IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SYSMEX CORPORATION and SYSMEX AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 19-1642-RGA-CJB
BECKMAN COULTER, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this action filed by Plaintiffs Sysmex Corporation and Sysmex America, Inc. ("Sysmex" or "Plaintiffs") against Defendant Beckman Coulter, Inc. ("BCI" or "Defendant"), Sysmex alleges infringement of United States Patent Nos. 10,401,350 (the "'350 patent") and 10,401,351 (the "'351 patent" and collectively with the '350 patent, "the asserted patents" or the "patents-in-suit"). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND

Sysmex commenced this action on September 3, 2019. (D.I. 1) The case was thereafter referred to the Court to hear and resolve all pretrial matters through the case-dispositive motion deadline. (D.I. 11)

Sysmex alleges that BCI's hematology analyzer systems infringe claims of the asserted patents. (D.I. 1 at ¶¶ 6, 17-56) The patents' specifications explain that blood samples and body fluid samples are routinely collected and used to diagnose and treat patients. ('350 patent, col.

1:25-30)[1] The asserted patents claim sample analyzers having a plurality of detectors for sensing blood samples or body fluid samples, including at least one multi-mode detector that can operate in both the blood measuring mode and the body fluid measuring mode. (D.I. 1 at ¶¶ 13, 16) Both patents are titled "Sample Analyzer and Computer Program Product." (*Id.*, exs. A-B)[2] Further details regarding the asserted patents will be provided below in Section III.

On October 14, 2020, the parties filed their joint claim construction brief. (D.I. 133) The Court conducted a *Markman* hearing by video conference on October 28, 2020. (D.I. 146 (hereinafter, "Tr.")) In February and March 2021, the parties submitted letters providing supplemental authority in support of their claim construction positions; these letters related to Institution Decisions in *inter partes* review ("IPR") proceedings involving the asserted patents. (D.I. 219; D.I. 220; D.I. 221)

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015).

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[1] The two patents-in-suit share the same specification. (*See* D.I. 133 at 2) All citations to the patent specification will be to the '350 patent unless otherwise indicated.

[2] The asserted patents appear on the docket in this action more than once. Citations to the patents will simply be to the '350 patent and '351 patent.

The Court should typically assign claim terms their "ordinary and customary meaning[,]" which is "the meaning that the term[s] would have to a person of ordinary skill in the art ['POSITA'] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent; rather it should endeavor to reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321; *see also Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

In proceeding with claim construction, the Court should look first and foremost to the language of the claims themselves, because "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "[d]ifferences among claims can also be a useful guide[,]" as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special

definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess" or may reveal an intentional disclaimer of claim scope. *Id.* at 1316. Even if the specification does not contain such revelations, it "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). And a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art[.]" *Id.* (internal quotation marks and citations omitted). Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* (internal quotation marks and citations omitted); *accord Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995).

In utilizing these resources during claim construction, courts should keep in mind that "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The parties set out eight disputed terms or sets of terms (hereinafter, "terms") for the Court's review. The Court takes up the terms in the order in which they were argued.

A. "controller programmed to"

The first disputed term "controller programmed to" appears in every independent claim of the asserted patents. Exemplary claim 7 of the '351 patent recites:

> **7.** A sample analyzer comprising:
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> 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;
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> 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 the body fluid measuring mode,
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> the *controller programmed to*:
> display on an input screen (1) at least two sample-type options that comprise 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 measurement mode to: analyze blood-sample measurements of the white blood cells sensed in the introduced blood measurement sample; count each of 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 sample-type 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 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.

('351 patent, cols. 18:13-19:25 (emphasis added)) The parties' competing proposed constructions for "controller programmed to" are set out in the chart below:

Term	**Plaintiffs' Proposed Construction**	**Defendant's Proposed Construction**
"controller programmed to"	This term is not a means-plus-function limitation. Plain and ordinary meaning, no construction necessary.	This is a means-plus-function term subject to 35 U.S.C. § 112, ¶ 6 (pre-AIA) / § 112(f) (AIA).

