

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECKMAN COULTER, INC.,
Petitioner,

v.

SYSMEX CORPORATION and SYSMEX AMERICA, INC.,
Patent Owner.

IPR2020-01503
Patent 10,401,351 B2

Before CHRISTOPHER L. CRUMBLEY, JO-ANNE M. KOKOSKI, and
ELIZABETH M. ROESEL, *Administrative Patent Judges*.

KOKOSKI, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6, and issue this Final Written Decision pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Beckman Coulter, Inc. (“Petitioner”) has shown by a preponderance of the evidence that claims 7–15 (“the challenged claims”) of U.S. Patent No. 10,401,351 B2 (“the ’351 patent,” Ex. 1001) are unpatentable.

A. *Procedural Background*

Petitioner filed a Petition to institute an *inter partes* review of claims 7–15 of the ’351 patent. Paper 1 (“Pet.”). Sysmex Corporation and Sysmex America, Inc. (collectively, “Patent Owner”) filed a Preliminary Response. Paper 6. Pursuant to 35 U.S.C. § 314(a), we instituted an *inter partes* review of claims 7–15 on the ground advanced in the Petition. Paper 10 (“Institution Decision” or “Dec.”), 7, 29–30.

After institution of trial, Patent Owner filed a Patent Owner Response (“PO Resp.,” Paper 15), Petitioner filed a Reply (“Pet. Reply,” Paper 18), and Patent Owner filed a Sur-reply (“Sur-reply,” Paper 24). We held an oral hearing on December 1, 2021, and a transcript is included in the record. Paper 32 (“Tr.”).

B. *Real Parties-in-Interest*

Petitioner identifies Beckman Coulter, Inc. as the real party-in-interest. Pet. 3. Patent Owner identifies Sysmex Corporation and Sysmex America, Inc. as the real parties-in-interest. Paper 5, 1.

C. *Related Matters*

The parties indicate that the ’351 patent is involved in the following proceeding: *Sysmex Corp. v. Beckman Coulter, Inc.*, Case No. 1:19-cv-01642-RGA-CJB (D. Del.). Pet. 3; Paper 5, 1.

D. The '351 Patent

The '351 patent is titled “Sample Analyzer and Computer Program Product,” and relates to “a sample analyzer and a computer program product capable of measuring not only blood, but also body fluids other than blood such as cerebrospinal fluid (spinal fluid), fluid of the thoracic cavity (pleural fluid), abdominal fluid and the like.” Ex. 1001, code (54), 1:19–23. The sample analyzer includes a measuring unit that measures blood and body fluids and a data processing unit that obtains analysis results by processing the output from the measuring unit. *Id.* at 4:20–24. Figure 2 of the '351 patent is reproduced below.

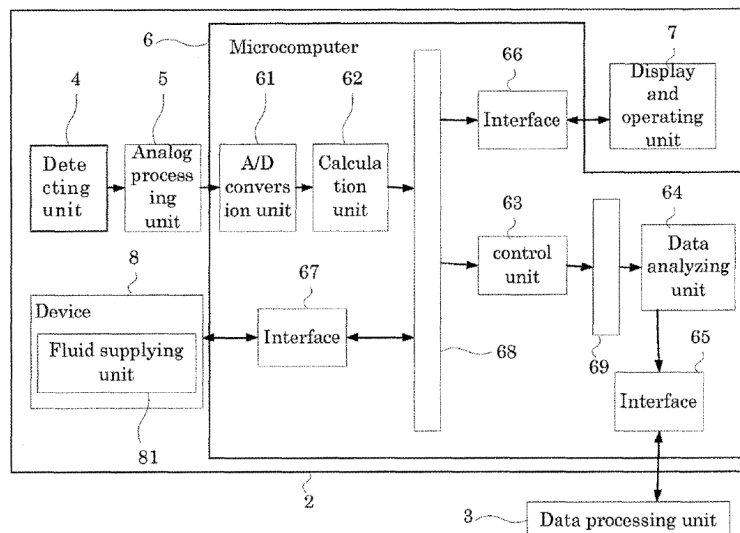


FIG.2

Figure 2 is a block diagram of the measuring unit of the sample analyzer described in the '351 patent. *Id.* at 3:14–15. Measuring unit 2 includes blood cell detecting unit 4, analog processing unit 5 that processes the output of detecting unit 4, microcomputer unit 6, display and operating unit 7, and device 8 for measuring blood and body fluids. *Id.* at 4:29–35. Blood cell detecting unit 4 further includes white blood cell (“WBC”) detection unit 41 (not shown) for detecting white blood cells and nucleated red blood cells and

reticulocytes, and red blood cell/platelet (“RBC/PLT”) detection unit 42 (not shown) for measuring the number of red blood cells and the number of platelets. *Id.* at 5:62–6:1.

The ’351 patent teaches that the blood measuring mode and the body fluid measuring mode are separate measuring modes that comprise different operations. *Id.* at 9:12–39, 10:53–11:4, 11:38–13:32. “In the standby state, the operator can change the measurement mode by operating the display and operation unit.” *Id.* at 9:12–14. Figure 8 of the ’351 patent is reproduced below.

Manual	Next No.	1	Num
CDNR	OP No.		OP
Measurement not possible			Xm
<manual sample number input>			
Sample number		1	
Mode	1	2	3
	manual	capillary	closed
Discrete			
1	2	3	4
CBC	CBC	CBC	CBC
		DIFF	DIFF
	NRBC		
		RET	RET
Sample 1	2	3	
Normal	HPC	Body Fluid	

Fig.8

Figure 8 is a schematic view of the display screen for setting the measurement mode. *Id.* at 3:22–23. The screen is provided with discrete display regions including sample number 120, type of sample uptake mode 121, type of discrete test (measurement mode) 122, and type of sample 123. *Id.* at 9:15–18. Sample uptake mode 122 includes a manual mode for aspirating a sample after the sample container is manually inserted in the sample aspiration nozzle, a capillary mode for aspirating a sample via the aspiration nozzle “after the operator has previously prepared the measurement sample by mixing a sample and reagent,” and a closed mode in

which the sample container is automatically transported using a conveyer device. *Id.* at 9:18–27. “The types of samples include NORMAL, which are normal blood samples; HPC, which are hematopoietic progenitor cell samples; and BODY FLUID, which are other fluids of the body.” *Id.* at 9:27–30. The ’351 patent explains:

The operator can specify the sample take-up mode, measurement mode, and type of sample. When the blood measurement mode has been specified, the NORMAL sample type is specified, and an optional sample take-up mode and measurement mode are specified. When specifying the BODY FLUID measurement mode, the operator specifies MANUAL mode as the take-up mode, [CBC+DIFF], [CBC+DIFF+RET], [CBC+DIFF+NRBC], or [CBC+DIFF [+] NRBC+RET] as the DISCRETE test, and [BODY FLUID] as the type of sample.

Id. at 9:30–39.

When the measurement mode is switched from blood measurement to body fluid measurement mode, the measuring unit runs a pre-sequence process to prepare for the body fluid measurement that includes a blank check operation to confirm the lack of carryover effect from the blood cell components. *Id.* at 10:60–11:10. This pre-sequence is not performed when the measurement mode is switched from body fluid measurement to blood measurement because there is no carry over effect on the normal blood measurement results. *Id.* at 11:10–14.

