveform permitting detection of an abnormality as recited in claim 1. Therefore, we are persuaded that claims 2–4 are also anticipated by Scharf.

4. Dependent claims 5 and 6

Claim 5 depends from claim 1 and recites the limitation “wherein a ratio of the derivative of order a to the derivative of order $a-1$ exists over a plurality of points over at least one cycle of the electrophysiological

signal.”¹¹ Ex. 1001 30:12–16. Claim 6 depends from claim 5 and in-part recites “wherein the ratio is used over at least one cycle of the electrophysiological signal in order to detect the abnormality.” *Id.* at 30:17–20.

Petitioner argues that Scharf discloses its method can include using first, third and fourth derivatives as well, and, that the first derivative, e.g., (2-1), satisfies the $a-1$ limitation recited in claim 5. Pet. 30–31 (citing Ex. 1005 ¶ 20). For claim 6, Petitioner argues that “Scharf also discloses using ratios of derivative values for quantitative analysis of the derivative signals.” *Id.* at 31 (citing Ex. 1005 ¶ 70).

Patent Owner essentially argues claims 5 and 6 together, asserting that “the abnormality is detected from not just (1) the derivative, but (2) from the ratio of the order a to the order $a-1$ derivative (claim 5), and (3) where that ratio is positive (Claim 6).” PO Resp. 22. Patent Owner argues persuasively that in Scharf “[t]he ratio of derivative values in Scharf (¶0070) involves *the same order* of numerical derivative in numerator and denominator but from different regions.” *Id.* at 23 (emphasis added)(citing Ex. 1005 ¶ 70, Fig. 4A).

Petitioner responds by arguing that in claim 5 “the obtained model term has *the property* of a recited ratio.” Pet. Reply 12 (emphasis added). Petitioner is essentially arguing that claim 5 does not recite an actual limitation beyond the steps in claim 1, specifically because, mathematically, if the derivative of a model term can be obtained, then the ratio of the

¹¹ Although the format of claim 5 does not italicize a and $a-1$, we do so here in our Decision for purposes of clarity of a as a mathematical variable.

derivative of order a to the derivative of order $a-1$, for example *exists*, as claim 5 recites.

Notably, claim 5 simply requires that the model *has* a derivative of a and $a-1$, and that the claimed ratio “exists.” Ex. 1001, 30:14. Petitioner’s argument is essentially one of inherency, namely that it is inherent, from a fundamental mathematical standpoint, as testified to by Dr. Anderson, that if a sinusoidal model term exists then its derivatives a and $a-1$ exist. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (to establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.”), *see also In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) (“a compound and all of its properties are inseparable.”). Dr. Anderson testifies persuasively to this point, that “[i]f sinusoidal terms are used, then their derivatives exist and are non-zero over a plurality of points.” Pet. Reply 12 (citing Ex. 1002 ¶ 114). Petitioner also points to Dr. Zalesky’s deposition testimony where he affirmed that apart from a flat-line, “any electrophysiological signal will have a derivative of order a over a derivative of order $a-1$.” *Id.* at 13 (citing Ex. 1021, 94:7–17).

We agree with Petitioner’s inherency position that if a sinusoidal model term exists, then, so too, do derivatives of that term exist. We determine, therefore, that Jay and Scharf inherently disclose differentiable model terms which have “a derivative of order a and also of order $a-1$,” and therefore, inherently, “a ratio . . . exists over a plurality of points over at least one cycle of the electrophysiological signal,” as recited in claim 5.

With respect to claim 6, however, we agree with Patent Owner that Scharf does not recognize or *use* the claimed ratio of the derivative of order

a to the derivative of order $a-1$. PO Resp. 22–23. Figure 4A of Scharf, for example, discloses a wave form obtained from taking just the second order derivative of a reconstructed photo-plethysmographic signal. See Ex. 1005 ¶ 33 (“Fig. 4a is a graphical illustration of a second order derivative of a photo-plethysmogram.”). Paragraph 70 of Scharf then explains the analysis including the ratios of various portions (positive and negative wave heights) of the same wave form. *Id.* ¶ 70. We find credible Dr. Zalesky’s testimony on this point, as it is consistent with our review of the entire reference, specifically, that although they may *exist*, Scharf does not disclose *obtaining* order a and $a-1$ derivatives of the same reconstructed signal and *using* the ratio of the order a to the order $a-1$ across at least one cycle of the signal as called for in claim 6. See Ex. 2026 ¶ 42 (“The ratios Scharf discussed are ratios of heights of a and b waves of the same order of a derivative, the SDPTG (Second order Derivative Photo-plethysmogram).”)

We are therefore not persuaded by the evidence in this case that Petitioner has shown by a preponderance of the evidence that claim 6 is anticipated by Scharf.

5. *Dependent claim 13*

Dependent claim 13 requires, *inter alia*, that “the electrophysiological signal comprises a portion of an electrocardiogram including portions of at least two lead signals, wherein an orthogonalization process is used to create at least two mutually orthogonal signals.” Ex. 1001, 31:3–7.

Petitioner concedes that “Jay and Scharf do not explicitly disclose that the FOS algorithm can be performed on an ECG,” but nonetheless, argues that a person of ordinary skill in the art would appreciate that Scharf’s signal

processing method could be used on signals from medical devices other than a pulse oximeter. Pet. 31–32 (citing Ex. 1005 ¶ 89; Ex. 1002, ¶¶ 121–122).

Although Scharf refers to its signal processing approach being potentially used with devices “not referred to as an oximeter,” Scharf does not describe what such alternative devices might be, or that a FOS orthogonalization process, as it is embodied in claim 13, would be used in conjunction with multiple leads and an ECG device. Moreover, Petitioner makes reference to Dr. Anderson’s testimony asserting the inherency of orthogonal signals being mutually derived from multiple lead signals. Ex. 1002 ¶ 121. Dr. Anderson’s testimony however does not explain how or from where in the reference a person of ordinary skill in the art would understand Scharf as disclosing the FOS transforms in the first place. *Id.* To establish anticipation, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). We are not persuaded that Petitioner has shown by a preponderance of evidence that claim 13 is anticipated by Scharf.

E. Claims 1–6 and 13 — Alleged obviousness over Jay and Scharf

Petitioner argues that claims 1–6, and 13 would have been obvious over Jay and Scharf. Pet. 20–33. Petitioner has established by a preponderance of the evidence that claims 1–5, and 13 would have been obvious for the reasons explained below. Petitioner, however, has not established that claim 6 would have been obvious.

1. Jay

Jay describes a device and method for monitoring a medical patient’s “pulsus paradox” to obtain data “useful for rapidly assessing the status of a

patient in acute respiratory distress.” Ex. 1006, 1:17–19. Jay explains that “[t]he medical term pulsus paradox refers to a quantifiable, exaggerated decrease in arterial blood pressure during inspiration.” *Id.* at 1:25–27. Jay explains further that in one embodiment cardiovascular pulsatile behavior is obtained from any known “device that outputs a waveform corresponding to a patient’s pulsatile volume.”¹² *Id.* at 3:52–54. Then, respiration data and cardiovascular pulse data are extracted “from the patient data indicative of cardiovascular pulsatile behavior using signal processing techniques.” *Id.* at 3:43–45.

The signal processing techniques discussed in Jay include various waveform analyses such as real-time Fourier analysis, fast-Fourier waveform analysis, and FOS. *See id.* at 4:11–58 (Jay explains that “a fast orthogonal search algorithm may be employed” to extract frequency components from the complex cardiovascular pulsatile behavior waveform.). Jay’s Figure 5 illustrates a signal-processing scheme for measuring pulses paradox.

¹² Jay lists a pulse oximeter, an optical plethysmograph, a blood pressure monitor, and a thoracic impedance plethysmograph, as examples of known devices for obtaining pulsatile behavior. Ex. 1006, 3:40–54.

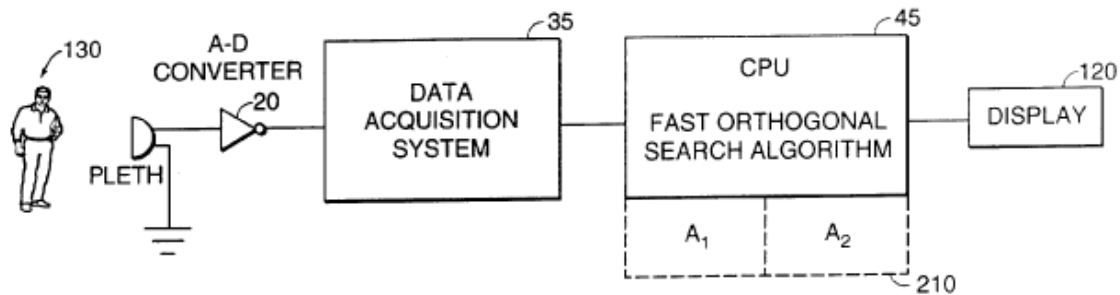


FIG. 5

Figure 5 from Jay, above, depicts an analog-to-digital converter 20 for digitizing the analog waveform acquired from patient 130. As shown in the figure, data acquisition system 35 sends a sample of the digitized waveform to CPU 45, which analyzes the waveform using fast Fourier transformation and FOS algorithm 210, measures the degree of pulsus paradox, and presents via display 120. *Id.* at 9:32–59.

2. Claim 1

Petitioner argues that Jay teaches expressly steps a) and b) of claim 1, specifically where Jay states:

[t]he invention describes a method of evaluating an electrophysiological signal, including receiving an electrophysiological signal, obtaining a model-derived reconstruction . . . over at least one cycle of the electrophysiological signal to identify a pathological condition (pulsus paradoxus).

