

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.

IPR2020-01501
Patent 10,401,350 B2

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

ROESEL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. *Background and Summary*

Beckman Coulter, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) seeking an *inter partes* review of claims 1, 3–16, and 18–28 (“the challenged claims”) of U.S. Patent No. 10,401,350 B2 (Ex. 1001, “the ’350 Patent”). Sysmex Corporation and Sysmex America, Inc. (collectively, “Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). After considering the parties’ arguments and evidence, we determine that the reasonable likelihood standard is not met. Accordingly, we deny institution of *inter partes* review.

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 (Mandatory Notice).

C. *Related Matters*

The parties indicate that the ’350 Patent is being asserted by Patent Owner against Petitioner in the following district court action: *Sysmex Corporation v. Beckman Coulter, Inc.*, No. 1:19-cv-01642-RGA-CJB (D. Del.) (the “Delaware case”). Pet. 3; Paper 5, 1. As indicated by the parties, Petitioner filed a second petition challenging the ’350 Patent in

IPR2020-01500. Pet. 3; Paper 5, 1. Petitioner is challenging a related patent, U.S. Patent No. 10,401,351 B2, in IPR2020-01502 and IPR2020-01503.

D. The '350 Patent (Ex. 1001)

The '350 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), 1:18–22. The sample analyzer has a blood measurement mode and a body fluid measurement mode. *See, e.g., id.* at code (57), 2:7–10.

According to the '350 Patent, the sample analyzer “is configured as an automatic multi-item blood cell analyzer which performs blood analysis by measuring blood samples held in sample containers (blood collection tubes), obtaining characteristics information representing the characteristics of the blood cells contained in the sample, and analyzing the characteristic information.” Ex. 1001, 3:51–57. The '350 Patent discloses that the sample analyzer “is also capable of analyzing body fluids . . . other than blood.” *Id.* at 3:57–61.

As disclosed in the '350 Patent, the sample analyzer includes a measuring unit that measures blood and body fluid samples and a data processing unit that obtains analysis results by processing the output from the measuring unit. Ex. 1001, 4:20–24, Fig. 1. The data processing unit includes a control unit, a display unit, and an input unit. *Id.* at 4:24–26. The measuring unit includes a blood cell detecting unit, an analog processing unit, a microcomputer unit, a display and operating unit, a device for

measuring blood and body fluids, and a fluid supplying unit. *Id.* at 4:29–36, Figs. 2, 3 (block diagrams showing measuring unit and fluid supplying unit, respectively). The detection unit includes: (1) an optical detection unit for detecting white blood cells (“WBC”) using a flow cytometry method, (2) an RBC/PLT detection unit for measuring the numbers of red blood cells (“RBC”) and platelets (“PLT”) by a sheath flow-DC detection method, and (3) a hemoglobin (“HGB”) detection unit for measuring the amount of pigment in the blood. *Id.* at 5:62–6:10, 7:7–13, 7:56–60, Figs. 4–6 (showing optical detection unit, RBC/PLT detection unit, and HGB detection unit, respectively).

The ’350 Patent describes the operation of the sample analyzer with reference to a flow chart. Ex. 1001, 8:56–59, Fig. 7. According to the ’350 Patent, the microcomputer sets the blood measurement mode as the initial operating mode, and the operator can change the measurement mode from the blood measurement mode to the body fluid measurement mode using the display and operation unit. Ex. 1001, 8:66–9:6, 9:12–15, 9:30–32, 9:39–43, Fig. 7 (steps S3, S5), Fig. 8 (input screen for setting the measurement mode). The ’350 Patent discloses that “[w]hen input specifying the measurement mode is received . . . , the microcomputer . . . sets the parameters (operating conditions) for the body fluid measurement, for example, the reaction chamber to use and the set time of the measurement and the like (step S8).” *Id.* at 10:53–57.