	Alternatively, "a microcomputer."	Functions: The various functions performed by the claimed controller [are set out at D.I. 133 at 35-37]. Structure: the corresponding structure is generally a microcomputer (e.g., Fig. 2, item 6) operating detection units, including a flow cytometric white blood cell detection unit 41 (see Fig. 4), programmed to perform algorithms as identified in [D.I. 133 at 35-37], to process and perform data analysis on signals, including photoreception signals. For [certain of the claimed functions, as indicated in D.I. 133 at 35-37], insufficient structure is provided in the patent specification, rendering the claims indefinite.

(D.I. 133 at 31) The parties' dispute with respect to this term is whether it should be construed as a means-plus-function limitation pursuant to 35 U.S.C. § 112, ¶ 6 ("Section 112, paragraph 6").[3] (*Id.* at 31, 37; *see also id.* at 5 (noting that the patent applications at issue are "part of a

[3] Section 112, paragraph 6 provided as follows:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The "means-plus-function" technique of claim drafting is a "convenience" that allows a patentee to express a claim limitation in functional terms "without requiring the patentee to recite in the

long chain of patent applications dating back to 2007[,]" such that pre-AIA Section 112, paragraph 6 applies here))

Given that the claims do not use the traditional "means" language often found in means-plus-function claims, "there is a rebuttable presumption that [Section 112, paragraph 6] does not apply." *Diebold Nixdorf, Inc. v. Int'l Trade Comm'n*, 899 F.3d 1291, 1298 (Fed. Cir. 2018). "[T]he presumption can be overcome and [Section 112, paragraph 6] will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id.* (internal quotation marks and citation omitted). The challenger must meet this burden by a preponderance of the evidence. *See Apex Inc. v. Raritan Comput., Inc.*, 325 F.3d 1364, 1372-73 (Fed. Cir. 2003). "To determine whether a claim recites sufficient structure, it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure,

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claims all possible structures" that could perform that function. *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003) (internal quotation marks and citation omitted). In exchange for getting the benefit of this drafting convenience, however, patentees must disclose, in the written description of the patent, a corresponding structure for performing the claimed function. *Noah Sys, Inc. v. Intuit Inc.*, 675 F.3d 1302, 1318 (Fed. Cir. 2012); *see also Elekta*, 344 F.3d at 1211 ("'[T]he price that must be paid for use of that convenience is limitation of the claim to the means specified in the written description and equivalents thereof.'") (citation omitted). A patentee satisfies this requirement "'only if the specification or prosecution history *clearly links or associates* that structure to the function recited in the claim.'" *In re Aoyama*, 656 F.3d 1293, 1297 (Fed. Cir. 2011) (emphasis added) (quoting *Elekta*, 344 F.3d at 1210); *see also Elekta*, 344 F.3d at 1220 ("The public should not be required to guess as to the structure for which the patentee enjoys the right to exclude. The public instead is entitled to know precisely what kind of structure the patentee has selected for the claimed functions, when claims are written according to section 112, paragraph 6."). "If the specification does not contain an adequate disclosure of the structure that corresponds to the claimed function, the patentee will have failed to particularly point out and distinctly claim the invention as required by . . . section 112, [paragraph 2], which renders the claim invalid for indefiniteness." *Blackboard, Inc. v. Desire2Learn Inc.*, 574 F.3d 1371, 1382 (Fed. Cir. 2009) (internal quotation marks and citation omitted).

even if the term covers a broad class of structures and even if the term identifies the structures by their function." *Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1019 (Fed. Cir. 2017) (internal quotation marks and citation omitted).

For the following reasons, the Court finds that BCI has failed to overcome the presumption against means-plus-function claiming here.