Pet 21–22 (citing Ex. 1001, 2:25–31). Petitioner notes that Jay does not expressly disclose steps c) and d), i.e. “obtaining the derivative of at least one term . . . over one cycle [of the electrophysiological signal],” but contends that “Scharf expressly discloses taking a second order derivative of

a reconstructed photo-plethysmogram signal – which is the **same** biological signal reconstructed using FOS in Jay.” Pet. 22–23 (citing Ex. 1002 ¶ 97). Petitioner relies on Dr. Anderson, who testifies that Scharf “provides express motivation to perform a derivative of the FOS reconstructed photo-plethysmogram signal in Jay because doing so would ‘facilitate[] efficient qualitative and quantitative morphological analysis . . . better than that of normal waves.’” Ex. 1002 ¶ 99 (citing Ex. 1005 ¶ 67).

Patent Owner disputes that a person of ordinary skill in the art would combine Jay and Scharf, and argues that there is no motivation to “cherry-pick a part of the SDPTG of Scharf (the derivative) and apply it to [Jay’s] FOS method.” PO Resp. 27. Patent Owner argues that Petitioner has failed to explain *why* a person of ordinary skill in the art would have taken the derivative, as taught by the SDPTG method described in Scharf, and “then apply it to a completely different method (FOS)” in Jay. *Id.* at 28.

Petitioner’s initial argument to support the combination of Jay and Scharf is that Jay discloses the FOS method, which inherently has differentiable terms, and that Dr. Korenberg, the sole inventor of the ’864 patent, apparently acknowledged as much during prosecution. Pet. 22 (citing Ex. 1012, 78). Petitioner’s argument, however, does not explore the complete circumstances of Dr. Korenberg’s acknowledgment that a sinusoidal series could be differentiated. Dr. Korenberg, in fact, in the cited office action, stated explicitly that Jay did not disclose differentiating any FOS terms:

Jay does not mention this method of obtaining a derivative, nor does he mention obtaining a derivative at all. Instead[,] Jay discloses complexing an electrophysiological signal with a signal resulting from using fast orthogonal search without claiming that this is a way of differentiating a signal.

Ex. 1012, 78. In this way, Dr. Korenberg was showing how his claimed method was specifically different from that in Jay. We take Petitioner's argument based on Dr. Korenberg's statement, for what it is, that Jay discloses sinusoidal terms that are differentiable. What we cannot extract from this particular evidence, however, is any reason or motivation to take or obtain the derivative of the FOS terms in Jay. Dr. Korenberg's statement perhaps explains that it *could* have been done, but not does provide any reasoning for *why it would* have been done.

On the other hand, Petitioner reasons that Scharf, like Jay, is reconstructing a photo-plethysmogram (pulse-oximetry) signal. Pet. 23. Petitioner argues that Scharf teaches the benefit of taking the derivative of Jay's FOS method because Scharf states "[t]he [second order derivative photo-plethysmogram (SDPTG)] ***facilitates efficient qualitative and quantitative morphological analysis of physiological signals*** since it visually represents physiological changes and other artifacts, better than that of normal waves." *Id.* (citing Ex. 1005 ¶ 67); Ex. 1002 ¶¶ 98–99. Petitioner's declarant, Dr. Anderson, explains that Jay discloses "cross-correlation of a base signal and test signal," and that "[a person of ordinary skill in the art] would understand that a cross-correlation operator of two signals would be susceptible of noise such as those from motion artifacts in one of the signals." Ex. 1002 ¶ 102. Dr. Anderson states that Scharf teaches that such artifacts, induced for example by patient movement, "can render it substantially difficult for the oximeter to accurately determine the patient's PPG signal, therefore causing errors in the pulse rate and oxygen saturation outputs." *Id.* ¶ 103 (citing Ex. 1005 ¶ 4) (emphasis added). Dr. Anderson explained that a person of ordinary skill in the art "reviewing **Jay** would be

particularly motivated to remove artifacts (such as noise from motion artifacts as disclosed in Scharf) by taking a second order derivative as provided in Scharf.” *Id.* According to Dr. Anderson, “by removing such inaccuracies in the SpO2 measurements, better oximeter measurements can be made. These more accurate reconstructed signals can then be used to assess for abnormalities.” *Id.* ¶ 106 (citing Ex. 1005 ¶ 4).

Although Patent Owner argues that “applying the derivative of SDPTG to FOS has not been shown in either reference to further minimize noise or to be useful or desirable at all” (PO Resp. 28), we understand from Scharf that taking derivatives of reconstructed signals was a mathematical analysis known to those of ordinary skill in the art. *See* Ex. 1005 ¶ 66 (Scharf states that “approaches of finding signal derivatives are already known to one of ordinary skill in the art of signal processing.”). Along with this, we are persuaded that one of skill in the art would have been aware, from Scharf’s teachings, of the benefits of a cleaner, more accurate waveform, obtained by taking the derivative of a reconstructed physiological signal. Ex. 1005 ¶¶ 66–67; Ex. 1002 ¶¶ 103–104. Although Scharf mainly discusses the 2nd derivative SDPTG analysis in terms of signal data transformed by fast Fourier analysis, it appears from Scharf and Dr. Anderson’s testimony that taking the derivative of a reconstructed signal was a known and useful signal analysis technique. Ex. 1002 ¶¶ 103–104. We are not apprised of compelling evidence that applying such a well-known mathematical technique to other signal processing transforms, such as FOS, is a tremendous leap. *See KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way,

using the technique is obvious unless its actual application is beyond his or her skill.”).

Patent Owner’s declarant, Dr. Zalesky, provides testimony on this point, but speaks mainly to the fact that “Jay does not describe a derivative at all.” Ex. 2026 ¶ 47. True, Jay does not describe obtaining a derivative, however Dr. Zalesky does not provide any technical or detailed explanation as to why a person of ordinary skill in the art would not have taken the derivative of FOS terms, simply concluding that “[n]o POSITA would find it obvious to cherry-pick a part of the SDPTG of Scharf (the derivative) and apply it to the FOS method.” *Id.* We appreciate that a similar position taken during prosecution may have overcome an anticipation rejection of certain claims in view of Jay. *See* Ex. 1012, 78, 92. But here, considering also the teachings of Scharf, we find Dr. Anderson’s testimony compelling as to the question of *why* one of ordinary skill in the art would have been motivated combine these references. Dr. Anderson explained in detail that a person of ordinary skill in the art would have understood from Scharf that a second order derivative of a reconstructed plethysmogram signal would produce a cleaner signal. Ex. 1002 ¶ 98. Dr. Anderson explained further that a person of ordinary skill in the art would have known that the second order derivative could also be obtained as to the terms of a FOS reconstructed signal in Jay to likewise “remove artifacts (such as noise from motion artifacts as disclosed in Scharf) by taking a second order derivative as provided in Scharf.” *Id.* ¶ 103. Dr. Anderson stated expressly that Scharf’s “motivation for removing unwanted artifacts utilizing a derivative of the biological signal reconstruction, [] would likewise apply to the reconstructed signal in Jay.” *Id.* ¶ 105. And, Dr. Anderson testifies persuasively that by

removing such artifacts “[t]hese more accurate reconstructed signals can then be used to assess for abnormalities.” *Id.* ¶ 106.

We determine that Petitioner has provided the necessary articulated reasoning supported by evidentiary underpinnings, which persuades us that one of ordinary skill in the art would have been aware of these references, and would have had the requisite technical knowledge and motivation to combine the teachings of Jay and Scharf to obtain a cleaner, more accurate signal. Petitioner has shown by a preponderance of the evidence that the combination of Jay and Scharf teaches all the limitations of independent claim 1, including the method steps arranged in the manner as is required by claim 1.

3. Dependent claims 2–4

As discussed above, each of claims 2–4 depend, directly or indirectly, from claim 1, and require that the order of the derivative is, respectively, “a real number,” “a positive number,” and “a positive integer.” Ex. 1001, 30:5–11. As for claim 1, Patent Owner argues that “there is nothing in Jay to suggest taking the derivative of any FOS term for any purpose, and certainly not to detect an abnormality.” PO Resp. 29.

As discussed above, we determined that the phrases “detecting an abnormality” and “in order to detect the abnormality” in claim 1 recite an intended use of the claimed method. As we explained previously, neither the order of the derivative, nor whether it is real, positive, and an integer, changes our fundamental analysis with respect to this determination. In addition, the challenge here is the combination of Jay and Scharf. We determined, above, that Scharf teaches a method of analyzing a pulse oximetry signal, and that Scharf’s method includes taking the second order

derivative that provides a waveform permitting detection of an abnormality, as recited in claim 1. Therefore, we are persuaded that claim 2–4 would have been obvious over Jay and Scharf.

4. *Dependent claims 5–6*

As discussed above, we determine that claim 5 does not recite an actual limitation beyond the steps in claim 1 specifically because, mathematically, if the derivative of a model term can be obtained, then the ratio of the derivative of order a to the derivative of order $a-1$, for example, *exists*, as claim 5 recites. For the same reasons as above with respect to Scharf and the anticipation challenge, we determine that Jay and Scharf disclose differentiable model terms, which have “a derivative of order a and also of order $a-1$,” and therefore, inherently, “a ratio . . . exists over a plurality of points over at least one cycle of the electrophysiological signal,” as expressly recited in claim 5.