With reference to Figure 7, the ’350 Patent describes steps performed in blood measurement mode. Ex. 1001, 9:43–10:52, Fig. 7 (flow chart). With reference to Figures 7 and 9, the ’350 Patent describes steps performed in body fluid measurement mode. *Id.* at 10:53–13:18, Figs. 7, 9. According to the ’350 Patent, some steps are performed in the same manner in both

measurement modes. *Id.* at 12:5–9 (in body fluid measurement mode, sample aspiration is performed “in the same manner as for the manual measurement of the blood sample”); *id.* at 12:13–15 (“After the body fluid sample has been aspirated, the body fluid sample is introduced to the sampling valve . . . in the same manner as the blood sample.”); *id.* at 12:41–43 (“The RBC/PLT measurement sample is introduced to the electrical resistance detection unit 41 in the same manner for all measurement modes . . .”).

The ’350 Patent describes differences between blood measurement mode and body fluid measurement mode. For example, the ’350 Patent discloses that, when switching from blood measurement mode to body fluid measurement mode, the measuring unit runs a pre sequence process to prepare for the body fluid measurement. Ex. 1001, 10:60–65, 11:38–41, Fig. 7 (steps S9, S10), Fig. 9 (flow chart showing the pre sequence process). The pre sequence includes a “blank check operation,” i.e., measurement of a blank sample that contains neither blood nor body fluid. *Id.* at 2:49–55, 8:62–66, 11:5, 11:41–55, Fig. 9 (steps S31–S33). According to the ’350 Patent, the blank check standard of the pre sequence is “more strict” than the standard of the blank check performed after “power on” and “automatic wash” in blood measurement mode. *Id.* at 11:5–10. The ’350 Patent explains that the pre sequence is “not performed” when switching from body fluid measurement mode to blood measurement mode, nor is it performed between samples in body fluid measurement mode. *Id.* at 11:10–17. When the blank check measurement result is not less than the tolerance after repeated measurements, the operator may elect to execute an automatic washing step before the blank check is repeated. *Id.* at 11:56–12:3, Fig. 9 (steps S34–S38).

In addition to the pre sequence, the '350 Patent describes additional post-measurement steps that are performed in body fluid measuring mode. Ex. 1001, 12:64–18, Fig. 7 (steps S23–S25). In these steps, the results are compared to a tolerance value, and if the tolerance is exceeded, then the operator may opt to run another blank check measurement. *Id.*

The '350 Patent identifies additional differences between blood measurement mode and body fluid measurement mode. The '350 Patent teaches that, in blood measurement mode, the sample is divided into a number of aliquots ranging from two to six, depending on the discrete tests selected by the operator, whereas in body fluid measuring mode, the sample is divided into two aliquots. Ex. 1001, 4:43–67. The '350 Patent discloses that, in blood measurement mode, white blood cells are classified into five types, whereas in body fluid measurement mode, white blood cells are classified into two types. *Id.* at 5:10–11, 5:28–30, 10:34–46, 12:48–57. According to the '350 Patent, in blood fluid measurement mode, the white blood cell detection unit measures four measurement samples (WBC/BASO, DIFF, RET, and NRBC),¹ whereas in body fluid measurement mode, the white blood cell detection unit measures only the DIFF measurement sample. *Id.* at 9:53–65, 12:17–25. Furthermore, the measurement time in body fluid measurement mode is longer than the measurement time in blood measurement mode. *Id.* at 10:57–59, 12:26–40. Still further, the blood measurement mode uses three detection units (the white blood cell detection unit, the RBC/PLT detection unit, and the HGB detection unit), and the body

¹ WBC/BASO refers to white blood cells and basophils. Ex. 1001, 5:50–51. DIFF refers to different types of white blood cells. *Id.* at 5:10–11, 5:28–30. RET refers to reticulocytes. *Id.* at 5:44. NRBC refers to nucleated red blood cells. *Id.* at 5:37.

fluid mode uses only two of these detection units (the white blood cell detection unit, the RBC/PLT detection unit). *Id.* at 9:55–60, 12:17–20.