As an initial matter, the caselaw strongly supports the notion that, as a general matter, "controller" describes a known class of structures and does not signal the use of means-plus-function claiming. (D.I. 133 at 32, 33, 49; Tr. at 42-43, 56) Indeed, there are numerous cases in which district courts have concluded just that. *See, e.g.*, *Va. Innovation Scis., Inc. v. Amazon.com, Inc.*, Civil Action No. 4:18-cv-474, 2019 WL 4259020, at *13-15 (E.D. Tex. Sept. 9, 2019) (rejecting defendants' argument that "central controller" should be construed as a means-plus-function limitation because "controller" refers to a known class of structures in the art, and nothing in the specification indicated that the claimed controller lacked structure); *Barkan Wireless IP Holdings, L.P. v. Samsung Elecs. Co.*, No. 2:18-CV-28-JRG, 2019 WL 49790, at *22-23 (E.D. Tex. Feb. 7, 2019) (same); *Maxell Ltd. v. Huawei Device USA Inc.*, 297 F. Supp. 3d 668, 748 (E.D. Tex. 2018) (same); *see also Sound View Innovations, LLC v. Facebook, Inc.*, No. 16-cv-116 (RGA), 2017 WL 2221177, at *5 (D. Del. May 19, 2017) ("'Controller' may be a class of structures, rather than one specific structure, and may be defined with functional terms, but that does not make it means-plus-function.").

Next, BCI's primary counter-argument is not persuasive—and indeed, it was effectively rebutted by evidence that Sysmex has put forward. BCI's argument is *not* that a POSITA would be unable to recognize a "controller" as a known structure. Indeed, the clear evidence of record is that, as a general matter, POSITAs do recognize "controller" to refer to a known class of

structures. (D.I. 133 at 33; *id.*, ex. 18 at ¶ 49; *id.*, ex. 18 at ex. H at ¶ 57; Tr. at 21, 70) Instead, BCI is asserting that "neither Sysmex nor its expert explain how or why *the claimed 'controller'* is a member of such a known class." (D.I. 133 at 57 (emphasis added)) Put differently, BCI is arguing that a "controller" is understood by a POSITA simply to be a known structure that performs "control functions"—but that the claimed controller falls outside of this category because it performs not just control functions, but also various additional "general purpose computing" or "generic data processing" functions (like processing data, or producing analysis or displaying results). (*Id.* at 41, 44, 57-60; *id.*, ex. 18 at ex. H at ¶ 57; Tr. at 22)

But in response, Sysmex and its expert, Vijay Madisetti, Ph.D., persuasively address why a POSITA would understand that a "controller" could perform functions similar to those called out in the claims. Specifically, Dr. Madisetti's declaration explains that:

> (1) The *IBM Dictionary of Computing* defines "controller" to mean a "'device that coordinates and controls the operation of one or more input/output devices, such as workstations, and synchronizes [the operation of such devices with] the operation of the system as a whole.'" (D.I. 133, ex. 18 at ¶ 49 (quoting *id.*, ex. 5 at 145)) Dr. Madisetti notes that the claimed controller meets this definition as it "coordinates and controls the operation of" the "data processing unit 3, display and operating unit 7, and device 8 for measuring blood and body fluids, which includes a fluid supplying unit 81, and the claimed 'controller' synchronizes the operation of the sample analyzer as a whole." (*Id.*);
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> (2) The *IEEE Standard Dictionary of Electrical and Electronics Terms* defines "controller" as a "'device or group of devices that serves to govern, in some predetermined manner, the electric power delivered to the apparatus to which it is connected.'" (*Id.* at ¶ 50 (quoting *id.*, ex. 6 at 217)) Dr. Madisetti notes that the claimed controller governs, in a predetermined manner, the electric power delivered to several apparatus, such as data processing unit 3, display and operating unit 7, and device 8 for measuring blood and body fluids. (*Id.*);