With respect to claim 6, Petitioner states that “Scharf also discloses using ratios of derivative values for quantitative analysis of the derivative signals.” Pet. 31 (citing Ex. 1005 ¶ 70). As discussed above, Patent Owner argues persuasively that in Scharf “[t]he ratio of derivative values in Scharf (¶0070) involves *the same order* of numerical derivative in numerator and denominator but from different regions.” PO Resp. 23 (emphasis added) (citing Ex. 1005 ¶ 70, Fig. 4A). The addition of Jay in this obviousness challenge does not rectify the inadequacies of Scharf discussed above, namely that Scharf does not disclose obtaining order a and $a-1$ derivatives of the same reconstructed signal and *using* the ratio of the order a to the order $a-1$ across at least one cycle of the signal, as called for in claim 6. Therefore, similar to our anticipation analysis *supra*, we are not persuaded

that Petitioner has shown by a preponderance of the evidence that claim 6 is obvious over Jay and Scharf.

5. Dependent claim 13

Claim 13 depends directly from claim 1 and requires that “the electrophysiological signal comprises a portion of an electrocardiogram including portions of at least two lead signals, wherein an orthogonalization process is used to create at least two mutually orthogonal signals.” Ex. 1001, 31:3–7.

Petitioner, relying on the testimony of Dr. Anderson, argues that Scharf teaches expressly that a person of ordinary skill in the art “would appreciate that [its] signal processing approach could be used in a device that functionally processes physiological signals but is not referred to as an oximeter.” Pet. 32 (citing Ex. 1002 ¶ 121–122 (citing Ex. 1005 ¶ 89)). Also, Petitioner points out that Jay states its method can be used on “any device that outputs a waveform indicative of patient pulsatile cardiovascular behavior.” *Id.* (citing Ex. 1006, Abstract). Petitioner contends that a person of ordinary skill in the art would have recognized that devices for measuring cardiovascular behavior included an ECG. *Id.* (citing Ex. 1002 ¶ 123). Additionally, Petitioner argues that a person of ordinary skill in the art understood, for example from Korenberg (Ex. 1007), that FOS could be applied in the context of an ECG with cardiovascular data and that Jay’s FOS analysis, when applied to ECG signal data, “would involve at least two lead signals being replaced by two mutually orthogonal signals in the reconstruction.” *Id.* (citing Ex. 1002 ¶ 124; Ex. 1007, 268).

Patent Owner argues for the patentability of claim 13, asserting that neither Jay nor Scharf explicitly discloses “replacement of the lead signals in

claim 1 by signals derived from these lead signals but corrected to be mutually orthogonal.” PO Resp. 30. Patent Owner cites Dr. Zalesky’s testimony, which explains that Scharf does not disclose using two mutually orthogonal signals, whereas in claim 13 “these mutually orthogonal signals are used in place of the portions of the at least two lead signals.” *Id.* (citing Ex. 2026 ¶ 44). Patent Owner’s argument is essentially that claim 13 should be understood to mean converting two separate lead signals from *the same patient* to separate mutually orthogonal signals, which “is not the same as applying FOS to each lead signal separately.” *Id.* at 26.

Even if claim 13 is interpreted as requiring mutually orthogonal signals from at least two lead signals from the physical leads attached to a patient, we are persuaded that Petitioner has the stronger argument. As Petitioner notes, vector orthogonalization and transformation of standard twelve-lead ECG data into a subset of leads (e.g., into three X, Y, Z, lead orthogonal components) was a known signal processing technique for processing ECG data and obtaining a visualization of the electrical activity of a particular patient’s heart. *See* Pet. Reply 16–17 (citing Ex. 1025, 13:56–14:6). We are persuaded on the complete record before us that a person of ordinary skill in the art would have recognized that Jay’s FOS analysis, similar as it is to other types of signal analyses and transforms, such as the Gram-Schmidt process, when applied to ECG signals, would have been “used to create at least two mutually orthogonal signals from the portions of the at least two lead signals” of a patient, as called for in claim 13 of the ’864 patent. Therefore, we determine that claim 13 would have been obvious over Jay and Scharf.

F. Claims 7–8, 14–15, and 17–18 — Alleged obviousness over Jay, Scharf and Ahlström

Petitioner contends that claims 7–8, 14–15, and 17–18 would have been obvious in view of Jay, Scharf, and Ahlström.

1. Ahlström

Ahlström discloses signal analysis methods and techniques used to view time-series data in three-dimensional phase space plots. Section 5.1, for example, is titled “Assessing and classifying systolic ejection murmursmurmurs.” Ex. 1011, 125. Figure 5.1 of Ahlström illustrates apparently normal and abnormal (a heart murmur) heart signals in state space. *Id.* at 126.

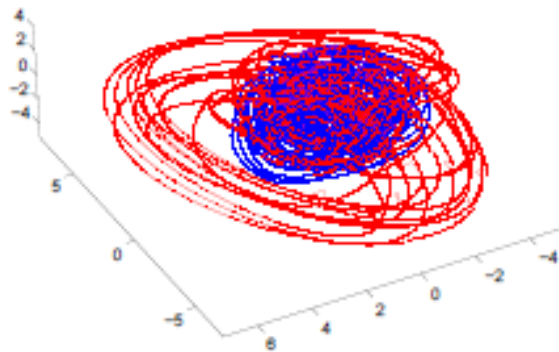


Figure 5.1 of Ahlström, above, depicts in three dimensions the phonocardiographic (“PCG”) heart signals including a heart murmur signal shown in blue, surrounded by typical heart signals shown in red. *Id.*

Also, Ahlström teaches that cardiovascular models can be superimposed with data to emulate different physical phenomena such as high and low blood flow velocity, as shown by the different color codes in Ahlström’s Figures 8.4(a)–(b) reproduced below. *Id.* at 193.

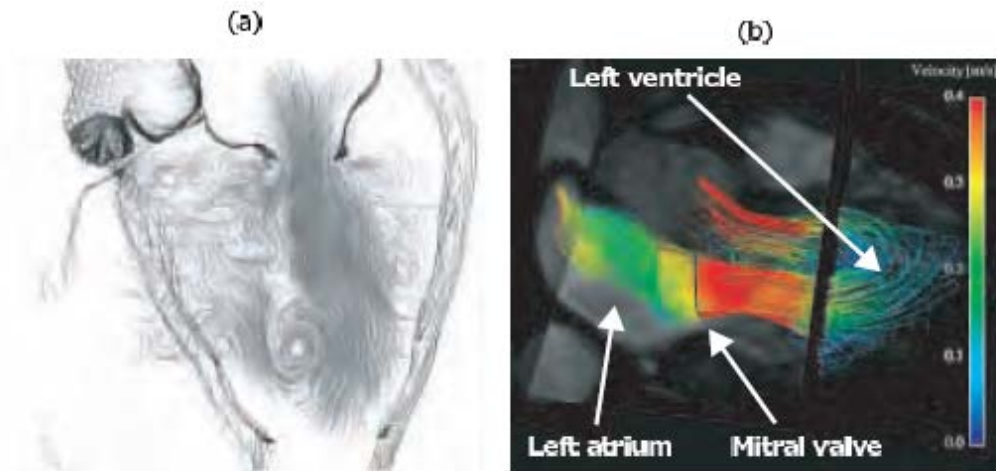


Figure 8.4(a), above left, depicts a section of the left ventricle, and Figure 8.4(b), above right, illustrates the left ventricle with color-coded blood flow velocity. *See id.*

2. Claims 7, 8, 14, and 15

Each of the claims in this ground are dependent, ultimately, on claim 1. Petitioner groups these dependent claims together, in part, because claims 7, 8, 14, and 15 “generally recite a method of analysis by visually presenting information derived from the reconstruction algorithm.” Pet. 34. For example, with respect to claim 7, Petitioner argues that a person of ordinary skill in the art “would understand that the ratio, as recited in the claims, are displayed to facilitate analysis of the reconstructed signal in a plot including a three-dimensional (3D) phase space plot.” *Id.* (citing Ex. 1002 ¶ 132). Petitioner also points to Figure 5.1 from Ahlström, as discussed and shown above, and, based on Dr. Anderson’s testimony, notes that such a “figure allows for assessment of abnormality in the signal, as the normal signal is shown in red and the abnormal signal is shown in blue.” *Id.* at 37 (citing Ex. 1002 ¶ 139).

Claim 7 depends from claim 6 and recites “wherein the ratio is displayed over at least one cycle of the electrophysiological signal to form a plot, and wherein one or more highlighted indicators are used in the plot to indicate those portions where the ratio is positive.” Ex. 1001, 30:21–25. Claim 8 depends from claim 7, and recites the additional limitation, “wherein the plot is placed over a portion of a 3-D outline of the heart.” *Id.* at 30:27–28. Although Ahlström discloses highlighted indicators visible on a 3-dimensional plot in Figure 5.1, and a plot in Figure 8.4 over what appears to be a 2-D outline of the heart, Ahlström does not recognize or reveal using the claimed “ratio of the derivative of order a to the derivative of order $a-1$,” as recited in claim 6 from which claims 7 and 8 depend. *Id.* at 30:11–20.

Claim 15 depends from claim 8 and recites “wherein the highlighted indicators comprise at least one of color coded indicators.” *Id.* at 31:32–33. As shown in Figure 5.1, above, reproduced from Ahlström, colored indicators provide for a visual assessment of normal and abnormal heart signals. To the extent it meets the limitations of claim 15, however, Ahlström does not remedy the deficiencies we identified above with respect to Jay and Scharf for claim 6, and we determine, therefore, that Petitioner has not demonstrated that claims 7, 8, and 15 are unpatentable in view of Jay, Scharf, and Ahlström.

Petitioner argues that dependent claim 14, which depends from claim 1, “generally recites the features of claims 5, 6, 7, 8, and 15 in a single claim.” Pet. 34. As discussed above, we determined that the Ahlström does not remedy the deficiencies we identified above with respect to Jay and Scharf for claim 6. Therefore, Petitioner has not shown by a preponderance

of the evidence that claim 14 is unpatentable in view of Jay, Scharf, and Ahlström.