E. Illustrative Claim

Petitioner challenges claims 7–15 of the ’351 patent. Pet. 1, 5. Claim 7, the only independent challenged claim, is illustrative of the claimed subject matter and is reproduced below.

7. A sample analyzer comprising:
 - a plurality of detectors comprising at least one optical detector for optically sensing cells in a sample and at

least one electrical detector for electrically sensing cells in the sample, the sample selectively comprising (i) a blood sample or (ii) a body fluid sample, wherein the body fluid sample contains body fluid, other than blood, which is selected from a group consisting of cerebrospinal fluid, thoracic fluid, abdominal fluid, fluid collected in a cardiac sac, synovial fluid, dialysate from peritoneal dialysis, and intraperitoneal rinse;

a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode, wherein the blood measuring mode includes a sequence of operations for measuring cells in the blood sample, and the body fluid measuring mode includes a sequence of operations for measuring cells in the body fluid sample, and wherein a respective sequence of operations for measuring cells in the blood sample and in the body fluid sample comprises (a) a sensing operation comprising operations of preparing for measurement and operating a detector to sense cells in the sample and (b) an analyzing operation comprising operations of analyzing measurements from the sensing operation and displaying analysis results, and further wherein the plurality of detectors include one or more multi-mode detectors configured to operate in both the blood measuring mode and body fluid measuring mode;

the controller programmed to:

display on an input screen (1) at least two sample-type options that comprise a concurrent display of a blood sample option and a body fluid sample option each independently selectable from the other on the input screen and (2) one or more test modes displayed separately from a selected one of the at least two sample-type options;

in response to (I) a user input, on the input screen, of selecting the blood sample option from the displayed at least two sample-type options and (II) an

additional user input, on the input screen, of setting one test mode from the displayed one or more test modes, perform the sensing operation in the blood measuring mode to: prepare a blood measurement sample from the blood sample; introduce at least part of the prepared blood measurement sample into an optical detector; and operate the optical detector to optically sense white blood cells in the introduced blood measurement sample, and further perform the analyzing operation in the blood measuring mode to: analyze blood-sample measurements of the white blood cells sensed in the introduced blood measurement sample; count each of the five types of white blood cells based on the analyzed blood-sample measurements; and display a count of each of the five types of white blood cells; and

in response to (I) a user input, on the input screen, of selecting the body fluid sample option from the displayed at least two test-sample options and (II) an additional user input, on the input screen, of setting said one or a different test mode from the displayed one or more test modes, perform the sensing operation in the body fluid measuring mode to: prepare a body fluid measurement sample from the body fluid sample; introduce at least part of the prepared body fluid measurement sample into an electrical detector; operate said electrical detector to electrically sense cells in the introduced body fluid measurement sample, and further perform the analyzing operation in the body fluid measuring mode to: analyze body fluid-sample measurements of the cells sensed in the introduced body fluid measurement sample; count mono-nucleated cells and poly-nucleated cells based on the analyzed body-fluid sample measurements; and separately display in a screen a count of the mono-nucleated cells and a count of the poly-nucleated cells.

Ex. 1001, 18:14–19:25.

F. The Asserted Ground of Unpatentability

Petitioner asserts that claims 7–15 of the '351 patent are unpatentable as having been obvious under 35 U.S.C. § 103 over the combined teachings of Nagai¹ and Jagtiani.² Pet. 5. Petitioner relies on the Declaration of John W. Roche (Ex. 1048) and the Supplemental Declaration of John W. Roche (Ex. 1049) to support its contentions. Patent Owner relies on the Declaration of J. Paul Robinson, Ph.D. (Ex. 2052) and the Supplemental Declaration of J. Paul Robinson, Ph.D. (Ex. 2069) to support its arguments.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Factors pertinent to a determination of the level of ordinary skill in the art include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) education level of workers active in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, “[t]hese factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In determining the level of ordinary skill, we may also look to the prior art, which may reflect an

¹ U.S. Patent No. 8,440,140 B2, issued May 14, 2013 (Ex. 1044).

² WO 2019/236682 A1, published Dec. 12, 2019 (Ex. 1045). Petitioner asserts that Jagtiani is prior art as of the Nov. 5, 2018 filing date of a provisional application to which benefit is claimed. Pet. 19.

appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Additionally, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421.

Petitioner contends that a person having ordinary skill in the art (“POSA”)

would have possessed at least a Bachelor’s or Master’s degree in biologic science, biomedical engineering, and/or electrical engineering or a related field, had at least five years of experience in developing hardware and/or software for hematology analyzers, and was familiar with the design and operation of hematology analyzers available in the market, including the Sysmex XN-Series analyzers, the Beckman Coulter DxH Series analyzers and other commercially available automated hematology analyzers.

Pet. 21–22.

Patent Owner argues that a person having ordinary skill in the art “would have possessed a Bachelor’s or Master’s degree in biological science, biomedical and/or electrical engineering, or a related field, or would have had at least three years of experience in developing or using hardware and/or software for blood and other body fluids.” PO Resp. 11 (citing Ex. 2052 ¶¶ 21–27). Dr. Robinson testifies “that someone with less technical education but more experience, or more technical education but less experience would have also met this standard.” Ex. 2052 ¶ 26. Dr. Robinson further testifies that his opinions “would be the same” using Petitioner’s proposed level of skill in the art. *Id.* ¶ 27.

Patent Owner argues that Petitioner’s proposed skill level “could be read narrowly to only include persons with 5 or more years of industry experience developing commercial products, and to exclude others who have vast knowledge of hematology analyzers, such as academics that have

engaged in years of research, teaching and publishing in the field,” and “also could exclude academics, researchers, laboratory directors and technicians who may not have personally developed a hematology analyzer, but are deeply knowledgeable about their design and operation from years of experience studying and using them.” PO Resp. 12.

Petitioner replies that, because “a POSA may include persons with more technical experience in one area and less in another” and “such experience need not necessarily be limited to hematology analyzers particularly if relevant experience was obtained in other areas of medical devices,” the differences between the parties’ proposals regarding the level of skill of a POSA do not affect the outcome of this proceeding. Pet. Reply 3. Mr. Roche also testifies that he “considered Dr. Robinson’s definition of a POSA” and “do[es] not believe that the differences between our respective positions regarding the level of skill of a POSA affect [his] opinions in this matter.” Mr. Roche also agrees “that a POSA may include persons with more technical education or experience in one area and less in another, and that hardware development experience need not necessarily be limited to hematology analyzers, particularly if relevant experience was obtained in other areas of medical devices.”

In the Institution Decision, we determined that Petitioner’s definition was consistent with the disclosure of the ’351 patent and the scope and content of the asserted prior art to the extent that Petitioner’s definition requires familiarity with the design and operation of automated hematology analyzers available in the market. Dec. 8 (citing Ex. 1001, 1:45–61, 15:52–58). We also determined that Petitioner’s proposal was more reasonable than Patent Owner’s with respect to the duration of a POSA’s practical experience, whether such practical experience is in addition to or possibly as

a substitute for an educational component, and whether a POSA's practical experience could be merely using hardware and/or software for an analyzer, as opposed to developing such hardware and/or software. *Id.* at 8–9.