(3) Controllers are able to do more than just coordinate and control; for example, controllers can regulate data flow, produce outputs in response to inputs, and format or process data. (*Id.* at ¶ 51; *see also id.* at ¶ 53 (Dr. Madisetti pointing out that BCI's own patents recognize that controllers are capable of inputting data and outputting data, and of being "'analyzer controllers'"); *see also* D.I. 133 at 53-54 & n.8); and

(4) The POSA would have understood that a "microcomputer" is one type of controller, and the patent specification makes clear that one exemplary "controller" described in the patents is "microcomputer 6." (*Id.*, ex. 18 at ¶¶ 54-55)[4]

Therefore, the extrinsic evidence persuasively indicates that not only does "controller" refer to a known class of structures, but that a POSITA would understand that the functions performed by the *claimed controller* are in line with those typically performed by a "controller." (Tr. at 58-59, 72); *Va. Innovation Scis., Inc.*, 2019 WL 4259020, at *13-15 (finding that the term "central controller" referred to a known class of structures in the art, where the claimed central controller did more than just perform generic "control" functions, and instead was configured to receive information regarding an item, identify the item, process a purchase request, communicate

[4] BCI argues that the microcomputer that is Sysmex's claimed controller is merely a general purpose computer, which establishes that the term should be treated as a means-plus-function limitation. (D.I. 133 at 42, 61-62 (citing *id.*, ex. 18 at exs. D, E, F, G); Tr. at 34-35) According to BCI, "[n]either Sysmex nor Dr. Madisetti argues that microcomputer 6 is not a general purpose computer." (Tr. at 34-35, 74) But that is incorrect. (*See* Tr. at 50) In Dr. Madisetti's declaration, he opines that: (1) a microcomputer was well-known as structure for a controller; (2) one exemplary controller described in the asserted patents is microcomputer 6; and (3) the "controller" described in the patents is "not a general purpose computer[.]" (D.I. 133, ex. 18 at ¶¶ 53-56) So Dr. Madisetti *is* thus opining that microcomputer 6 is not a general purpose computer.

Moreover, as Sysmex points out, the prosecution history for the '350 and '351 patent families supports the notion that: (1) a controller is a known structure and (2) a microcomputer can be a type of controller. Indeed, in assessing claims in an application for a related patent, the Examiner concluded that a prior art microcomputer satisfied the "controller" limitation in those claims. (D.I. 133 at 33 (citing D.I. 132 at JA00184); Tr. at 61)

information and send information); *Sound View Innovations, LLC*, 2017 WL 2221177, at *4-5 (finding that the claimed "controller," which similarly did more than perform generic "control" functions and instead also "monitor[ed]" characteristics and "delete[d]" data records, was not a means-plus-function limitation because it fell within a class of known structures).[5]

Lastly, BCI's other counter-argument is similarly unpersuasive. This argument has to do with two structures referenced in the specification: the afore-mentioned "microcomputer 6" and "controller 63." It is undisputed that "microcomputer 6" is an embodiment of the controller recited in the claims. (D.I. 133 at 40 (BCI noting that the "microcomputer 6 controls the operations of the hematology analyzer"); *id*. at 49 (Sysmex indicating that "the specification identifies a structure for the controller—microcomputer 6—which is described in detail"), *id*. at 52, 55; Tr. at 34) BCI nevertheless argues that because the specification also references *another* controller ("controller 63"), this demonstrates that the term "controller" as used in the claims must be a nonce word—i.e., a word connoting broad functionality and no specific structure. (D.I. 133 at 40-41) But "controller 63" is clearly not the controller recited in the claims—it is simply a *component* of microcomputer 6. And the Court is not persuaded that just because the specification describes another "controller" that has different functions than the claimed "controller," this means that the claimed "controller" is a "black box" that must get means-plus-function treatment. (*Id*. at 52); *cf. Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1375 (Fed. Cir. 2020) (finding that the defendant overcame the presumption against applying means-plus-