3. *Claims 17 and 18*

Dependent claims 17 and 18 depend from dependent claims 2 and 3 respectively. Ex. 1001, 32:4–16. Petitioner argues that a person of ordinary skill in the art would have understood that for real and positive numbers, it is inherent that mathematically “a function of a second order derivative would have a value at each of the plurality of points over a set of points,” and that Ahlström teaches that “a derivative value is displayed over one of the points.” Pet. 41 (citing Ex. 1011, 54–55, 77, 125–126; Ex. 1002 ¶ 142). Patent Owner argues mainly that claims 17 and 18 are patentable for the same reasons as claims 2 and 3 and that Petitioner has not set forth the requisite motivation to combine Ahlström with Jay and Scharf. PO Resp. 30. Because we determined *supra* that Petitioner has shown that claims 2 and 3 are unpatentable, we address the motivation to combine issue below.

Petitioner’s analysis is not, we acknowledge, a superlative example of articulated reasoning to combine. Petitioner, however, does explain that a person of ordinary skill in the art would have known from Ahlström’s disclosure “that time-series data (such as a reconstructed signal) [] could be presented as a 3D phase space plot” and “[t]he state space representation makes it[] obvious where unstable areas are located.” Pet. 34–35 (citing Ex. 1002 ¶ 135). Petitioner relies on Dr. Anderson as well, who states that “Ahlstrom further disclosed using cardiovascular models to illustrate different physical phenomena.” Ex. 1002 ¶ 137. Jay and Scharf do not discuss specific types and characteristics of outputs; Scharf and Jay do,

however, disclose state that their systems include a display. Ex. 1005 ¶ 3; Ex. 1006, Fig. 5.

We acknowledge that Petitioner did not explicitly state the word “motivation” in assessing the combination here, but it is reasonable to understand, as described in both methods and systems of Jay and Scharf, that their signal analyses necessitated an output, i.e., a visual display of some type, including a representation of the reconstructed signal for a physician to review. *Id.* Ahlström certainly fits the bill, as it describes specific visual outputs of a PCG signal analysis including a 3-D reconstructed PCG signal and a 2-D representation of intra-cardiac blood flow overlaid with a diagram of the heart in Figures 5.1 and 8.4 respectively. We understand Petitioner’s explanation to include sufficient reasoning and motivation such that one of ordinary skill in the art would have been motivated to display Jay and Scharf’s reconstructed signal representations in a display, such as that shown in Ahlström, to facilitate the necessary review by a physician. Given that “a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp” and that Patent Owner has not provided any evidence or persuasive arguments as to why Ahlström’s material, in particular, would be excluded from the purview of one of ordinary skill in the art, we are persuaded that Petitioner’s obviousness analysis has shown by a preponderance of the evidence a motivation to combine. *KSR*, 550 U.S. at 421 (2007).

We determine, therefore, that Petitioner has shown by a preponderance of the evidence that Ahlström, as properly combined with Jay and Scharf, teaches displaying a representation of a reconstructed signal over

a plurality of points, and therefore, claims 17 and 18 would have been obvious over Jay, Scharf, and Ahlström.

G. Claims 9–12 and 16 — Alleged anticipation by Korenberg

Petitioner argues that claims 9–12 and 16 would have been obvious in view of, or anticipated by, Korenberg. Pet. 41–55.

1. Korenberg

Petitioner asserts that Dr. Korenberg, the sole inventor of the subject matter of the '864 patent, described the FOS algorithm that is the subject of the '864 patent in certain manuscripts that were published between 1988 and 1994, and thus predated, under 35 U.S.C. § 102(a)(1), the effective filing date of the '864 patent. Pet. 12. Specifically, Petitioner relies upon Korenberg, Exhibit 1007, titled “A Robust Orthogonal Algorithm for System Identification and Time-Series Analysis.” Ex. 1007, 267. This manuscript by Dr. Korenberg was incorporated by reference in its entirety, along with others, in the '864 patent. *See* Ex. 1001, 6:58–7:7 (Noting that “[t]he FOS process was introduced by the scientist M.J. Korenberg,” the '864 patent lists various articles by Dr. Korenberg apparently detailing the FOS process and techniques.).

Korenberg describes “methods for obtaining a parsimonious sinusoidal series representation or model of biological time-series data,” and emphasizes that “[a] key aspect is a rapid search for significant terms to include in the model for the system or the time-series.” Ex. 1007, 267. To achieve the rapid search Korenberg teaches FOS and ROS (Robust orthogonal search) analysis as an alternative to Fourier transforms, and building an orthogonal function based on a series of candidate terms where “the reduction in mean-square error achievable by selecting any given

candidate is readily obtained from the norm of the corresponding orthogonal function and the orthogonal expansion coefficient.” *Id.* at 269. Korenberg explains that FOS is “capable of higher resolution than a conventional Fourier series analysis. In addition, the methods can cope with unequally-spaced or missing data, and are applicable to time-series corrupted by noise.” *Id.* at 267.

2. Claims 9–12 and 16

Patent Owner does not address claims 9–11 and 16, but focuses its arguments, here, on claim 12, which is also addressed in the Motion to Amend in the context of proposed substitute claim 26 (as amendments to claim 9), which incorporate the specific “modified fast orthogonal search (MFOS)” limitations. PO Resp. 32–35; Mot. Amend 18–21. We address first claims 9–11 and 16.

Petitioner argues that independent claim 9 recites simply the “known attributes of FOS as published by Dr. Korenberg at least in 1989.” Pet. 42 (citing Ex. 1002 ¶¶ 144–153; Ex. 1007, 269, 270, 272). Petitioner argues specifically that FOS is a method of approximating an electrophysiological signal that chooses a model, i.e. a “measure” approximating the signal, for example mean-square error. Pet. 45 (citing Ex. 1002 ¶153; Ex. 1007, 269, 271). Petitioner argues further that Korenberg discloses using a computer processor to select appropriate terms, and multiple terms, to add to the model at a given stage. *Id.* at 45–46 (citing Ex. 1002 ¶153; Ex. 1007, 269–274). Also, Petitioner asserts that a person of ordinary skill in the art would have understood that Korenberg’s FOS method “will ‘cause the greatest reduction in measure of approximating a signal’ and, a second selected candidate selected after the first term will naturally cause ‘a relative

maximum of the reduction of the measure of approximating the signal,” as called for in claim 9. *Id.* at 46 (citing Ex. 1002 ¶ 153; Ex. 1007, 270, 275).

Claim 10 depends from claim 9 and adds the limitations of “separating a noise component from the plurality of terms selected for the model; and . . . forming a reconstructed electrophysiological signal whereby the noise component is removed by using a subset of the plurality of terms selected for the model.” Ex. 1001, 30:52–56. Petitioner argues that Korenberg’s FOS method also separates out a noise signal and thus “can be used to *reduce dramatically the degree of noise corruption.*” Pet. 49 (citing Ex. 1002 ¶ 159; Ex. 1007, 273). Claim 11 also depends from claim 9 and adds the limitation that “at least one of the two candidate terms . . . is a complex exponential.” Petitioner points out persuasively that the output of FOS include complex exponentials. *Id.* (citing Ex. 1001, 1:50–58; Ex. 1002 ¶ 160). Claim 16 further limits claim 9 by reciting that the measure of approximating the signal includes “at least . . . the mean-square error.” Ex. 1001, 31:36–32:3. Petitioner asserts for claim 16, as for claim 9, that Korenberg’s FOS method explicitly uses mean square error for approximating the signal. *Id.* at 50–51 (citing Ex. 1002 ¶ 164–66; Ex. 1007, 269).

For its part, claim 12 recites the step of “applying a modified fast orthogonal search (MFOS) transform.” Ex. 1001, 30:61–62. We determined in our claim construction, based on the express written description of MFOS in the ’864 patent, that the correct interpretation of an MFOS transform of an electrophysiological signal “includes selecting candidate terms to add to the model at successive stages, wherein at least two distinct candidate terms are selected at the same stage at least once.”

See Section II.A.1. Petitioner argues that the robust orthogonal search (“ROS”) method described in Korenberg “is indistinguishable from MFOS provided in the ’864 patent.” Pet. Reply 50 (citing Ex. 1002 ¶ 162). Neither Petitioner nor its declarant, Dr. Anderson, however, explains persuasively how ROS, although it may teach selecting multiple terms at a single stage, discloses a method consistent with the correct claim construction of MFOS requiring the hybrid approach of both successive stages and selecting at least two candidate terms to be added to the model at one or more of the successive stages. See *id.* at 49–50. Dr. Anderson points to a phrase in Korenberg regarding ROS, which states that “similar strategies . . . to select terms can be set down: e.g. considering two or more candidates at a time,” as equivalent to MFOS. Ex. 1002 ¶ 153 (citing Ex. 1007, 274, Section 5.1). However, Dr. Zalesky’s deposition testimony is consistent with his declaration, and persuasive that this passage in Korenberg would *not* have been understood by a person of skill in the art as selecting multiple terms in successive stages. See Ex. 1021, 101:5–9 (Dr. Zalesky testified that “my reading of [Korenberg] versus the claim is that the claim requires the combination of at least two terms per stage and going through sequential multiple stages.”).¹³ We find most persuasive here Patent Owner’s argument that the phrase “considering two or more candidates at a time” does not, by itself, indicate that multiple terms are selected and added by the ROS method, simply that they are “considered.” We are persuaded by Dr. Zalesky’s sentiment that it seems just as likely, if not more so in light of

¹³ We appreciate that Dr. Zalesky acknowledged that Dr. Anderson had come to a different conclusion, namely that Korenberg teaches the limitation of selecting multiple terms in successive stages. Ex.1021, 102:24–103:3.