E. Illustrative Claim

Petitioner challenges claims 1, 3–16, and 18–28 of the '350 Patent. Pet. 1, 5–6. Claims 1, 12, and 19–21 are independent claims. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. A sample analyzer comprising:

a plurality of detectors each configured to sense cells in a 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, 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 the cells in the sample and (b) an analyzing operation comprising operations of analyzing sample measurements and displaying analysis results, the sensing operation performed in the body fluid measuring mode being different, at least partially, from the sensing operation performed in the blood measuring mode, and further wherein the plurality of detectors includes one or more multi-mode detectors configured to operate in both the blood measuring mode and the body fluid measuring mode, the controller programmed to:

perform the sensing operation in the blood measuring mode to: introduce the blood sample into a multi-mode detector; operate said multi-mode detector to

sense cells in the introduced blood sample; and derive blood-sample measurements of cells in the introduced blood sample; and

perform the sensing operation in the body fluid measuring mode to: introduce the body fluid sample into said multi-mode detector; operate said multi-mode detector to sense cells in the introduced body fluid sample; and derive body-fluid-sample measurements of cells in the introduced body fluid sample.

Ex. 1001, 16:40–17:14.

F. Asserted Grounds and Evidence

Petitioner asserts the following grounds of unpatentability under 35 U.S.C. § 103(a):²

Claims Challenged	Reference(s)
1, 3–16, 18–28	XE2100, ³ LH700, ⁴ LH-BFA, ⁵ POSA's general knowledge ⁶
1, 3–16, 18–28	XE2100, LH700, LH-BFA, Ornstein, ⁷ POSA's general knowledge

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the ’350 Patent has an effective filing date before this date, the pre-AIA version of § 103 applies. Ex. 1001, code (63).

³ Ex. 1004, “Operator’s Manual, Automated Hematology Analyzer XE-2100 Main Unit,” Sysmex Corporation (“XE-2100”).

⁴ Ex. 1006, “Coulter LH 700 Series System Reference,” Beckman Coulter, Inc. (“LH700”).

⁵ Ex. 1007, “Coulter LH Series Workstation Body Fluid Application: Operator’s Guide,” Beckman Coulter, Inc. (“LH-BFA”).

⁶ A person of ordinary skill in the art (“POSA”) is defined in Section II.B. below.

⁷ Ex. 1008, US 2003/0215890 A1, published Nov. 20, 2003 (“Ornstein”).

Claims Challenged	Reference(s)
1, 3–16, 18	XE2100, LH700, LH-BFA, Behrens, ⁸ POSA’s general knowledge
1, 3–16, 18–28	XE2100, LH700, LH-BFA, XE-BFA, ⁹ POSA’s general knowledge

Pet. 5–6. Petitioner relies on the Declaration of John W. Roche to support its challenges. Ex. 1003.

II. ANALYSIS

A. Legal Standards

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)); *see also* 37 C.F.R. § 42.104(b) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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

⁸ Ex. 1011, US 5,378,633, issued Jan. 3, 1995 (“Behrens”).

⁹ Ex. 1005, “XE-Series Body Fluid Application,” Sysmex Corporation (“XE-BFA”).

(2007). The question of obviousness is resolved based on 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 ordinary skill in the art; and (4) when presented, objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)). 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).

B. Level of Ordinary Skill in the Art

Petitioner contends that a 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” and “at least five years of experience in developing hardware and/or software for hematology analyzers.” Pet. 13. Petitioner further contends that such a person “would have been familiar with the design and operation of hematology analyzers available in the market, including Patent Owner’s XE-Series analyzers, the Coulter LH-700 analyzers, and other commercially available hematology analyzers.” *Id.*

Patent Owner states that a POSA “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 analyzers for blood or other body fluids.” Prelim. Resp. 46. Patent Owner further states that “[t]he difference between the level of ordinary skill in the art proposed by Patent Owner and Petitioner’s level does not affect the arguments” in the Preliminary Response. *Id.*

As compared with Patent Owner’s definition of a POSA, we find that Petitioner’s definition is more complete and more consistent with the disclosure of the ’350 Patent and the scope and content of the asserted prior art because Petitioner’s definition requires familiarity with “the design and operation of hematology analyzers available in the market, including Patent Owner’s XE-Series analyzers, the Coulter LH-700 analyzers, and other commercially available hematology analyzers.” Pet. 13. We find that such familiarity is consistent with the ’350 Patent, which discloses that a blood cell analyzer capable of measuring cells in body fluid was known in the art and that “the functions of the present invention can be realized in a conventional blood cell analyzer by installing the computer program in a conventional blood cell analyzer.” Ex. 1001, 1:45–61, 15:52–58. The parties’ definitions of a POSA differ in additional respects, including 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. In each of these respects, we find that Petitioner’s proposal is more reasonable than Patent Owner’s. Accordingly,

for purposes of determining whether to institute an *inter partes* review, we apply Petitioner’s definition of a POSA.