Neither party contends that the differences in proposals affect the outcome of this proceeding, and we find that they do not. Nonetheless, on the full record now before us, we find that our identification of the level of ordinary skill in the art in the Institution Decision, modified to state that a higher level of experience can compensate for less technical education, is supported by the '351 patent, the prior art of record, and the opinions of Mr. Roche and Dr. Robinson (which, as discussed above, recognize that additional work experience can compensate for technical education). Thus, we find that a POSA would have had at least a Bachelor's or Master's degree in biologic science, biomedical engineering, and/or electrical engineering or a related field and at least five years of experience in developing hardware and/or software for hematology analyzers, and would have been familiar with the design and operation of hematology analyzers available in the market. We also find that less technical education may be compensated by a higher level of experience, or vice versa.

B. Claim Construction

We apply the claim construction standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) (2019). Under *Phillips*, the “words of a claim ‘are generally given their ordinary and customary meaning,’” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312–13. “[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the

controversy.” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Tecs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

In the Petition, Petitioner proposes constructions for the claim terms “a controller programmed to,” “optical detector,” “electrical detector,” and “mono-nucleated cells and poly-nucleated cells” as recited in claim 7, and “total count of nucleated cells” as recited in claims 8 and 13. Pet. 22–29. Patent Owner responds that “[t]he District Court issued an opinion regarding claim construction on April 6, 2021,” and, “[f]or purposes of this proceeding, Patent Owner applies the District Court’s constructions.” PO Resp. 13. Patent Owner also specifically addresses the terms “controller programmed to” and “electrical detector.” *Id.* at 13–14. Petitioner replies that its proposed claim constructions are consistent with the District Court’s constructions. Pet. Reply 4–5. At the oral hearing, the parties confirmed that they do not dispute the District Court’s claim constructions. *See* Tr. 16 (Petitioner’s counsel stating that “Petitioner would request that this Board adopt these same [District Court] constructions in this IPR”), 34 (Patent Owner’s counsel agreeing that “neither side has objected to the court’s claim construction”).

Based on the parties’ apparent agreement, and considering the record before us and the Report and Recommendation from the District Court (Ex. 2065), we agree with and adopt the District Court’s claim constructions. *See* 37 C.F.R. § 42.100(b) (“Any prior claim construction determination concerning the claim in a civil action . . . that is timely made of record in the *inter partes* review proceeding will be considered.”). Accordingly, we construe the terms “controller programmed to,” “electrical detector,” and “optical detector” as set forth below.

“controller programmed to”	plain and ordinary meaning
“electrical detector”	detector that measures electrical properties, rather than optical properties
“optical detector”	detector that measures optical properties, rather than electrical properties

Ex. 2065, 13, 25–28. We determine it is not necessary to expressly construe any other claim term to resolve the parties’ dispute. *Nidec Motor*, 868 F.3d at 1017.

C. Earliest Effective Filing Date of the ’351 Patent

The ’351 patent issued from U.S. Patent Application Serial No. 16/363,694 (“the ’694 application”), filed on March 25, 2019 as a continuation of application No. 16/214,417, filed on Dec. 10, 2018, which is a continuation of application No. 15/908,339, filed on Feb. 28, 2018, now Pat. No. 10,151,746, which is a continuation of application No. 14/594,319, filed on Jan. 13, 2015, now Pat. No. 9,933,414, which is a continuation of application No. 13/891,667, filed on May 10, 2013, now Pat. No. 8,968,661, which is a continuation-in-part of application No. 12/023,830, filed Jan. 31, 2008, now Pat. No. 8,440,140.

Ex. 1001, codes (21), (22), (63). The earliest application in this chain, Application No. 12/023,830 (“the ’830 application”) filed on January 31, 2008, issued as Nagai. Ex. 1044, code (21); *see* Pet. 18. Petitioner contends that “[c]laims 7–15 lack adequate written description support in the applications to which the ’351 patent claims priority” and “are not entitled to the benefit of the filing dates of the cited priority applications.” Pet. 1.

Instead, Petitioner contends that the earliest effective filing date for the '351 patent is the March 25, 2019 filing date of the '694 application. *Id.* at 42.

“It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.” *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *see also Research Corps. Techs. v. Microsoft Corp.*, 627 F.3d 859, 871–72 (Fed. Cir. 2010) (holding the later-filed application, with claims that were not limited to a “blue noise mask,” was not entitled to the priority filing date of the parent application, which was “limited to a blue noise mask”); *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1377–78 (Fed. Cir. 2009) (holding that “spikeless” claims “added years later during prosecution” were not supported by the specification which “describe[d] only medical valves with spikes”); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158–60 (Fed. Cir. 1998) (holding the generic shaped cup claims of the later-filed child application were not entitled to the filing date of the parent application that “disclosed only a trapezoidal cup and nothing more”). “To satisfy the written description requirement the disclosure of the prior application must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.” *PowerOasis*, 522 F.3d at 1306 (alteration in original, emphasis omitted). The sufficiency of written description support is based on “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Petitioner has the burden to persuade us that Nagai and Jagtiani are qualified as prior art. “In an *inter partes* review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ . . . and that burden never shifts to the patentee.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (quoting 35 U.S.C. § 316(e)). Petitioner asserts that the combined teachings of Nagai and Jagtiani disclose each limitation of claims 7–15, and that the ’351 patent is not entitled to an effective filing date before March 25, 2019. Following Petitioner’s showing regarding the alleged obviousness of the subject matter of the challenged claims in view of Nagai and Jagtiani (Dec. 10–20), the burden of production shifted to Patent Owner to produce evidence and present persuasive argument based on the evidence to show that Nagai and Jagtiani are not prior art because the challenged claims are entitled to the benefit of the January 31, 2008 filing date of the ’830 application. *See Dynamic Drinkware*, 800 F.3d at 1379. Petitioner has the burden of persuasion, based on all of the evidence, to prove unpatentability of the challenged claims, and this burden never shifts. *Id.*

Petitioner’s contention that the challenged claims are not entitled to the January 31, 2008 filing date is based on the following limitations of claim 7:

the controller programmed to . . . in response to . . . user input . . . introduce at least part of the prepared body fluid measurement sample into an electrical detector; operate said electrical detector to electrically sense cells in the introduced body fluid measurement sample, and further perform the analyzing operation in the body fluid measuring mode to: analyze body-fluid-sample measurements of cells sensed in the introduced body fluid measurement sample; count mono-nucleated cells and poly-nucleated cells based on the analyzed body-fluid-sample measurements; and separately display in a

screen a count of the mono-nucleated cells and a count of the poly-nucleated cells.

Ex. 1001, 18:44, 19:4–25; *see generally* Pet. 32–41. Specifically, Petitioner argues that the '351 patent specification³ “does not disclose, nor did the inventors possess, any ‘electrical detector’ for obtaining measurements from which the classification of white blood cells could be obtained,” and does not describe “how the claimed ‘controller’ might classify or count mono-nucleated cells and poly-nucleated cells based on an analysis of body fluid measurements by an electrical detector.” Pet. 34, 38, 40.