Korenberg's express examples, that the phrase could mean eliminating a term. See Ex.1007, 275 (Following the above noted "considering" phrase, Korenberg states that "[w]ithin a given subset, a candidate term was permanently dropped from consideration if its potential reduction of mean-square error was less than a specified percentage of the output mean-square.").

We determine that Petitioner has shown by a preponderance of evidence that claims 9–11 and 16 are anticipated by Korenberg. Petitioner has not, however, shown by a preponderance of evidence that claim 12 is anticipated by Korenberg.

H. Claim 12— Alleged obviousness over Korenberg

Petitioner does not explicitly differentiate, in its arguments and application of Korenberg, between the stated challenges that "Korenberg anticipates or at a minimum renders obvious Claim 12." Pet. 50. Petitioner essentially leaves it to the Board to untangle its conflated analyses and arguments as between the two different legal standards for anticipation and obviousness. Having determined that Petitioner has failed to show that Korenberg expressly sets forth the MFOS analysis as recited in claim 12, the question left, therefore, resolves to whether Petitioner has established a *prima facie* case of obviousness that Korenberg would have suggested to a person of ordinary skill in the art the MFOS methodology as recited in claim 12, and as required in view of the proper claim construction. *In re Rinehart*, 531 F.2d at 1051.

Petitioner's main argument for both anticipation and obviousness is that "Korenberg discloses this method as ROS." Pet. 49 (citing Ex. 1002 ¶ 162). Petitioner, here, in the case of obviousness, fails to provide an

articulated reasoning with evidentiary underpinnings as to why and how a person of ordinary skill in the art would have understood ROS as teaching “selecting candidate terms to add to the model at successive stages, wherein at least two distinct candidate terms are selected in at least one stage at least once,” as MFOS is properly construed. Petitioner’s obviousness conclusion appears to be that a person of ordinary skill in the art would simply have understood ROS as teaching the hybrid MFOS approach of multiple stages and would have selected at least two terms in one of the stages, as claimed and described in the ’864 patent. It is unclear, however, from Petitioner’s arguments and evidence, *why* the MFOS approach is the same, or would follow from ROS as understood by a person of ordinary skill in the art.

Petitioner’s declarant, Dr. Anderson, simply concludes that ROS “is the same as the claimed MFOS.” Ex. 1002 ¶ 162. Dr. Anderson reaches this conclusion, apparently, based on the statement in Korenberg that suggests “considering two or more candidates at a time.” *Id.* (citing Ex. 1007, 274). As discussed above with respect to the anticipation challenge, this language may be read as described in the example at page 275 in Korenberg to mean eliminating terms, not necessarily selecting multiple terms to add at a given stage. *See* Ex. 1007, 275 (“Within a given subset, a candidate term was permanently dropped from consideration if its potential reduction of mean-square error was less than a specified percentage of the output mean-square.”). Korenberg itself, does not, without more than a conclusory statement by Dr. Anderson, explain sufficiently why a person of ordinary skill in the art would have both selected a term or terms at successive stages and, in at least one of the successive stages, selected at least two distinct candidate terms as is properly understood under the proper

construction of MFOS. The fact that such a combination of multiple stages and multiple selection of terms per stage, could have been done, does not explain why one of ordinary skill in the art would have done so. *See In re Laskowski*, 871 F.2d 115, 117 (Fed. Cir. 1989) (The mere fact that the prior art reference could be modified does not satisfy the requirements for a finding of obviousness.).

We are not persuaded that Petitioner has shown by a preponderance of evidence that claim 12 would have been obvious in view of Korenberg.

I. Claims 19 and 20 — Alleged anticipation by Adeney

Petitioner contends that independent claim 19, and respective dependent claim 20, of the '864 patent are anticipated by Adeney. Pet. 55.

1. Adeney

Adeney is authored by Michael J. Korenberg, the sole inventor of the '864 patent, and Kathryn M. Adeney, and describes a method of mathematically modeling time-series data where “[a]ccurate sinusoidal series models of biological time-series data may be obtained using a modeling algorithm known as fast orthogonal search (FOS).” Ex. 1008, Abst. Adeney discusses using FOS, and iterative fast orthogonal search (IFOS), for modeling time series data “for example, in the spectral analysis of electrocardiograms, respiration and heart rate data, and electroencephalograms.” Ex. 1008, 315.

2. Claims 19 and 20

Claim 19 recites “[a] method of using a model-building procedure to select a concise subset of electrocardiogram (ECG) leads to use out of a larger set of ECG leads.” Ex. 1001, 32:16–18. Petitioner asserts that the method recited by independent claim 19 is “a well-known type of problem

referred to as a feature subset selection problem (also referred to as a sensor selection problem).” Pet. 55 (citing Ex. 2001, 167). According to Petitioner, the FOS and IFOS methodology explained in Adeney discloses identification of significant sinusoidal components from biological signal data and determining a single model from multiple leads, i.e. experiments, thus disclosing each limitation of claim 19. *Id.* at 56. Petitioner argues that selecting a subset of leads from all the leads as called for in claim 19 is inherent in Adeney because a person of ordinary skill in the art would have known that “a few of the leads having these common basis functions would be representative of the set of multiple leads.” Pet. 58 (citing Ex. 1002 ¶ 173).

Patent Owner argues that the FOS and IFOS methods described in Adeney are not directed to determining a subset of leads from a larger set and eliminating redundant leads to speed up the calculations, but is “describing multiple sets of FOS model calculations, not multiple leads and not selecting from multiple leads.” PO Resp. 35–36. Patent Owner argues that Adeney’s method of “[f]inding a single set of model terms from multiple experiments is just what it says –selecting the best set of model terms after multiple experiments. It is not selecting a subset of lead signals.” *Id.* at 36. Dr. Zalesky testifies that Adeney’s method describes “[a] series of basis functions thus represents the original function, or signal. It is a representation of a signal. Where applied to ECG signals, it would be a representation of the signal from a single lead.” Ex. 2026 ¶ 58.

Petitioner responds, asserting that claim 19 does not actually claim selecting a subset of lead signals out of a larger set, as the preamble states. Pet. Reply 21–22. Petitioner was able to get Dr. Zalesky to state that the

claim does not explain entirely how the subset is eventually determined. *See* Ex. 1021, 114:1–5 (Discussing claim 19, Dr. Zalesky conceded that the inventor “doesn’t detail the specific steps and the procedure he uses.” Dr. Zalesky did, however, clarify his testimony with respect to both claims 19 and 20 that “it doesn’t give you detailed process specifications, but it does reference the methodologies used in the leads subselection.” *Id.* at 114: 12–15

We understand Dr. Zalesky’s testimony to be that certain steps for achieving the desired subset as set forth in the preamble are not explicitly recited, such as, comparing and then eliminating redundant signals are not specifically set out in claim 19, but that steps for determining the basis functions of each lead, which allows such comparison and elimination of redundant signals and the associated leads, are recited. *Id.* at 114:5–115:12. Dr. Zalesky explained his understanding of claim 19—even without all the explicit steps— that the inventor is

trying to identify one concise subset of model terms, [] selected from the candidate functions to fit the data from all the experiments. So put another way, he started with 12 leads. He wants to reduce that down to a smaller number of leads that can be well represented and yet still reflect the entire model of the EKG.

Ex. 1021, 108:21–109:3.

Whether or not the preamble is limiting, we are not persuaded that Petitioner’s arguments here with respect to either Adeney, or the language of claim 19 are sufficient to show anticipation. *See Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) “[W]hen the limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the

claimed invention.”). Claim 19, as a whole, is not simply focused on the signal from one lead, but recites in the body of the claim a “subset” and “larger set” of multiple leads as well as several steps performing the method “for each lead in the larger set,” and “selecting the same subset of lead signals, out of the candidate signals, to approximate all the target signals from all the experiments.” Ex. 1001, 32:20–27.

Petitioner has not explained sufficiently how these steps are each disclosed by Adeney’s lead signal selection from multiple experiments so as achieve a smaller set of leads to use out of a larger set of leads. Inherency does not always follow simply because something can be done. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”). Petitioner and Dr. Anderson alleging that the steps of claim 19 are “inherent” does not persuade us that the claimed steps involving multiple ECG leads are disclosed, explained, or even flow from the disclosure in Adeney. *See* Pet 58, *see also* Ex. 1002 ¶ 173.

Claim 20 depends from claim 19, reciting different mathematical transform analyses which may be used with the method of claim 19. We determine that claims 19 and 20 are not anticipated by Adeney.

J. Claims 19 and 20 — Alleged obviousness over Adeney and Mao

Petitioner alleges that claims 19 and 20 would have been obvious over Adeney and Mao. Pet 55.