C. Claim Construction

In an *inter partes* review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.100(b). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012).

Below we address the meaning of “a blood measuring mode” and “a body fluid measuring mode.” We determine that no other claim terms require express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of *inter partes* review).

“a blood measuring mode”; “a body fluid measuring mode”

Patent Owner argues that “a blood measuring mode” should be construed as “a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample.” Prelim. Resp. 48. Patent Owner argues that “a body fluid measuring mode” should

be construed as “a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample.” *Id.*

Patent Owner states that it proposed these same constructions in the Delaware case. Prelim. Resp. 48. Patent Owner’s proposed constructions, along with citations to intrinsic evidence, are set forth in a Joint Claim Construction Chart filed July 6, 2020, in the Delaware case. Ex. 1043, Appendix A-2, 2–3. According to a Scheduling Order in the Delaware case, Patent Owner was to serve its opening claim construction brief on or before July 20, 2020, and the content of that brief was to be copied and pasted into a Joint Claim Construction Brief filed no later than October 14, 2020. Ex. 2012, 12–13. A Joint Claim Construction Brief filed October 14, 2020, in the Delaware case includes Patent Owner’s proposed constructions for “a blood measuring mode” and “a body fluid measuring mode” and Patent Owner’s opening position in support of those constructions. Ex. 2035, 9–12.¹⁰

Despite receiving Patent Owner’s proposed constructions and supporting evidence and arguments more than a month before the August 8, 2020, filing date of the Petition, Petitioner does not propose any constructions for these claim terms, nor respond to Patent Owner’s proposed constructions or arguments. Instead, Petitioner relies on a catch-all statement, “All other claim elements take on a plain and ordinary meaning, as would be understood by a POSA.” Pet. 16. Although Petitioner’s proposed constructions and arguments from the Delaware case are disclosed

¹⁰ A claim construction hearing in the Delaware case was held October 28, 2020. Ex. 2027. As of February 22, 2021, the district court has not issued a claim construction order.

in exhibits (Ex. 1043, Appendix A-2, 2; Ex. 2035, 12–15, 17–18), we do not consider them because they are not presented in the Petition.

The independent claims of the '350 Patent each contain the following claim recitation:

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.

See, e.g., Ex. 1001, 16:49–55 (emphasis added). We find that this claim language supports Patent Owner’s proposed constructions for two reasons. First, we agree with Patent Owner that, by separately reciting “a blood measuring mode” and “a body fluid measuring mode,” the claim language implies that the two modes are distinct. *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (“Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004))); *see* Prelim. Resp. 48–49. Second, the above-quoted claim language supports Patent Owner’s contention that “a blood measuring mode” and “a body fluid measuring mode” should each be construed as “a sample analyzer operation mode . . . used for measuring cells.” Prelim. Resp. 48.

Independent claims 1 and 12 include the following “wherein” clause:

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 the cells in the sample and (b) an analyzing operation comprising operations of analyzing sample measurements and displaying analysis results,

the sensing operation performed in the body fluid measuring mode being different, at least partially, from the sensing operation performed in the blood measuring mode.

Ex. 1001, 16:55–65, 18:31–41 (emphasis added). We find that this claim language is consistent with Patent Owner’s constructions for “a blood measuring mode” and “a body fluid measuring mode.” In our view, the above-quoted claim limitation provides one example of a possible difference between the body fluid measuring mode and the blood fluid measuring mode. It does not suggest that, in the absence of this limitation, the body fluid measuring mode could be the same as the blood fluid measuring mode. Independent claims 19–21 each recite operations performed in the body fluid measuring mode, e.g., pre-washing and counting mono-nucleated cells and poly-nucleated cells, which are not required in the blood measuring mode. *Id.* at 19:63–20:4, 20:28–35, 20:57–64. Again, we view these claim limitations as examples of potential differences between the body fluid measuring mode and the blood fluid measuring mode.