Patent Owner responds that the '351 patent specification provides written description support for the challenged claims, and that the claims are entitled to an effective filing date of January 31, 2008. PO Resp. 14–38. In particular, Patent Owner contends that the language of claim 7 does not limit the use of the recited electrical detector to detecting only white blood cells. PO Resp. 17–19. Patent Owner contends that the '351 patent specification “describes an embodiment of an electrical detector that electrically senses cells including red and white blood cells, in a blood sample or in a body fluid sample.” *Id.* at 20 (citing Ex. 2052 ¶ 110). Patent Owner also contends that the '351 patent specification describes a detection device in the measuring unit of the analyzer that is provided with a detection unit for detecting white blood cells and a detection unit for detecting red blood cells

³ The parties cite to the '351 patent specification to support their arguments with respect to whether the challenged claims have written description support in the priority applications. *See generally* Pet. 32–42; PO Resp. 16–38. There is no dispute that the content of the specification of Nagai (and the other applications in the '351 patent's chain of priority) and the specification of the '351 patent are the same. Pet. 18; PO Resp. 1. Therefore, we treat the parties' statements regarding a lack of disclosure in the '351 patent specification as applying equally to the priority applications.

and platelets, and that an ordinarily skilled artisan “would know that the two most common types of devices for detecting red or white blood cells are electrical detectors and optical detectors, whose structure and function were well known in the art for many years.” *Id.* at 21 (citing Ex. 2052 ¶ 111).

Based on our review of the full record now before us, we determine that Petitioner has established that the priority applications do not provide adequate written description support for the challenged claims. More specifically, we find that the priority applications do not reasonably convey to a POSA that the inventors were in possession of a sample analyzer that both (1) uses an electrical detector to electrically sense cells in a body fluid measurement sample, and (2) from the analysis of the cells sensed by the electrical detector, counts the number of mono-nucleated cells and poly-nucleated cells in the body fluid measurement sample as required by claim 7.

We begin with the language of claim 7. In relevant part, claim 7 requires a controller programmed to: (1) “introduce at least part of the prepared body fluid measurement sample into an electrical detector;” (2) “operate said electrical detector to electrically sense cells in the introduced body fluid measurement sample;” (3) “perform the analyzing operation in the body fluid measuring mode to: analyze body-fluid-sample measurements of cells sensed in the introduced body fluid measurement sample;” and (4) “count mono-nucleated and poly-nucleated cells based on the analyzed body-fluid-sample measurements.” Ex. 1001, 18:44, 19:13–25. In claim 7, “the introduced body fluid measurement sample” in element (2) above refers back to the part of the prepared body fluid measurement that is introduced in an electrical detector in element (1). Element (3) then requires that the analyzing operation be performed on the cells sensed by the electrical detector in the introduced body-fluid measurement sample. Accordingly, in

element (4), the mono-nucleated cells and poly-nucleated cells that are counted in the body fluid measurement sample are those that were introduced into, and sensed by, the electrical detector. Therefore, in order to prevail on its assertion that the '351 patent is not entitled to an effective filing date before March 25, 2019, Petitioner must show that the '351 patent specification, which the parties agree is the same as that in the earlier-filed priority applications, “does not convey with reasonable clarity to those skilled in the art” that the inventors were in possession of a controller programmed to analyze the cells in a body fluid measurement sample that were sensed by an electrical detector, and then to count the mono-nucleated cells and poly-nucleated cells. *See PowerOasis*, 522 F.3d at 1306.

We now turn to the '351 patent specification, which teaches that the detection device in the sample analyzer is provided with a WBC detection unit and an RBC/PLT detection unit. Ex. 1001, 5:62–6:1. The WBC detection unit is configured as an optical detection unit that uses scattered light to obtain information on the characteristics of the blood cells, such as their size and interior composition, that is then used to classify and count the cells. *Id.* at 6:18–38. The RBC/PLT detection unit is used “for measuring the number of red blood cells and the number of platelets,” and is described as the “electrical resistance detection unit.” *Id.* at 5:66–6:1, 12:41–44.

The '351 patent specification teaches that the WBC detection unit performs a DIFF measurement that classifies different types of white blood cells. Ex. 1001, 5:9–11 (“the sample and reagent are mixed to prepare a measurement sample for four classifications of white blood cells (DIFF)”), 9:55–57 (stating that, for blood samples, the DIFF measurement sample is measured by the WBC detection unit); 12:17–18 (same for body fluid samples). From the DIFF measurement, information is calculated for two

subclasses of white blood cells (mononuclear cells and polymorphonuclear cells) in the body fluid measurement mode, using the same classification algorithm. *Id.* at 12:48–63.

The '351 patent specification describes an example of the operation of the sample analyzer in body fluid measuring mode, wherein the body fluid sample is divided into at least a DIFF measurement sample that is measured by the WBC detection unit and an RBC/PLT measurement sample that is measured in the RBC/PLT detection unit. Ex. 1001, 12:13–25. A scattergram is obtained by measuring and analyzing the DIFF measurement sample of body fluid, and, because “fewer and damaged blood cells are contained in the body fluid, white blood cells are classified and counted as mononuclear white blood cells and polynuclear white blood cells in body fluid.” *Id.* at 13:33–59. The '351 patent specification further describes displaying the results of the body fluid sample measurements in a “value display region” that

includes the name of the measurement items for body fluid measurement rather than the measurement results for the blood measurement mode; WBC-BF (WBC count), RBC-BF (RBC count), MN# (mononuclear cell count (lymphocytes+monocytes)), PMN# (polymorphonuclear cell count (neutrophils+basophils+eosinophils), MN % (ratio of mononuclear cells among white blood cells), PMN % (ratio of polymorphonuclear cells among white blood cells), measurement values, and units are associated and displayed.

Id. at 15:9–18.

Accordingly, the '351 patent specification teaches that the mono-nucleated and poly-nucleated cells in the body fluid measurement sample are classified and counted based on the analysis of the DIFF measurement sample in the WBC detection unit, which the '351 patent teaches is an

optical detector. Notably, although the '351 patent specification teaches that the RBC/PLT detection unit electrically senses cells in the body fluid measurement sample (Ex. 1001, 7:7–40), it does not teach that the RBC/PLT detection unit electrically senses cells in that sample in order to count the number of mono-nucleated cells and poly-nucleated cells as required by claim 7. Further, although the '351 patent specification teaches a WBC detection unit for sensing cells in a body fluid measurement sample in order to count the number of mono-nucleated cells and poly-nucleated cells (*id.* at 6:3–46, 12:53–60), it does not teach that the WBC detection unit is an electrical detector that electrically senses cells in that sample as required by claim 7.

Patent Owner points to the last two sentences of the '351 patent specification, which cite to U.S. Patent No. 5,138,181 (“Lefevre,” Ex. 1047) and state that “electrical resistance may be measured rather than scattered light, in which case white blood cells can be classified by the electrical resistance and absorbed light.” PO Resp. 26 (quoting Ex. 1001, 16:35–37; citing Ex. 2052 ¶ 121). Patent Owner contends that this is “clear evidence that the inventors were in possession of the type of electrical detector disclosed in Lefevre that was used to differentiate types of white blood cells by the size of the cells,” and, therefore, “the last two sentences of the '351 specification expressly discloses that the inventors were in possession of using electrical resistance to classify white blood cells.” *Id.* (citing Ex. 2052 ¶ 128; Ex. 2069 ¶¶ 9–15); *see also* Sur-reply 11 (arguing that the '351 patent specification’s reference “to Lefevre’s use of electrical resistance to classify white blood cells shows that the inventors were in possession of this subject matter” (citing Ex. 2069 ¶¶ 9–15; Ex. 2052 ¶ 128)).