1. Mao

Mao teaches using common search methods, specifically orthogonal forward selection (OFS) and an orthogonal backward elimination (OBE), to

determine an improved feature subset selection employing orthogonal transforms. Ex. 1010, Abst. This is important, Mao explains, because “[q]uite often, data acquisition process collects samples on a large number of variables when it is unknown which specific ones are most important for class discrimination.” *Id.* at 629. To obtain a more optimum solution using the most appropriate variables, Mao describes certain algorithms where “[t]he goal of feature subset selection is to identify and to select the most important and nonredundant variables from the large pool of potential variables.” *Id.*

2. Claims 19 and 20

To the extent that Adeney does not expressly disclose analysis of a multiple ECG lead configuration, Petitioner turns to Mao and argues that “Mao describes a *feature subset selection procedure* using an orthogonal forward selection algorithm with the purpose of selecting a subset of features.” Pet. 59 (citing Ex. 1010, 629 (Mao states that “[s]electing a subset of features from a pool of many potential variables is a common problem in pattern classification.”). Petitioner, relying on Dr. Anderson’s testimony, argues further that a person of ordinary skill in the art would have understood the multiple “feature” variables described in Mao to essentially equate to multiple “leads” as recited in claim 19 and “feature vector, x_i , $i = 1, \dots, n$ ” to equate to a “[l]ead [s]ignal from lead i .” *Id.* (citing Ex. 1002 ¶¶ 176–177). Petitioner argues that although neither reference discloses expressly the application of the mathematical methods and “features” to electrocardiogram leads, Adeney explains the need to “‘identify significant sinusoidal components within time-series data arises frequently in biological signal processing’, for example, in the spectral analysis of

electrocardiograms.” *Id.* at 59–60 (citing Ex. 1008, 315). Further, Dr. Anderson testifies that a person of ordinary skill in the art would have understood that Mao’s method of selecting a subset of features from a larger pool of variables, could be applied to biological signal leads, “such as from multiple ECG lead inputs.” Ex. 1002 ¶¶174.

The combination of Adeney and Mao would have been made by a person of ordinary skill in the art, Petitioner argues, because FOS was known “to achieve increased computational speed and linear approximation of all target signals” and “the Orthogonal Forward Feature Subset Selection algorithm of Mao is functionally equivalent to FOS, thus providing motivation to use FOS instead.” Pet. 63 (citing Ex. 1002 ¶¶ 182–183, 187). We find Petitioner arguments and evidence, here, persuasive.

Patent Owner argues that “[t]he term ‘lead’ doesn’t even appear in Adeney [] at all,” and neither Adeney nor Mao, alone or in combination, disclose “selecting a subset of leads” and “lead signals,” because “[l]ead signals are signals from ECG leads.” PO Resp. 36–37. Additionally, Patent Owner asserts that Petitioner has failed to explain “in the Petition why one would apply the math of Adeney or Mao to ECG lead selection.” *Id.* at 37.

We agree, to some extent with Patent Owner, that there is no explicit “suggestion in Mao or Adeney of the problem of selecting a concise subset of ECG leads out of a larger set of ECG leads.” *Id.* at 39. There is, however, no legal requirement that a specific suggestion or teaching of using an ECG lead or ECG signal itself, must be expressed in the prior art. *See KSR*, 550 U.S. at 420 (“any need or problem known in the field ... and addressed by the patent can provide a reason for combining the elements in the manner claimed”). It is error to “hold[] that courts and patent examiners

should look only to the problem the patentee was trying to solve.” *Id.* Petitioner has articulated in its briefs the relevance of the disclosure and teaching in both Mao and Adeney, along with reasoning and evidentiary underpinnings in the form of testimonial evidence from Dr. Anderson, which persuasively explains why and how one of ordinary skill in the art would have combined Mao’s feature subset selection with FOS as taught by Adeney. And, Petitioner has explained through its declarant, Dr. Anderson, that a person of ordinary skill in the art would have understood that the algorithms and methods described in the references would have been applied in the context of electrocardiogram lead inputs and procedures. *See* Pet. 55–63; Ex. 1002 ¶¶ 168–178.

Apart from pointing out that neither reference contains the word “lead” Patent Owner does not provide compelling evidence that the FOS, and IFOS analyses in Adeney, as applied to biological signals, or the orthogonal forward and backward transforms described by Mao, would have been difficult to implement for one of ordinary skill in the context of multiple ECG leads. PO Resp. 35. Patent Owner has not presented credible evidence that applying the feature subset selection in Mao to multiple features, such as ECG leads, from which variable lead signals emanate and are input to the described analyses, was unknown and would have been beyond the level of ordinary skill in the art. *See KSR*, 550 U.S. at 401 (“if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

Contrary to Patent Owner's assertion that Petitioner failed to show that either reference suggests undertaking analysis of ECG leads, Petitioner did argue in its Petition that a person of ordinary skill in the art "would have readily known from Adeney that there "existed a 'need to identify significant sinusoidal components within time-series data arises frequently in biological signal processing, for example, in the spectral analysis of electrocardiograms, respiration and heart rate data, and electroencephalograms.'" Pet. 56 (citing Ex. 1008, 315; Ex. 1002 ¶ 169). Also, Petitioner's declarant, Dr. Anderson, presents unrebutted testimony that biological signal processing using sensor selection algorithms from sensors, such as ECG leads, and the issue of redundancy and subset selection, was known by 2011 to those of ordinary skill in the art. Ex. 1002, ¶ 174. Dr. Anderson testifies persuasively that one of ordinary skill in the art would have understood that "the mathematical description recited in Mao would be one way of selecting the most important and non-redundant leads from a large pool of potential biological candidate leads, such as from multiple ECG lead inputs." *Id.* The FOS and IFOS algorithms described in Adeney, Dr. Anderson testifies, were known to those of ordinary skill in the art "who would be motivated to use FOS to improve computational speed and efficiency of the orthogonal search (OS) disclosed by Mao." Ex. 1002 ¶ 187.

We are persuaded that Petitioner has shown by a preponderance of evidence that claim 19 would have been obvious in view of Adeney and Mao. Also, claim 20 includes the additional limitation that "selecting the same subset of lead signals uses at least one of fast orthogonal search (FOS), modified fast orthogonal search (MFOS), least angle regression (LARS),

LASSO, and iterative fast orthogonal search (IFOS).” As discussed above, Adeney teaches the use of FOS as recited in claim 20. We are persuaded, therefore, that Petitioner has shown by a preponderance of evidence that claim 20 would have been obvious in view of Adeney and Mao.

IV. CONTINGENT MOTION TO AMEND

Having determined that claims 1–5, 9–11, 13, and 16–20 of the ’864 patent are unpatentable, we address Patent Owner’s contingent Motion to Amend.

In an *inter partes* review, amended claims are not added to a patent as of right but, rather, must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). We must assess the patentability of the proposed substitute claims “without placing the burden of persuasion on the patent owner.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017). Thus, we determine whether substitute claims are patentable by a preponderance of the evidence based on the entirety of the record. Patent Owner’s proposed substitute claims still must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. See “Guidance on Motions to Amend in view of *Aqua Products*” (Nov. 21, 2017) (https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf). Accordingly, Patent Owner must demonstrate (1) the amendment responds to a ground of unpatentability involved in the trial; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment proposes a reasonable number of substitute claims; and (4) the original disclosure sets forth written description support for each proposed claim. See 37 C.F.R. § 42.121.

A. Proposed substitute claims 21–27

Patent Owner proposes contingently substituting claims 21–27 for canceled original claims 1–5, 9, and 19. Mot. Amend 1. Patent Owner asserts that the proposed substitute claims do not enlarge the scope of the claims and are supported by the original specification. *Id.* at 6–11. Patent Owner characterizes the substitute claims as responsive to a ground of unpatentability involved in the proceeding. *Id.* at 2–3. Patent Owner explains that proposed independent claims 21–27 correspond to original independent claims 1–5, 9 and 19, but include, now, additional limitations to clarify and “to specifically set forth what is done with the abnormality shown in the derivative – that it is detected and displayed.” *Id.* at 3.

Proposed independent substitute claim 21 is reproduced below, with underlined material indicating language added to original claim 1.

21. (Substitute for Claim 1 if Claim 1 is cancelled) A method of detecting an abnormality in a patient from an electrophysiological signal, comprising:

- a) obtaining an electrophysiological signal corresponding to the patient;
- b) finding, using a processor of a computing device, a model corresponding to the electrophysiological signal wherein at least one term in the model is differentiable;
- c) obtaining the derivative of the at least one term; and
- d) using the derivative over at least one cycle of the electrophysiological signal in order to detect the abnormality;
- e) detecting the abnormality based on a value related to the derivative, wherein the derivative is not used to separate the signal from noise or motion artifacts; and
- f) displaying a plot, during at least one cycle of the electrophysiological signal, representative of the value related to

the derivative, wherein at least one highlighted indicator is used in the plot to indicate a portion corresponding to the abnormality.

Id. at 32.

B. Analysis of Substitute Claims

Petitioner does not challenge whether the number of substitute claims is reasonable. *See generally* Opp. Mot. Amend. Petitioner argues initially that proposed substitute claims 21–25 and 27 impermissibly enlarge the scope of the original claims and also that claims 21–25 introduce new matter, lack written description support, and are not enabled. *Id.* at 2–7. We do not address the issue of claim scope because we find in our analyses below that the proposed amendments enter new matter not supported by the specification of the '864 patent, and, even if the proposed amendments do not introduce new matter, that the amendments in proposed substitute claims 21–25 and 27 do not distinguish the proposed substitute claims from the prior art.

1. New Matter

Before discussing patentability, we note that a motion to amend claims may also be denied if it introduces new matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). A threshold question, therefore, is whether there is support in the specification of the '864 patent for the step of “detecting the abnormality based on a value related to the derivative” as added in claim 21. We find for the reasons set forth below that there is not adequate support.

Patent Owner argues that the newly claimed step of “detecting the abnormality based on a value related to the derivative” is supported by the specification, citing for example this description in the '864 patent:

Similarly, in other embodiments, by following the value of the ratio of the second derivative with the first derivative, it can be determined when the first derivative is increasing in amplitude, and may be helpful in predicting arrhythmias in various locations in the heart.