We find that the Specification supports Patent Owner’s constructions for “a blood measuring mode” and “a body fluid measuring mode.” Explicit support for Patent Owner’s constructions is found in the Abstract, which discloses in relevant part:

A sample analyzer . . . sets either a blood measurement mode for measuring the blood sample, or a body fluid measurement mode for measuring the body fluid sample ***as an operating mode***; and measures the measurement sample prepared from the blood sample by executing operations in the blood measurement mode when the blood measurement mode has been set, and measuring the measurement sample prepared from the body fluid sample by ***executing operations in the body fluid measurement mode that differs from the operations in the blood measurement mode when the body fluid measurement mode has been set.***

Ex. 1001, code (57) (emphasis added). The Abstract supports Patent Owner's construction of "a body fluid measuring mode" as an "operation mode" that is "different from the blood measuring mode." Prelim. Resp. 48.

Patent Owner's constructions are also supported by Figures 7 and 9 of the '350 Patent and the descriptions of those figures. Patent Owner provides the following annotated version of Figure 7 as support for its constructions:

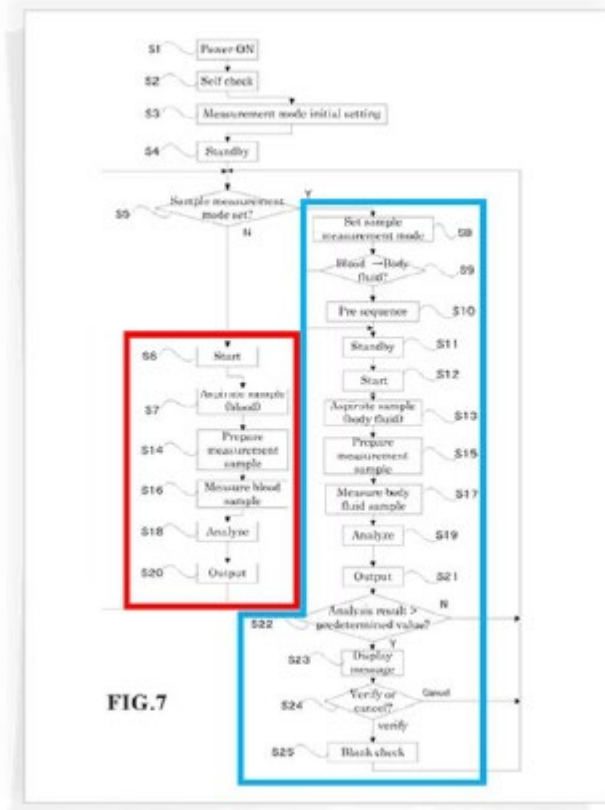


Figure 7 of the '350 Patent is a flow chart of the sample measuring process.

Prelim. Resp. 50. Referring to its annotated version of Figure 7, Patent Owner asserts that "[t]he operations in the red box are executed in 'a blood measuring mode,' and the operations in the blue box are executed in 'a body fluid measuring mode.'" Prelim. Resp. 50 (citing Ex. 1001, 8:56–13:18). The Specification supports Patent Owner's assertion that, "[w]hile some

individual operations in each mode may be similar, each mode's sequence of operations is different." *Id.* As discussed above, the '350 Patent discloses that some steps are performed in the same manner in both measurement modes. Ex. 1001, 12:5–9, 12:13–15, 12:41–43. The '350 Patent also describes differences between blood measurement mode and body fluid measurement mode. For example, a pre sequence process is performed only when switching from blood measurement mode to body fluid measurement mode and not the reverse. *Id.* at 10:60–65, 11:10–14, 11:38–41, Fig. 7 (steps S9, S10), Fig. 9 (flow chart showing the pre sequence process).

Although Patent Owner directs us to the prosecution history of a related application (Prelim. Resp. 51 (citing Exs. 2032, 2033)), we are not persuaded that it supports Patent Owner's constructions. Nevertheless, we determine that the claim language and the Specification provide adequate support for Patent Owner's constructions, which are unopposed by Petitioner on this record.