[5] BCI also asserts that because the claims fail to specify how the controller is connected to other claimed components, this is additional evidence that "controller" should be construed as a means-plus-function limitation. (D.I. 133 at 38-39) But Sysmex persuasively replies that a POSITA would understand that the controller (i.e., the microcomputer) is electrically connected to the detectors as depicted in Figure 2 of the patent. (*Id.* at 52; *id.*, ex. 18 at ¶ 55; *see also* '350 patent, col. 8:20-55; FIG. 2)

function claiming to the claim term "logic," where as used, "'logic' is no more than a black box recitation of structure that is simply a generic substitute for means") (certain quotation marks omitted).

For all of these reasons, BCI has not met its burden to demonstrate that the presumption against means-plus-function claiming has been overcome here. Having thus resolved the Section 112, paragraph 6 issue, and with there being no other existing dispute as to the construction of "controller programmed to," the Court recommends that no construction is needed for this term.

B. "a blood measuring mode" and "a body fluid measuring mode"

Every independent claim of the asserted patents makes reference to "a blood measuring mode" and "a body fluid measuring mode." The patent claims explain that the sample analyzer may be operated in a "blood measuring mode" or a "body fluid measuring mode," with each mode "includ[ing] a sequence of operations for measuring cells" in the blood sample or body fluid sample. ('350 patent, col. 16:49-55) The parties' proposed constructions for these terms are as follows:

Term	**Sysmex's Proposal**	**BCI's Proposal**
"a blood measuring mode"	"a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample"	Plain and ordinary meaning. Alternatively: "a setting of a sample analyzer used for measuring blood"
"a body fluid measuring mode"	"a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample"	Plain and ordinary meaning. Alternatively: "a setting of a sample analyzer used for measuring body fluid"

(D.I. 133 at 9)

In the briefing, Sysmex explained that BCI's position was flawed because its alternative constructions "do not preclude the 'setting' used for measuring blood from being the same 'setting' used for measuring body fluid." (D.I. 133 at 17) Sysmex contended that while prior art analyzers "operated the same way" whether used for blood or bodily fluids, in the claimed inventions "samples are measured by executing operations in the body fluid measurement mode *that differ in one or more ways* from the operations in the blood measurement mode." (*Id.* (internal quotation marks and citation omitted) (emphasis added)) While its position on this issue was not entirely clear in its briefing, during the *Markman* hearing, BCI did not appear to be asserting that the setting for measuring blood could be the same as the setting for measuring bodily fluids. (Tr. at 95)

In the IPR proceedings, Sysmex proposed the same constructions for these terms that it proposes here. (*See, e.g.*, D.I. 219, ex. 1 at 12-13) Ultimately, the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") agreed with Sysmex that the claim language and patent specification was consistent with Sysmex's proposed constructions. (*Id.* at 14-17) In doing so, the PTAB pointed out, for example, that certain claims provide examples of possible differences between the body fluid measuring mode and the blood fluid measuring mode—such as claims 1 and 12 of the '350 patent, which specify that the sensing operation is "different, at least partially" between the two modes,[6] and claims 19-21 of the '350 patent, which recite a pre-washing step and a counting step in the body fluid measuring mode that is not required in the blood measuring mode.[7] (D.I. 219, ex. 1 at 14-15; *see also* D.I. 133 at 9-10, 15)

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[6] Claim 1 of the '351 patent also recites this language. ('351 patent, col. 16:64-67)

[7] Claim 16 of the '351 patent also recites the "pre-washing" step in the body fluid measuring mode. (*Id.*, col. 21:6-10)

It also referenced the Abstract's disclosure of a sample analyzer that 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 that "execut[es] 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." (D.I. 219, ex. 1 at 15 (quoting '350 patent, Abstract); *see also* D.I. 133 at 10) The PTAB also cited in support to Figures 7 and 9 in the patents, as well as the descriptions of those figures; the PTAB noted that this intrinsic evidence discloses that while some steps are performed identically in both measurement modes, there are also differences between these modes. (D.I. 219, ex. 1 at 15-17; *see also* D.I. 133 at 10-11, 15)