Ex. 1001, 11:59–63. We agree from this portion of the written description that there is support for the claimed limitation of “a value related to the derivative.” The ’864 patent specification clearly describes the value as “the ratio of the second derivative with the first derivative.” Ex. 1001, 11:60–61. The claim limitation at issue, read in its entirety requires, “*detecting the abnormality* based on a value related to the derivative.” Mot. Amend 32 (emphasis added). What we are not apprised of is support in the asserted portion of the specification for the limitation that the “ratio,” as the claimed “value,” is actually *detecting* an abnormality.

Petitioner explains persuasively that “any indicators associated with the ratio disclosed in FIG. 21A and 21B provide only information about the signal, not a medical diagnosis of an abnormality in the patient.” Opp. Mot. Amend 5. We find this explanation to be factually accurate and, frankly, the most reasonable reading of the specification language and the claims. For instance, we understand that the specification of the ’864 patent describes certain values, for instance a predetermined range of values, that may be color coded red, for example, to indicate potential instability. Ex. 1001, 11:64–12:11. But, as the specification also states, this color coding is simply highlighting some range of values of the model that “could represent the current status of the patient.” *Id.* at 12:10–11. Indeed, Dr. Zalesky acknowledged during his deposition that the model based on the derivative, i.e. a ratio of derivatives, is a representation of heart function, that allows a physician to make a diagnosis of an abnormality.

Q. So you state in your declaration that order used to detect the abnormality, and, again, the derivative doesn't detect the abnormality, correct?

A. Correct.

...

Q. Again, this is a first order derivative of the signal over the signal itself ?

A. Correct.

Q. And that creates a ratio?

A. Correct.

Q. And that ratio is the model, so to speak, that we're discussing?

A. That leads to the model, yes.

Q. Leads to the model that then leads to –

A. A representation.

Q. -- a representation that then leads to a doctor being able to assess the representation for an abnormality?

A. A diagnosis, yes.

Ex. 1021, 50:15–51:19. Our finding here—namely that the specification does not support the conclusion that the model determined from a ratio of derivatives is actually detecting an abnormality—is consistent with our claim construction in which we determined that the order of the derivative is also not “detecting” an abnormality. *See* Section II.A.4. Claim 21, as a whole, recites steps for producing an analytical mathematical model of the electrophysiological signals of a patient. The model, plotted for example in 2 or 3-dimensional space and appearing on a computer screen, is, as the specification describes, fundamentally a representation of physical function from an ECG signal, both normal and abnormal of a patient. Ex. 1001, 10:31–11:27, Figs. 9–11. This representation, however claimed or described

in the specification, and even including visually apparent highlights or indications of predefined values of the plotted signal data, is not sufficient evidence that there is adequate disclosure in the specification to support the claimed step of the method itself: “detecting the abnormality based on a value related to the derivative.” We are persuaded that Petitioner has shown that neither the specification nor Dr. Zalesky’s testimony adequately supports that the electrophysiological signal, the processor, or any portion of the claimed structure and function recited in claim 21 is “detecting the abnormality.”

2. Proposed substitute claim 21 would have been obvious over Scharf and Ahlström

We determined *supra* that the limitation of paragraphs (a)–(d) of claim 1 are anticipated by Scharf. See Section III.D.2. The same limitations (a)–(d) are again recited in proposed substitute claim 21. See Mot. Amend 32. The question, therefore, is whether Scharf discloses the new limitations, (e) and (f), added in proposed substitute claim 21.¹⁴ We find that except for “a highlighted indicator,” as disclosed by Ahlström, it does.

As discussed above, we determined that Scharf discloses taking a derivative of non-linear terms of a signal to obtain a better, more useful waveform, visually indicative of the patient’s cardiovascular behavior. Section III.D.2.; Ex. 1005 ¶ 67. Scharf states that “[t]he 2nd order derivative of PPG signals . . . facilitates efficient qualitative and quantitative morphological analysis of physiological signals since it visually represents

¹⁴ We use the term “limitation” regardless of whether such recitations are actual limitations or, in fact, statements of intended use. Because we find Scharf discloses these recitations, we need not determine whether “detecting the abnormality” is merely a statement of intended use.

physiological changes and other artifacts, better than that of normal waves.” Ex. 1005 ¶ 67. With respect to the newly added limitation “e) detecting the abnormality based on a value related to the derivative,” Scharf discloses using the ratio of the heights of different portions of the SDPTG waveform as “[a]nother significant qualitative parameter that is taken into consideration” to determine a unique cardiac morphology. *Id.* ¶ 69. Such a height ratio, or even simply the height, is quite plainly a “value related to the derivative” as recited in limitation e), which facilitates an accurate representation of the patient’s cardiac function and, hence, is the basis for detection of an abnormality in a patient. *See id.* ¶ 89 (Scharf summarizes its description by stating that “[t]he present invention utilizes the novel signal processing method in an oximeter to provide the enhanced detection of physiological signals.”).

Claim 21 e) also recites the limitation “wherein *the derivative is not* used to separate the signal from noise or motion artifacts.” Mot. Amend 32 (emphasis added). We acknowledge that negative limitations can be acceptable ways to claim certain subject matter. *See* MPEP 2173.05(i). Here, the wherein clause appears to be drafted to take advantage of the fact that Scharf allegedly does not explicitly state a similar negative proposition. But in actuality, it does. As Petitioner points out, Scharf discloses that it is not necessary to separate out the noise and artifacts where Scharf states “The SDPTG facilitates efficient qualitative and quantitative morphological analysis of physiological signals since it visually represents physiological changes and other artifacts, better than that of normal waves.” Opp. Mot. Amend 9 (citing Ex. 1005 ¶ 67), *see also* Ex. 1005 ¶¶ 23–25 (Scharf describes an embodiment with “[o]ptionally, the removal of motion

artifacts from the photo-plethysmographic signal.”). Although certain embodiments in Scharf may, in fact, separate out “noise or motion artifacts” from the signal, nothing in Scharf’s initial description with respect to the second order derivative photo-plethysmogram demands that this be done. In the above description from Scharf, a reasonable reading of one embodiment of SDPTG analysis describes evaluation of the derivative as a whole without separation of noise and artifacts.

Moreover, Patent Owner has failed to provide a cogent explanation apprising us of support in the specification of the ’864 patent for the wherein clause, or why the wherein clause distinguishes claim 21 from Scharf. Without explanation, Patent Owner implies written description support for this clause at “[Ex.] 1001, 9:24–35, 30:60–31:2.” Mot. Amend 8. We have reviewed these portions of the specification, including original claim 12, and find them unclear as to support for this particular wherein clause. *See, e.g.*, Ex. 1001, 9:24–28 (The referenced portion of the ’864 patent written description describes that “the time series was contaminated with additive zero-mean uncorrelated uniformly-distributed noise, with variance equal to that of the original time series, to create a noisy time series with SNR of unity (i.e., 0 dB, the 100% noise contamination case in FIG. 4C).”). How this embodiment provides support for the proposed wherein clause is unexplained by Patent Owner. *See* Mot. Amend 8. Patent Owner similarly fails to explain specifically how the wherein clause distinguishes over Scharf and the prior art in this proceeding. *Id.* at 13. Patent Owner states summarily that “[m]oreover the phrase ‘[]wherein the derivative is not used to separate the signal from noise or motion artifacts’ in element e) clearly distinguishes claim 21 from Scharf.” *Id.*

Proposed amended claim 21 also includes the recitations of new paragraph (f):

f) displaying a plot, during at least one cycle of the electrophysiological signal, representative of the value related to the derivative, wherein at least one highlighted indicator is used in the plot to indicate a portion corresponding to the abnormality.

Id. at 32 (emphasis omitted). Scharf discloses that its measurement system includes a visual display and outputs of a patients pulse rate and oxygen saturation, and illustrates in Figure 4a, a plot of SDPTG exhibiting a “unique cardiac morphology” for conducting a qualitative morphological analysis. Ex. 1005 ¶¶ 3–4, 68, Fig.4a. In addition, Petitioner’s declarant, Dr. Anderson, testifies that a person of ordinary skill in the art “would have known that such normalized signals provided useful information, such as rate of change of velocity, when presented in graphical form.” Ex. 1022 ¶ 24.

As discussed previously, Ahlström teaches that cardiovascular models can be displayed and superimposed with data to emulate different physical phenomena such as high and low blood flow velocity, as shown by the different color codes in Ahlström’s Figures 8.4(a)–(b). Ex. 1011, 193. Petitioner, supported by testimony from Dr. Anderson, argues that plotting and highlighting data in 2 and 3 dimensions to indicate an abnormality was well known to those of ordinary skill in the art. Pet. 34 (citing Ex. 1002 ¶¶ 132–135). Dr. Anderson explains persuasively that those of ordinary skill in the art would have known that graphical reconstructed biological time-series data “are displayed to facilitate analysis of the reconstructed signal in a plot including a three-dimensional (3D) phase space plot.” Ex. 1002 ¶ 132.

Having considered the complete record now before us and the evidence and arguments of both parties in this proceeding, we determine that Petitioner has provided the necessary articulated reasoning supported by evidentiary underpinnings, which persuades us that one of ordinary skill in the art would have been aware of Scharf and Ahlström, and would have had the requisite technical knowledge and motivation to combine these references to facilitate the identification in a visually displayed image and highlighted plot of a biological and physical abnormality in a patient as taught by Ahlström. Ex. 1011, 1, 193, Figs. 8.3–8.4. Petitioner has shown by a preponderance of the evidence that the combination of Scharf and Ahlström teaches all the limitations of proposed substitute independent claim 21, including the method steps arranged in the manner as required by claim 21. We deny Patent Owner’s Motion to Amend as to claim 21.