Accordingly, we construe "a blood measuring mode" as "a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample," and we construe "a body fluid measuring mode" as "a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample."

D. Petitioner's Obviousness Challenges

Our analysis focuses on the following limitation, which is recited identically in each of the independent claims of the '350 Patent:

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.

Ex. 1001, 16:49–55 (claim 1), 18:25–31 (claim 12), 19:40–46 (claim 19), 20:14–21 (claim 20), 20:45–51 (claim 21).

Petitioner refers to the above-quoted claim limitation as “CL4.”

Pet. 18. Petitioner’s contentions for CL4 are the same across all four asserted grounds. For Ground 1, Petitioner addresses CL4 in Section VIII.B.2.(d) of the Petition (Pet. 29, 34–36), and Petitioner’s contentions for Grounds 2–4 do not include a separate discussion of a controller programmed as recited in CL4 (Pet. 63–76).¹¹

The asserted references for Petitioner’s Ground 1 are XE2100, LH700, LH-BFA, and a POSA’s general knowledge. Pet. 5. XE2100 is an operator’s manual for Patent Owner’s XE-2100 analyzer and describes operation of the analyzer to analyze blood samples. Ex. 1004, 1-1, 1-2.¹² LH700 is a reference manual for the “Coulter LH 700 Series,” which is “a quantitative, automated hematology analyzer.” Ex. 1006, xiv, 1-1. LH-BFA is an operator’s manual for the “Body Fluid Application” of the Coulter LH-700 Series System. Ex. 1007, Title, viii.

¹¹ Although CL4 is included in the heading for Section VIII.E.2. of the Petition (Pet. 71), that section does not address whether it would have been obvious to modify a known sample analyzer, e.g., XE-2100, to include a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode, as recited in CL4.

¹² Patent Owner argues that Petitioner has not established that XE2100 (Ex. 1004) and XE-BFA (Ex. 1005) are printed publications. Prelim. Resp. 32–46. In view of our determination regarding the merits of Petitioner’s obviousness challenges, we need not consider the sufficiency of Petitioner’s showing regarding the status of these references as printed publications.

Petitioner contends that “it would have been obvious to modify the XE-2100 analyzer to include a body fluid mode that utilized known techniques suitable for body fluid analysis.” Pet. 29. Petitioner further contends that “XE2100 describes the same controller as that of the ’350 patent, and a POSA would have known based on XLH700/LH-BFA and general knowledge to provide for selective operation of the XE-2100 analyzer in blood and body fluid measuring modes having respective sequences of operations.” Pet. 34. According to Petitioner, a POSA would have known that the sequence of operations disclosed in XE2100 for measuring cells in blood “was also applicable for body fluid analysis.” Pet. 34–35 (citing Ex. 1003 ¶ 425). Petitioner contends that a POSA “would have been motivated to add a body fluid measuring mode to the XE-2100 analyzer in view of LH700/LH-BFA.” Pet. 35 (citing Ex. 1003 ¶ 426; Ex. 1007, 1-1).

As support for its contention, Petitioner presents the following:

In particular, LH700 teaches a sample analyzer which performs a sequence of operations in a blood measuring mode (Ex. 1006, 1-1), and LH-BFA teaches a body fluid measuring mode for that sample analyzer (Ex. 1007, 1-1). LH-BFA further teaches a “Body Fluid (CBC) checkbox (☒)” for selecting between blood and body fluid measuring modes performing of a pre-washing operation in the body fluid measuring mode. Ex. 1007, 2-3. It would have been obvious based on LH700/LH-BFA, to similarly selectively operate the XE-2100 analyzer of XE2100 in a blood measuring mode or a body fluid measuring mode. Ex. 1003, ¶ 426. Prior to the critical date, a POSA was aware of the problems associated with analyzing body fluids on hematology analyzers (for example, carryover and imprecision due to the low cell concentrations in body fluid), and a POSA was also aware of solutions to those problems (for example, implementing pre-wash and longer measurement time). Ex. 1007, 2-3; Ex. 1003, ¶¶ 426–427; *infra* Section VIII.B.2.(f).