Here, the Court agrees with Sysmex and the PTAB that Sysmex's proposed constructions for "a blood measuring mode" and "a body fluid measuring mode" are consistent with the claim language and the intrinsic record. It does so for all of the reasons, referenced above, that the PTAB relied upon to come to the same conclusion. And the Court notes that this outcome gibes with the claim construction principle that "[w]here a claim lists elements separately, the clear implication of the claim language is that those elements are distinct component[s] of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (internal quotation marks and citations omitted).[8]

[8] The Court also notes that BCI did not push back against these proposed constructions at all in the IPR proceedings. (D.I. 219, ex. 1 at 13) And in its supplemental letter to the Court regarding the IPR Institution Decisions, BCI did not cite any persuasive evidence suggesting that Sysmex's proposed constructions were incorrect. Instead, in that supplemental letter, BCI noted only that if "the Court is inclined to construe these terms in light of the IPR Institution Decisions . . . then they should be construed consistent with the argument made by Sysmex that was accepted by the Board, namely, that [] the different measuring modes refer to different *measuring* operations." (D.I. 220 at 2 (emphasis in original)) It is not exactly clear

For these reasons, the Court recommends that "a blood measuring mode" be construed to mean "a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample" and that "a body fluid measuring mode" be construed to mean "a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample."

C. "separately displaying" / "separately display"

The term "separately displaying" appears in claims 8, 9, 20 and 21 of the '350 patent, and the term "separately display" appears in claims 7, 11, 12 and 24-26 of the '351 patent. Exemplary claim 8 of the '350 patent recites:

> **8.** The sample analyzer according to claim **7**, wherein the sensing operation performed in the body fluid measuring mode comprises operations of counting mono-nucleated cells and poly-nucleated cells among the cells in the introduced body fluid sample and *separately displaying* in a screen a count of the mono-nucleated cells and a count of the poly-nucleated cells.

('350 patent, col. 17:54-60 (emphasis added)) And exemplary claim 20 of the '350 patent, for example, recites a sample analyzer that, for the blood measuring mode, "*separately display*[s] in a screen a count of each of said five types of white blood cells" and, for the body fluid measuring mode, "*separately display*[s] in a screen a count of the mono-nucleated cells and a count of the poly-nucleated cells." (*Id.*, col. 20:25-27, 32-34 (emphasis added))

The parties' proposed constructions are as follows:

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what BCI means by this, because Sysmex advanced the same claim construction "argument" (and the same supporting evidence) to the PTAB that it did here, and the PTAB construed the terms consistent with Sysmex's proposed constructions here. (D.I. 221 at 1; *see also* D.I. 220, ex. E at 48-51) To the extent that what BCI is getting at here amounts to a disputed issue of claim scope, the issue is not well-briefed; if necessary, the parties can re-raise it with the Court in the future.

Term	Sysmex's Proposal	BCI's Proposal
"separately displaying" / "separately display"	"are each individually displayed"	Plain and ordinary meaning.

(D.I. 133 at 18)

Frustratingly for the Court, the true nature of the parties' dispute regarding this term remained obscured throughout the briefing and for most of the argument about the term during the *Markman* hearing. Only at the very end of that argument did the parties clearly articulate what they were really disagreeing about. The dispute is this: if the claim requires, for example, "separately displaying" a "count of the mono-nucleated cells" or a "count of the poly-nucleated cells," how can this requirement be met? Sysmex argues that the only way to do so is by having an "individual count shown for each count that is recited in the claim[.]" (Tr. at 109) In other words, if the claim required, for example, "separately displaying" a "count of the mono-nucleated cells," this could only be accomplished by a display (like that in Figure 14) that depicts the letters "MN#" (or some other identifier for "mono-nucleated cells") alongside a corresponding number of cells. ('350 patent, FIG. 14) But BCI's view is that if the claim calls for "separately displaying" a "count of the mono-nucleated cells," that limitation could be satisfied if the analyzer separately displayed, for example, counts of *subcategories* of mono-nucleated cells. (Tr. at 111; *see also id.* at 105 ("The dispute is whether instead of just [mono-nucleated] and [poly-nucleated], [if the screen] instead [displays] the five white blood cell types [in five entries, then BCI's position is that that is] separately displaying [a count of the mono-nucleated cells and a count of the poly-nucleated cells]."')) For the following three reasons, the Court concludes that Sysmex's position is the correct one here.