We disagree. The '351 patent specification refers to Lefevre after stating that although the described embodiment teaches that, in the body fluid measuring mode, white blood cell classification is performed using scattered light and fluorescent light, “the present invention is not limited to this configuration inasmuch as white blood cell classification may also be performed in the body fluid measurement mode using, for example, scattered light and absorbed light.” Ex. 1001, 16:17–23. In particular, the '351 patent specification states that “[s]uch measurement of absorbed light is disclosed in U.S. Pat. Nos. 5,122,453 and [Lefevre]. [F]urthermore, electrical resistance may be measured rather than scattered light, in which case white blood cells can be classified by electrical resistance and absorbed light.” *Id.* at 16:34–38. In this context, the '351 patent specification's reference to Lefevre is limited to what Lefevre discloses with respect to the measurement of absorbed light. *See Advanced Display Sys. Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (stating that, “to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found” in the incorporated material). For this reason alone, the '351 patent's reference to Lefevre does not show that the inventors were in possession of sample analyzer that uses an electrical detector to count mono-nucleated cells and poly-nucleated cells.

Even considering Lefevre's disclosures outside of the portion identified with detailed particularity in the '315 patent specification, we are not persuaded that the reference to Lefevre demonstrates that the inventors were in possession of such a sample analyzer. Lefevre teaches that one

drawback of using resistivity to analyze and count a leucocytic⁴ sub-population is “the fact that leucocytes are only differentiated by their final size,” lysis of certain cell types “frequently causes overlapping, even superimposition of the populations,” and that optical methods “suffer from great sensitivity of the optical alignment which means that the diffraction measurements have only relative stability.” Ex. 1047, 1:49–56, 2:23–32. To avoid these problems, Lefevre teaches “an apparatus for counting and determining at least one leucocytic sub-population using at least partially an analysis and counting method by resistivity” and “at least partially an optical method” that includes measuring absorbed light. *Id.* at 2:42–54.

Although Lefevre does teach using resistivity as part of its method for counting white blood cells in a blood sample, it does so only in conjunction with an optical method, and further criticizes using resistivity alone to perform that function. Ex. 1047, 1:49–56 (stating that the main drawback of using resistivity “resides in the fact that leucocytes are only differentiated by their final size”), 2:42–54, 5:15–65 (describing the process of counting leucocytes where the solution passes through an orifice such that each cell “causes an increase of the resistivity” that creates “a voltage pulse proportional to the volume of the leucocyte,” then a light beam passes perpendicularly through the flow of the solution and each cell passing through the light beam “causes a reduction of the light intensity” proportional to the intensity of its absorption, and stating that, “[t]o be taken into account, a blood cell must, previous to the optical measurement, be measured resistively by the passage through calibrated orifice 12). As set forth above, the term “electrical detector” in claim 7 means a “detector that

⁴ White blood cells are also known as “leucocytes.”

measures electrical properties, rather than optical properties.”

See Section II.B, *supra*. Because Lefevre teaches using a detector that measures electrical *and* optical properties to analyze and classify the cells in a blood sample, it is not an “electrical detector” according to the claim construction agreed to by the parties and adopted in this case. For these reasons, we disagree that the ’351 patent specification’s reference to Lefevre is “clear evidence that the inventors were in possession” of an electrical detector that senses cells in body-fluid measurement sample that are then analyzed to count the mono-nucleated cells and poly-nucleated cells as recited in claim 7.

Patent Owner also argues that “Lefevre’s Fig. 3 graphically demonstrates that a POSA knew before 2008 that the type of impedance-based electrical detector disclosed in Lefevre was used to sense and classify white blood cells.” Sur-reply 11. Lefevre Figure 3 is reproduced below.

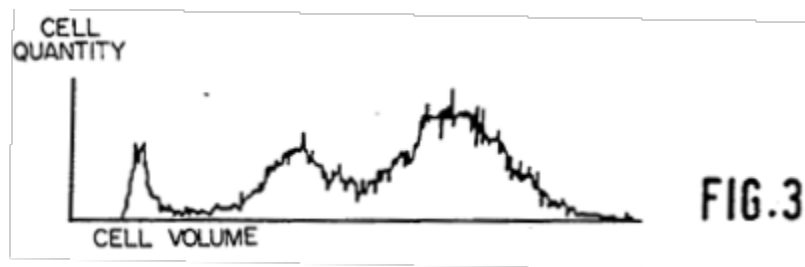


Figure 3 shows a three-peaked curve representing a size distribution of leucocytes analyzed using resistivity, with the cell quantity on the y-axis and cell volume on the x-axis. Ex. 1047, 6:36–39. Lefevre explains that Figure 3 shows three distinct populations: the most leftward portion of small sized particles considered to be background noise, and two right-hand populations “considered as being the whole of the leucocytes in the sample analyzed.” *Id.* at 6:39–46. Lefevre draws no further conclusions about the leucocyte population from Figure 3 and does not rely on only the

information in Figure 3 to count the number of mono-nucleated cells and poly-nucleated cells in the sample.

Figure 5 of Lefevre is reproduced below and shows absorbance values obtained from optical detection.

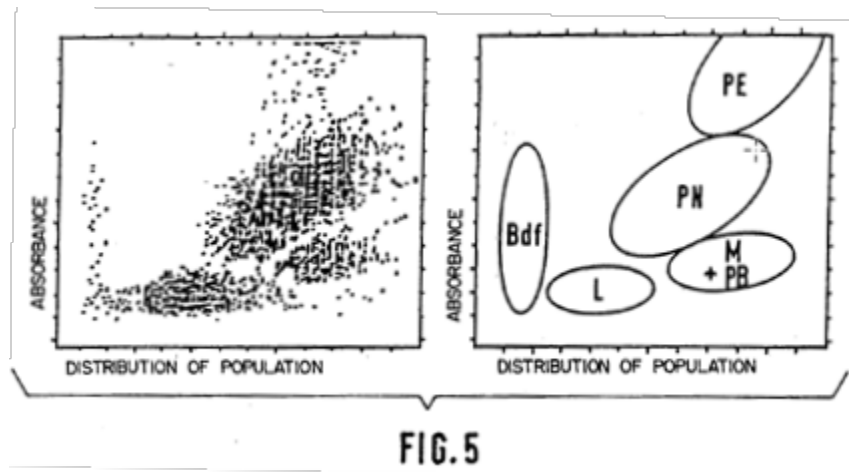


Figure 5 is a matrix graphic representation showing the size distribution of the leucocyte population along the x-axis and the absorbance on the y-axis. Ex. 1047, 6:52–65. Lefevre teaches that Figure 5's representation makes it possible to identify populations of lymphocytes (L), monocytes (M), polynuclear basophils (PB), polynuclear neutrophils (PN), and polynuclear eosinophils (PE), as well as the background noise (Bdf). *Id.* at 6:55–65. Taken together, the disclosures in Lefevre indicate that absorbance values from optical detection as well as volume measurements using resistivity are necessary in order to identify populations of mono-nucleated cells and poly-nucleated cells. *Id.* at 1:49–56 (discussing drawbacks of resistivity method), 2:42–54 (cells are counted using both a resistivity method and an optical method). There is no indication in Lefevre that resistivity alone is sufficient to count the mono-nucleated and poly-nucleated cells in a sample. Accordingly, consideration of Lefevre's disclosures as a whole reinforces our finding that the '351 patent specification's reference to Lefevre does not

show that the inventors were in possession of sample analyzer that uses an electrical detector to count mono-nucleated cells and poly-nucleated cells.