Providing a separate mode for body fluid analysis relative to blood analysis, as taught by LH700/LH-BFA, allows for implementing software solutions for body fluid analysis to address these known problems. *Id.*

Pet. 35–36. Petitioner also contends that, “[i]n view of the user interface element taught in LH-BFA, it would have been obvious to modify the user interface taught in XE2100 to include a third option corresponding to a body fluid sample.” Pet. 36 (citing Ex. 1003 ¶¶ 428–431).

Patent Owner argues that Petitioner does not show that LH700/LH-BFA has the claimed blood measuring mode and a separate body fluid measuring mode, as properly construed. Prelim. Resp. 56–57.

According to Patent Owner, “LH-BFA does not disclose a separate body fluid measuring mode; the LH-700 uses the same sequence of operations for measuring blood and body fluids.” *Id.* at 57. Referring to LH-BFA, Patent Owner argues that Petitioner has not shown that the “Body Fluid (CBC) checkbox” alters any operation of the LH700 analyzer, nor does the checkbox imply the existence of a body fluid measuring mode that is different from the LH700 blood measuring mode. *Id.* at 58. Patent Owner disputes Petitioner’s assertion about a “pre-washing operation.” *Id.* at 59.

After considering both parties’ arguments and evidence, we agree with Patent Owner that Petitioner does not show sufficiently that it would have been obvious to a POSA to modify the XE-2100 analyzer to include “a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode,” as recited in the challenged claims.

For the reasons discussed above, we construe “a blood measuring mode” as “a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample,” and we

construe “a body fluid measuring mode” as “a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample.” These constructions were proposed by Patent Owner no later than July 6, 2020, in the Delaware case. *See* Ex. 1043, Appendix A-2, 2–3. Despite receiving Patent Owner’s proposed constructions more than a month before the August 8, 2020, filing date of the Petition, Petitioner does not address those constructions. Nor does Petitioner show sufficiently that CL4 would have been obvious under those constructions. More particularly, Petitioner does not show sufficiently that it would have been obvious to a POSA to program the controller of the XE-2100 analyzer to selectively operate the sample analyzer in two different operation modes, one for measuring cells in a blood sample and the other for measuring cells in a body fluid sample.

Petitioner also does not show sufficiently that, even when combined, XE2100, LH700, LH-BFA, and a POSA’s general knowledge teach or suggest “a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode,” as recited in the challenged claims. Nor does Petitioner present argument or evidence sufficient to show how or why a POSA would have modified the XE-2100 analyzer to include such a programmed controller. Missing from Petitioner’s argument addressing CL4 is any discussion of modifying or reprogramming the controller of the XE-2100 analyzer so that it selectively operates the sample analyzer in two different operation modes, one for blood and another for body fluid.

There is no dispute that neither XE2100 nor LH700 teaches “a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode,” as recited in the

independent claims. Each of these manuals describes the operation of a hematology analyzer to measure blood samples, not body fluid samples. As support for its argument that it would have been obvious to add a body fluid measuring mode to the XE-2100 analyzer, Petitioner relies on LH-BFA in combination with LH700. Pet. 35. Under our claim construction for “body fluid measuring mode,” we are not persuaded by Petitioner’s assertion that “LH-BFA teaches a body fluid measuring mode for that sample analyzer.” *Id.* (citing Ex. 1007, 1-1). We agree with Patent Owner that “LH-BFA does not disclose a separate body fluid measuring mode; the LH-700 uses the same sequence of operations for measuring blood and body fluids.” Prelim. Resp. 57.

Although Petitioner relies on LH-BFA’s disclosure of a “Body Fluid (CBC) checkbox (☑)” (Pet. 35), Petitioner does not show that selecting this checkbox amounts to selection of an operation mode that is different from the operation mode used to measure blood. Even the name for the checkbox—“Body Fluid (CBC)” —suggests otherwise. “CBC” stands for “complete blood count” (Ex. 1007, GLOSSARY-3) and is a type of analysis performed by the LH-700 for measuring blood samples. Ex. 1006, 3-1, GLOSSARY-3. Our finding is supported by LH-BFA, which discloses that “[b]ody fluid analysis defaults to the CBC mode.” Ex. 1007, 2-1 (“Body Fluids Application Overview”). Again, “CBC mode” refers to a type of analysis performed by the LH-700 for measuring blood samples. Ex. 1006, 4-3, INDEX-1.