3. Proposed substitute claims 22–25

Proposed substitute dependent claims 22–25 depend, ultimately, from claim 21 and do not remedy the new matter deficiency discussed above in claim 21.¹⁵ Therefore, we also deny Patent Owner’s Motion to Amend as to claims 22–25. *See* 37 C.F.R. §§ 42.121(a)(2)(ii), 42.221(a)(2)(ii).

In addition, we are persuaded that Petitioner has demonstrated that proposed substitute claims 22–25 are unpatentable. Opp. Mot. Amend. 7–16. Petitioner has set out, in its Opposition to Patent Owner’s Motion to

¹⁵ Patent Owner proposed a claim construction for the added term “analytically differentiable” recited in proposed substitute claim 24, which depends directly from claim 21. Mot. Amend 4–5. Neither the proposed construction of this term nor this added limitation rectifies the underlying issues of new matter and obviousness of the steps e) and f) in proposed substitute claim 21.

Amend, a detailed, and persuasive analysis explaining how and why dependent claims 22–25 would have been obvious over Jay and Scharf. *Id.* For example, with respect to claim 22, Petitioner argues persuasively that in addition to the order of the derivative being a real number as taught by Jay, Scharf discloses an inverse Fast Fourier Transform and explains that “an IFFT operation can be expressed as a complex sinusoid term, a sine term, and a cosine terms,” as recited in claim 22. *Id.* at 13 (citing Ex. 1005, ¶¶65–66; Ex. 1022 ¶¶ 70–75). Because it is consistent with our analysis and review of the prior art disclosure and the knowledge and level of skill of one of ordinary skill in the art, we agree with, and adopt Petitioner’s arguments and unpatentability analysis with respect to proposed dependent claims 22–25. For this reason, we also deny the Motion to Amend as to dependent claims 22–25.

4. Proposed substitute claim 26

Patent Owner proposes that if independent claim 9 is found unpatentable, proposed substitute claim 26 should be considered. Mot. Amend. 1–2. Proposed substitute claim 26 recites not only selecting terms to add to the model at successive stages as was set forth in claim 9, but also “wherein at least two distinct candidate terms are selected in one stage.” Mot. Amend. 3, 34. We determined, above, that the appropriate claim construction of MFOS includes selecting candidate “terms to add to the model at successive stages, wherein at least two distinct candidate terms are selected in at least one stage at least once,” as expressly described in the ’864 patent. Section II. A.1. (citing Ex. 1001, 9:48–50). Proposed substitute claim 26 does not recite the acronym “MFOS,” but it does, with the

proposed amendments, recite language describing MFOS that is consistent with our claim construction and findings with respect to claim 12 above.

As discussed above with respect to claim 12, we are not persuaded that Petitioner and its declarant, Dr. Anderson, have adequately explained how Korenberg's disclosure of ROS, although it may teach selecting multiple terms at a single stage, discloses a method consistent with the correct claim construction of MFOS requiring the hybrid approach of both successive stages and selecting at least two candidate terms to be added to the model at one or more of the successive stages. Pet. Reply 49–50 (citing Ex. 1002 ¶ 162). Petitioner's Opposition relies essentially on the same arguments from their Petition with respect to Korenberg and sheds no new light that persuades us to overturn our findings above. See Opp. Mot. Amend 21–23 ("Petitioner summarizes its arguments that "substitute Claim 26 is unpatentable in light of the prior art of record and for the same reasons as original Claim 12.").

The claimed hybrid approach of MFOS, as properly construed, is now specifically set forth in proposed amended claim 26. Therefore, we determine that Petitioner has not shown claim 26 to be unpatentable.

5. Proposed substitute claim 27

We determined above that Petitioner has shown a preponderance of evidence that claim 19 would have been obvious in view of Adeney and Mao. Section III.J.2. Patent Owner's proposed substitute claim 27, intended to replace claim 19, is reproduced below showing the proposed amendments, as compared to claim 19, in underlining and brackets.

27. (Substitute for claim 19 if claim 19 is canceled) A method of using a model-building procedure on a processor of a computing

device to select a concise subset of electrocardiogram (ECG) leads to use out of a larger set of ECG leads, comprising:

- a. for each lead in the larger set, using the corresponding lead signal to define a candidate signal;
- b. for each lead in the larger set, using the corresponding lead signal to define a desired target output signal from an experiment; and
- c. selecting on the processor the [same] concise subset of [lead signals] leads, using [out of] the candidate signals, where each lead signal corresponds to a different lead, to approximate all the target signals from all the experiments by linear combinations of the selected lead signals, while allowing the coefficients of the selected lead signals to vary in approximating the target signals from one experiment to another.

Mot. Amend 34–35.

Patent Owner states that, in addition to inclusion of “a processor,” the amendments are intended “to clarify that selecting a subset of ‘lead signals’ means selecting a subset of ‘leads,’ not a subset of signals from a lead.” *Id.* at 10. Patent Owner argues that “the prior art shows selecting a subset of functions or features, and none of the prior art shows selecting a subset of lead signals.” *Id.* at 23. We discern little substantive difference between this argument, if any and that made with respect to claim 19, where Patent Owner argues that “[t]he term ‘lead’ doesn’t even appear in Adeney [] at all.” Neither Adeney nor Mao, alone or in combination, discloses “selecting a subset of leads” and “lead signals” because “[l]ead signals are signals from ECG leads.” *Compare* Mot. Amend 22–23, *with* PO Resp. 36–37.

Based on Petitioner’s arguments and evidence, we determined for claim 19 that a person of ordinary skill in the art would have understood the multiple “feature” variables described in Mao to equate to multiple “leads”

as recited in claim 19 and that Mao's "feature vector, x_i , $i = 1, \dots, n$ " to equate to a lead signal from lead i . Pet. 59 (citing Ex. 1002 ¶ 177). Dr. Anderson provides unrebutted testimony that a person of ordinary skill in the art "would have been motivated to use [Adeney's] disclosed method of selecting a subset of experiments (*e.g.*, sensors, trials, etc.) with regarding to any type of biological signal, including ECG leads." Ex. 1022 ¶ 43. We determined, also, that Petitioner has adequately supported the asserted combination of Mao and Adeney with articulated reasoning and evidentiary underpinnings in the form of persuasive testimonial evidence by Dr. Anderson, explaining why and how one of ordinary skill in the art would have combined Mao and Adeney. See Pet. 58, *see also* Ex. 1002 ¶¶ 174–175. Dr. Anderson testifies that "Mao describes a *feature subset selection procedure* using an orthogonal forward selection algorithm with the purpose of selecting a subset of features (such as ECG leads) in an attempt to maximize a measure of fitness or goodness for the subset." Ex. 1002 ¶ 176. The FOS and IFOS algorithms described in Adeney, Dr. Anderson testifies, were known to those of ordinary skill in the art "who would be motivated to use FOS to improve computational speed and efficiency of the orthogonal search (OS) disclosed by Mao." *Id.* ¶ 187. The arguments and evidence presented by Petitioner for claim 19 hold true and are persuasive even in the face of amendments specifying selection of a "concise subset of leads" as opposed to "lead signals." Therefore, we determine that proposed substitute claim 27 does not overcome the prior art of record in this proceeding. We determine that Petitioner has shown by a preponderance of the evidence that proposed substitute claim 27 would have been obvious in view of Adeney and Mao.

Based on the complete record before us and Petitioner's arguments and evidence as discussed above with respect to claims 1–5, 9, and 19, we determine that a preponderance of the evidence shows that the subject matter of proposed claims 21–25 and 27 would have been obvious in view of Scharf and Ahlström (claims 21–25), and Adeney and Mao (claim 27). Accordingly, we *deny* Patent Owner's Contingent Motion to Amend as to claims 21–25 and 27.

We determine that Petitioner's arguments and evidence do not show a preponderance of evidence that claim 26 is anticipated by or obvious over Korenberg. We therefore *grant* Patent Owner's Motion to Amend as to claim 26.

V. SUMMARY

Petitioner has proved by a preponderance of the evidence that claims 1–5 are anticipated by Scharf, and that claims 1–5 and 13 would have been obvious in view of Jay and Scharf;

Petitioner has not proved by a preponderance of the evidence that claim 6 is anticipated by Scharf or obvious in view of Jay and Scharf.

Petitioner has not proved by a preponderance of the evidence that claims 7, 8, 14, and 15 are unpatentable over Jay, Scharf, and Ahlström.

Petitioner has proved by a preponderance of the evidence that claims 17 and 18 would have been obvious over Jay, Scharf, and Ahlström.

Petitioner has proved by a preponderance of the evidence that claims 9–11 and 16 are anticipated by or obvious in view of Korenberg.

Petitioner has not proved by a preponderance of the evidence that claim 12 is anticipated by or obvious over Korenberg.

Petitioner has proved by a preponderance of the evidence that claims 19–20 would have been obvious in view of Adeney and Mao.

We deny Patent Owner’s Contingent Motion to Amend to replace claims 1–5 and 19 with substitute claims 21–25 and 27.

We grant Patent Owner’s Contingent Motion to Amend to replace claim 9 with substitute claim 26.

VI. ORDER

For the reasons given, it is

ORDERED, based on a preponderance of the evidence, that claims 1–5, 9–11, 13, and 16–20 are unpatentable;

FURTHER ORDERED, based on a preponderance of the evidence, that claims 6–8, 12, 14, and 15 are not unpatentable;

FURTHER ORDERED, Patent Owner’s Motion to Amend is *denied* as to replacing claims 1–5 and 19 with substitute claims 21–25 and 27;

FURTHER ORDERED, Patent Owner’s Motion to Amend is *granted* as to replacing claim 9 with substitute claim 26; and

FURTHER ORDERED, because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 9,131,864 B2

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