Patent Owner also argues that a POSA would have understood that the '351 patent specification's description of an electrical detector that senses blood cells in a body fluid sample, and its description of analyzing and interpreting the measurement of cells sensed by an electrical detector, demonstrates that the inventors were in possession of a controller programmed to analyze cells sensed in a body fluid measurement sample by an electrical detector and to count the mono-nucleated and poly-nucleated cells therein. PO Resp. 19–20 (citing Ex. 2052 ¶¶ 107–109). Similarly, Dr. Robinson testifies that “a POSA would have been well aware that electrical detectors were capable to measure sub-classes [of] white blood cells in a measurement sample.” Ex. 2052 ¶ 112 (citing Ex. 1001, 16:16–37). Dr. Robinson cites to the '351 patent specification's reference to Lefevre, which, as discussed above, does not teach an electrical detector for counting the mono-nucleated and poly-nucleated cells in a sample. Moreover, Patent Owner appears to be arguing that a person of ordinary skill in the art would have found it obvious to use an electrical detector to sense cells in a body fluid sample, and then analyze the sensed cells and count the mono-nucleated cells and poly-nucleated cells. Although the written description requirement does not require “that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy that requirement.” *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (citing *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571–1572 (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (“[A] patentee cannot always satisfy the requirements of

section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed. . . . the description of one method . . . does not entitle the inventor . . . to claim any and all means for achieving that objective.”).

For the foregoing reasons, we determine that Petitioner shows, by a preponderance of the evidence, that independent claim 7, and claims 8–15 that directly or indirectly depend therefrom, lack written description support in the ’351 patent specification and its priority applications. Specifically, we find that the priority applications do not contain adequate written description for a controller programmed to analyze the cells in a body fluid measurement sample that were sensed by an electrical detector, and to count the mono-nucleated cells and poly-nucleated cells. Accordingly, we determine that Petitioner establishes, by a preponderance of the evidence, that the challenged claims of the ’351 patent are not entitled to the benefit of the January 31, 2008 filing date of the ’830 application, and the earliest effective filing date of the challenged claims is the March 25, 2019 filing date of the ’694 application.

D. Obviousness over Nagai and Jagtiani

Petitioner contends that the subject matter of claims 7–15 of the ’351 patent would have been obvious under 35 U.S.C. § 103⁵ over the combined teachings of Nagai and Jagtiani. Pet. 42–64. Petitioner argues that Nagai is prior art under 35 U.S.C. § 102(a)(1) because it “issued on May 14, 2013, more than one year prior to March 25, 2019, which is the earliest effective

⁵ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284–88, amended as 35 U.S.C. §§ 102 and 103. Because the effective filing date of the challenged claims of the ’351 patent is after March 16, 2013, the post-AIA versions of 35 U.S.C. §§ 102 and 103 apply.

filing date of the '351 patent.” *Id.* at 18. Similarly, Petitioner argues that Jagtiani is prior art because it “is fully supported by” a series of provisional applications and “is considered to have been effectively filed under 35 U.S.C. § 102(d)(2) as of no later than” the November 5, 2018 filing date of the last such provisional application. *Id.* at 19. As set forth above, we determine that Petitioner establishes by a preponderance of the evidence that the effective filing date of the '351 patent is not earlier than March 25, 2019. Accordingly, on the present record, we determine that Nagai is prior art under 35 U.S.C. § 102(a)(1) because it issued more than one year before the effective filing date of the '351 patent. Patent Owner does not dispute that Jagtiani is prior art to the '351 patent if the challenged claims are not entitled to a January 31, 2008 priority date. *See* PO Resp. 38.

There is no dispute that the content of Nagai and the content of the '351 patent specification is the same. Pet. 18; PO Resp. 1. Jagtiani is directed to cartridges and devices for analyzing a biological sample (such as blood, serum, sweat, tears, mucus, urine, or any other biological sample or derivative suspended in a fluid), including by “transporting the biological sample through a sensor comprising a channel or pore; applying an electrical current or voltage to the channel or pore; and determining a cell count or detecting the analyte based on the detected impedance.” Ex. 1045, code (57), ¶ 113. Jagtiani teaches that different types of cartridges can be configured to perform different assays of the biological sample, such as a complete blood count (“CBC”) assay that “can distinguish and count different blood cell types, such as red blood cells, platelets, and white blood cells (including eosinophils, basophils, neutrophils, monocytes, and lymphocytes).” *Id.* ¶ 113. Jagtiani also teaches that “the same controlling device can engage with the different cartridges, allowing for a single

versatile device that can be used to perform a plurality of assays by interfacing with a selected cartridge.” *Id.*

1. Motivation to Combine Nagai and Jagtiani

In order to demonstrate obviousness, a petitioner must demonstrate that a skilled artisan would have had a reason to combine the teachings of the prior art in the manner claimed in the patent and would have had a reasonable expectation of success in doing so. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

Petitioner contends that a POSA would have been motivated to replace Nagai’s electrical detector (which measures only the number of red blood cells in determining a CBC measurement) with Jagtiani’s electrical detector (which senses and analyzes cells of body fluids in order to count white blood cells) in order to “to perform both measurements of red blood cells, and of mono-nucleated cells and poly-nucleated white blood cells in body fluid measurement samples.” Pet. 43–44, 54–55 (citing Ex. 1045 ¶¶ 21, 25, 119, 486; Ex. 1048 ¶¶ 102–104). Petitioner contends that modifying Nagai in this manner would yield the predictable result of using an electrical detector, instead of an optical detector, to detect mono-nucleated and poly-nucleated white blood cells in body fluid samples. *Id.* at 43–44 (citing Ex. 1048 ¶ 104). Petitioner also contends that a POSA “would have made the combination as proposed to simplify the number of sensors to be used to measure body fluid.” *Id.* at 45 (citing Ex. 1048 ¶ 108).

Petitioner further contends that a POSA would have had a reasonable expectation of success in modifying Nagai as proposed. Pet. 45. Petitioner contends that, because the modification is “little more than a substitution of the electrical sensor disclosed by Nagai (or optical sensor used in the body fluid measurement mode) for the electrical sensor disclosed by Jagtiani,” it “would have been well within the skill of a POSA.” *Id.* at 45–46 (citing Ex. 1048 ¶ 109).