LH-BFA discloses that, “[i]n Body Fluid analysis, there are differences in flagging and result reporting compared to whole blood.” Ex. 1007, 2-1. Petitioner does not address any of these differences, nor rely upon these differences to show “a sample analyzer operation mode, different

from the blood measuring mode, used for measuring cells in a body fluid sample,” as set forth in our claim construction.

We are not persuaded by Petitioner’s assertion that “LH-BFA . . . teaches . . . performing of a pre-washing operation in the body fluid measuring mode.” Pet. 35 (citing Ex. 1007, 2-3). LH-BHA makes no reference to any pre-washing operation. LH-BHA provides a set of operator instructions for processing body fluid samples in manual mode. Ex. 1007, 2-2, 2-3. The second instruction is: “2. Cycle a diluent blank prior to analyzing a body fluid specimen. If the WBC and RBC results are above the acceptable background limits, repeat the diluent blank.” *Id.* at 2-3. Petitioner neither asserts that cycling a diluent blank includes a pre-washing operation, nor provides any explanation or evidence to support such an assertion. Even assuming that cycling a diluent blank includes a pre-washing operation, Petitioner does not show that the cited references (XE2100, LH700, and LH-BFA) teach or suggest a controller programmed to carry out these steps. No such controller is suggested by LH-BHA, which instructs the operator to “[c]ycle a diluent blank prior to analyzing a body fluid specimen,” negating any suggestion that this step has been programmed into a controller. *Id.* at 2-2, 2-3.

We are also not persuaded by Petitioner’s argument that pre-washing and longer measurement times were known solutions to problems associated with analyzing body fluids on hematology analyzers. Pet. 35. Even if true, Petitioner’s argument is not sufficient to demonstrate how or why a POSA would have modified the controller of the XE-2100 analyzer. Although Petitioner argues that providing a separate mode for body fluid analysis “allows for implementing software solutions for body fluid analysis to address these known problems” (*id.*), that argument does not explain what

the software solution would be, nor whether it would involve programming the controller to operate the sample analyzer in a body fluid measuring mode that is different from the blood measuring mode.

Furthermore, we are not persuaded by Petitioner’s argument that “it would have been obvious to modify the user interface taught in XE2100 to include a third option corresponding to a body fluid sample.” Pet. 36. Modifying XE2100’s user interface is not enough to teach or suggest a controller programmed to operate the sample analyzer in a body fluid measuring mode that is different from a blood measuring mode. LH-BFA, for example, teaches a user interface that includes a “Body Fluid (CBC) checkbox,” but does not suggest programming the controller to operate the sample analyzer in a body fluid measuring mode that is different from a blood measuring mode.

We have considered the paragraphs of the Roche Declaration relied upon by Petitioner (Ex. 1003 ¶¶ 421–431), and we find that they are deficient for the same reasons as discussed above.

In sum, Petitioner does not show sufficiently that the combination of XE2100, LH700, LH-BFA, and a POSA’s general knowledge would have taught or suggested “a controller programmed to selectively operate the sample analyzer in a blood measuring mode or a body fluid measuring mode,” where the body fluid measuring mode is different from the blood measuring mode.

E. Discretion under 35 U.S.C. §§ 314(a), 325(d)

Patent Owner argues that the Board should exercise its discretion to deny the Petition under 35 U.S.C. §§ 314(a) and 325(d). Prelim. Resp. 12–32. In view of our determination that Petitioner has not met the

threshold for instituting review on the merits, we need not consider Patent Owner's arguments for a discretionary denial of institution.

III. CONCLUSION

For the above reasons, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that claims 1, 3–16, and 18–28 of the '350 Patent are unpatentable on the grounds asserted in the Petition.

IV. ORDER

It is

ORDERED that, the Petition is *denied*, and no trial is instituted.

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