Patent Owner argues that a POSA “would not be motivated to combine Jagtiani with Nagai for the measurement of the body fluid types identified in claims 7–15 of the ’351 patent.” PO Resp. 43 (citing Ex. 2069 ¶ 20). In particular, Patent Owner argues that “none of the types of body fluids identified in claims 7–15 are mentioned in Jagtiani,” and “Jagtiani fails to disclose how his cartridge could provide an accurate measurement of the low number of blood cells that may be present in the types of body fluid identified in claims 7–15.” *Id.* at 40 (citing Ex. 2069 ¶ 18).

Based on our review of the record, we determine that Petitioner has established that a POSA would have had reason to combine the teachings of Nagai and Jagtiani to achieve the claimed subject matter. Nagai describes an electrical detector (RBC/PLT detection unit 42) that “is capable of measuring the number of red blood cells and platelets by a sheath flow-DC detection method.” Ex. 1044, 6:58–63, Fig. 5. Nagai also describes WBC detection unit 41 that produces a DIFF scattergram that, in the body fluid measuring mode, is analyzed in order to classify the white blood cells into two subclasses, namely, mono-nucleated cells and poly-nucleated cells. *Id.* at 5:56–58, 12:27–36. Nagai teaches that WBC detection unit 41 is “configured as an optical detection unit” that performs white blood cell classification in the body fluid measurement mode using a combination of

scattered light and fluorescent light, scattered light and absorbed light, or electrical resistance and absorbed light. *Id.* at 5:56–58, 15:52–16:6.

Jagtiani teaches a channel sensor that can detect impedance to differentiate between different types of cells in a biological sample, including differentiating between red blood cells, white blood cells, and platelets. Ex. 1045 ¶¶ 21, 25; *see also id.* ¶ 187 (“The channel sensor is based on impedance sensing using the Coulter principle.”). Jagtiani teaches the sensor can be configured to differentiate between and count the number of eosinophils, basophils, neutrophils, monocytes, and lymphocytes in the biological sample. *Id.* ¶ 25; *see also id.* ¶ 121 (“In some embodiments, the cell count can include a white blood differential, and can include a count of basophils, a count of eosinophils, a count of lymphocytes, a count of neutrophils, and/or a count of monocytes.”). Jagtiani further teaches that “[s]uch biological samples can include, for example, blood, serum, saliva, sweat, tears, urine, or any other biological sample or derivative suspended in a fluid.” *Id.* ¶ 119.

In light of these teachings in Nagai and Jagtiani, we credit Mr. Roche’s testimony that

Jagtiani demonstrates a known technique of detecting poly-nucleated and mono-nucleated white blood cells using an electrical detector. A POSA at the time of the invention would have been led to modify Nagai with the teaching of Jagtiani in the manner claimed to allow the body fluid measurement of Nagai to differentiate poly-nucleated and mono-nucleated blood cells (instead of measuring red blood cells alone). Such a motivation is found, for example, in Petitioner’s DxH system, which discloses use of an electrical detector in both a blood measuring mode and a fluid measuring mode. Ex. 1042 ¶¶ 30, 31. In the DxH system, use of an electrical detector in both the blood measuring mode and body fluid measuring mode allows identification of total number of cells in measured body fluid.

Thus, one having ordinary skill in the art would have made the combination as proposed to simplify the number of sensors to be used to measure body fluid.

Ex. 1048 ¶ 107. That Nagai teaches using electrical detection to analyze red blood cells and platelets, and also teaches that a combination of resistivity (electrical detection) and absorbed light (optical detection) can be used to detect and analyze white blood cells, and Jagtiani teaches using electrical detection alone to detect and analyze white blood cells, supports Mr. Roche's testimony that the proposed modification of Nagai would simplify the number of sensors used to measure a body fluid sample by eliminating the need for an optical detector. *See* Ex. 1044, 5:56–58, 6:57–62, 15:52–16:6; Ex. 1045 ¶¶ 21, 25, 119, 187; *see also Perfect Web Techs., Inc. v. Info USA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (A reason to combine or modify the prior art may be found explicitly or implicitly in market forces, design incentives, the “interrelated teachings of multiple patents,” “any need or problem known in the field of endeavor at the time of the invention and addressed by the patent,” and “the background knowledge, creativity, and common sense of the person of ordinary skill in the art.” (quoting *KSR*, 550 U.S. at 418–421)).

We determine that Petitioner's showing outweighs Patent Owner's arguments and evidence. Patent Owner argues that “Jagtiani does not disclose an electrical detector that is suitable for use with the types of body fluids identified in claims 7–15 of the '351 patent.” PO Resp. 43. In that regard, Patent Owner argues that Jagtiani does not identify any of the body fluids listed in the challenged claims. *Id.* at 40. Patent Owner's argument, however, overlooks Jagtiani's teaching that, in addition to the exemplary

biological fluids listed, “any other biological sample or derivative suspended in a fluid” can be analyzed by the described sensors. Ex. 1045 ¶ 119. Patent Owner does not contend that the body fluids identified in claims 7–15 are not “biological sample[s] or derivative[s] suspended in a fluid.” *See* Ex. 1050, 179:13–181:20 (Dr. Robinson testifying that the term “biological fluids” as used in Jagtiani would include the body fluids identified in the challenged claims).

Patent Owner also argues that “Jagtiani was not designed to have the type of accuracy required for the body fluids listed in claims 7–15.” PO Resp. 40. In particular, Patent Owner argues that Jagtiani “fails to disclose” how its detectors “could provide an accurate measurement of the low number of blood cells that may be present in the types of body fluids identified in claims 7–15.” *Id.* However, like the body fluids identified in the challenged claims, some of the specific biological samples enumerated in Jagtiani also contain a low number of blood cells. Ex. 1049 ¶ 37; Ex. 1050, 183:16–187:4. Moreover, Jagtiani teaches that “[t]he channel sensor is based on impedance sensing using the Coulter principle.” Ex. 1045 ¶ 187. Patent Owner’s argument that Jagtiani’s electrical detector is unsuitable for detecting blood cells in biological samples with a low count of blood cells is inconsistent with its assertion that a “POSA would have readily understood” that Nagai’s electrical detection unit 42 “was an example of the well-known Coulter principle type of electrical detector for measuring various types of cells, including white blood cells,” and that Nagai “is explicitly directed to providing an accurate count of blood cells in the types of fluids with very few cells.” PO Resp. 22, 41 (citing Ex. 2052 ¶ 113; Ex. 2069 ¶ 18). In view of this inconsistency, we give little credence to Patent Owner’s argument that Jagtiani’s electrical detector, which

operates on the same principle as the electrical detector in the '351 patent, was not designed to have the accuracy required for the types of body fluids recited in the challenged claims.

We also do not agree with Patent Owner that “Jagtiani teaches away from using an electrical detector for measuring white blood cells in the types of body fluids identified in Claims 7–15.” Sur-reply 22 (citing Ex. 2069 ¶¶ 16–21). “Under a proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosure are unlikely to produce the objective of the [patented] invention.” *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) (citing *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Patent Owner does not direct us to any statements in Jagtiani that criticize or discredit the use of an electrical detector to measure white blood cells in body fluids with low white blood cell counts, nor anything that would discourage the use of an electrical detector to count white blood cells in the types of body fluids identified in the challenged claims. On the contrary, Jagtiani does not limit the types of biological samples that can be used with its analyzer, stating that they “can include, for example, blood, serum, saliva, sweat, tears, mucus, urine, or any other biological sample or derivative suspended in a fluid.” Ex. 1045 ¶ 119. Furthermore, the evidence shows that, like the body fluids recited in the challenged claims, some of the biological samples that Jagtiani specifically names also have a low blood cell count. Ex. 1049 ¶ 37; Ex. 1050, 183:16–187:4. Jagtiani also explicitly states that “the cell count can include a white blood differential, and can include a count of basophils, a count of eosinophils, a count of lymphocytes, a count of neutrophils, and/or a count of monocytes,” with no qualification as to the types of biological samples that can be analyzed in this manner. Ex. 1045 ¶ 121.

We have considered Patent Owner’s argument and Dr. Robinson’s testimony that a POSA would have understood that it would take Jagtiani at least 90 minutes “to complete the analysis of the types of body fluids identified in claims 7–15,” and that “[t]his amount of time is not suitable for these types of body fluids when results are needed rapidly while patients are in surgery or undergoing other invasive medical procedures.” PO Resp. 42–43; Ex. 2069 ¶ 20. Neither Patent Owner nor Dr. Robinson direct us to any statements in Nagai that the results from the body fluid sample analysis “are needed rapidly” such that a POSA would be discouraged from looking at a reference such as Jagtiani to improve Nagai’s sample analyzer. In addition, Dr. Robinson’s 90 minute estimation is based on his analysis of one of Jagtiani’s examples that was directed to detecting cells in a whole blood sample. *Id.* ¶ 19; Ex. 1045 ¶¶ 489–490. Dr. Robinson, however, could not confirm that the flow cytometer detector in this example was an electrical detector, and testified that it “uses both electrical and optical detectors.” Ex. 1050, 210:2–212:11. Dr. Robinson also testified that “there is no information” in the figures he relied on to support his 90 minute estimation “as to exactly how they made those measurements.” *Id.* at 213:23–214:7. Furthermore, even if rapid results are sometimes required, there is no evidence that is always the case. Consequently, we give little weight to Dr. Robinson’s testimony in this regard.

For these reasons, after considering Petitioner’s and Patent Owner’s positions as well as the supporting evidence, we determine that Petitioner has established that a POSA would have had sufficient reason to combine the teachings of Nagai and Jagtiani in the manner proposed by Petitioner.

2. *Claims 7–15*

Petitioner contends that Nagai teaches or suggests all of the elements of independent claim 7, except for the use of an electrical detector to electrically sense cells in the body fluid measurement sample, and the analysis of those sensed cells to count the number of mono-nucleated cells and poly-nucleated cells in that body fluid measurement sample. Pet. 46–54, 57–58. Petitioner contends that “Jagtiani discloses the use of an electrical detector to sense and analyze cells of body fluids” and “to count white blood cells in a body fluid sample.” *Id.* at 54–55 (citing Ex. 1045 ¶¶ 21, 25, 119, 486). Petitioner contends that “[a] POSA would have understood that Nagai’s electrical detector measures only the number of red blood cells in determining a CBC measurement,” and would have replaced Nagai’s electrical detector with Jagtiani’s electrical detector “to perform measurements of red blood cells, and of mono-nucleated cells and poly-nucleated white blood cells in body fluid measurement samples.” *Id.* at 43 (citing Ex. 1048 ¶¶ 102–104). Petitioner provides a claim chart identifying where each element of claim 7, and claims 8–15 that depend therefrom, can be found in Nagai and Jagtiani. *Id.* at 46–64.

Other than the arguments with respect to the suitability of Jagtiani’s electrical detector for use with the body fluids identified in claim 7 addressed above, Patent Owner does not otherwise dispute Petitioner’s evidence that the combined teachings of Nagai and Jagtiani disclose the limitations of claims 7–15. PO Resp. 38–43; Sur-reply 19–22.

Having reviewed Petitioner’s assertions regarding claims 7–15, as well as the supporting evidence, we determine on this record that Petitioner has established by a preponderance of the evidence that the combined

teachings of Nagai and Jagtiani account of all the limitations recited in claims 7–15. Pet. 46–64; Ex. 1045 ¶¶ 116–137.

3. *Mr. Roche’s Testimony*

Patent Owner argues that “[t]he weight given to Petitioner’s expert should be deeply discounted” because Mr. Roche “was shielded during his deposition” by “Petitioner’s excessive, improper objections.” PO Resp. 44–46 (citing *Ericsson Inc. v. Intellectual Ventures LLC*, IPR2014-01149, Paper 68 at 8–10 (PTAB Dec. 9, 2015)). In particular, Patent Owner argues that Petitioner’s counsel repeatedly objected “to questions as ‘outside the scope of the declaration,’ when clearly they were not.” *Id.* at 44. Petitioner responds that “Patent Owner’s own expert repeatedly refused to answer questions within the scope of his report” and “the questions put to Petitioner’s expert were frequently beyond the scope of the witness’s declaration.” Reply 8 n.2.

On this record, we decline to generally discount the weight given to Mr. Roche’s testimony based on Petitioner’s counsel’s objections during Mr. Roche’s deposition. As an initial matter, Patent Owner does not contend, nor do we find, any instances where Mr. Roche was instructed by Petitioner’s counsel to not answer Patent Owner’s questions based on the objections. Additionally, our Consolidated Trial Practice Guide advises that, at any time during the testimony, a party may move to terminate or limit the testimony on the ground that it is being conducted in bad faith, and the testimony may be “suspended for the time necessary to obtain a ruling from the Board.” PTAB Consolidated Trial Practice Guide, App. D at 130 (Nov. 2019), <https://go.usa.gov/xpvPF>. Despite Patent Owner’s concerns regarding the propriety of Petitioner’s counsel’s objections, Patent Owner did not avail itself of this option during Mr. Roche’s deposition.

Additionally, this case is distinguishable from *Ericsson*, where the Board discounted a declarant's testimony because the proponent of the testimony shielded the declarant from information "so that he did not address it in his declaration and was unprepared to testify about it at [his] deposition." *Ericsson*, Paper 68 at 9–10. Here, Patent Owner does not allege that Mr. Roche was shielded from any particular information, or that Mr. Roche was unprepared to testify as a result.

It is within our discretion to assign the appropriate weight to Mr. Roche's testimony. *See, e.g., Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding that the Board has discretion to give more weight to one item of evidence over another "unless no reasonable trier of fact could have done so"); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declaration and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."). Patent Owner's contentions do not persuade us that we should generally discount Mr. Roche's testimony as requested.

III. CONCLUSION⁶

After reviewing the record and weighing the evidence offered by both parties,⁷ we determine that Petitioner has shown, by a preponderance of the evidence, that claims 7–15 of the '351 patent would have been obvious over the combined teachings of Nagai and Jagtiani.

In summary:

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not shown Unpatentable
7–15	103	Nagai, Jagtiani	7–15	
Overall Outcome			7–15	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 7–15 are unpatentable; and

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

⁶ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

⁷ Patent Owner did not introduce any evidence of objective indicia of nonobviousness in this proceeding.

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Patent 10,401,351 B2

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