First, the plain language of the claims supports Sysmex's construction. As noted above, claim 20 of the '350 patent recites, for the blood measuring mode, "separately display in a screen *a count of each of said five types of white blood cells*" and, for the body fluid measuring mode, "separately display in a screen *a count of the mono-nucleated cells and a count of the poly-nucleated cells*." ('350 patent, col. 20:25-27, 32-34 (emphasis added)) White blood cells can include both mono-nucleated and poly-nucleated cells. (D.I. 133 at 20) So the way this claim was drafted indicates that when the patentees were listing what types of counts must be "separately displayed," they did so in precise fashion. When they wanted a count of certain subcategories of mono- or poly-nucleated cells to be separately displayed, they said so, and when they wanted only a top-line display of mono- or poly-nucleated cells, they made that plain too. (*Id.* at 18-19; *see also, e.g.*, Tr. at 109 (Sysmex's counsel explaining that for claim 7 of the '351 patent, which recites "separately display in a screen a count of the mono-nucleated cells and a count of the poly-nucleated cells" "there should be a count for mononucleated cells, and there should [also] be an individually displayed poly[-]nucleated cell count"))[9]

Second, Figures 13 and 14 of the patent specification are also consistent with Sysmex's proposed construction. (D.I. 133 at 19; Tr. at 97, 100) Figure 13, which represents "a display screen showing the measurement results in the blood measurement mode[,]" clearly depicts separate counts for the five types of white blood cells ("NEUT#[,]" "LYMPH#[,]" "MONO#[,]"

[9] When asked by the Court during the *Markman* hearing about what in the patent supports its position, BCI's counsel responded: "just the plain language of the words." (Tr. at 111) Yet BCI has never explained, in the briefing or during oral argument, how the claim language would allow for its interpretation (e.g., that having five separate entries of subcategories of mono-nucleated or poly-nucleated cells on a screen would amount to separately displaying *a count* of the "mono-nucleated cells" or *a count* of the "poly-nucleated cells"). Nor does BCI point to anything else in the intrinsic record to persuade the Court that its position is the winning one here. (*Id.* at 100-01)

"EO#[,]" and "BASO#"), with each being individually displayed in a screen. ('350 patent, FIG. 13; *id.*, col. 3:34-35; *see also* D.I. 133 at 19) And Figure 14, which represents "a display screen showing the measurement results in the body fluid measurement mode[,]" depicts a separate count of the mono-nucleated cells ("MN#") and a count of the poly-nucleated cells ("PMN#"), with each individually displayed in a screen. ('350 patent, FIG. 14; *id.*, col. 3:36-37; *see also* D.I. 133 at 19) These figures, then, are also consistent with Sysmex's position that the claims' use of "separately" establishes that the particular measurements/results that are recited in the claim limitations "are each individually displayed." *See, e.g.*, *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1348 (Fed. Cir. 2012) (looking to figures of the patent to establish a term's correct construction); *Altair Eng'g, Inc. v. LEDdynamics, Inc.*, 413 F. App'x 251, 256 (Fed. Cir. 2011) ("[T]he figures and prosecution history support the district court's claim construction.").

Third, Sysmex points to dictionary definitions from 2007 that define "individual" as "separate" (or "separate" as "individual"). (D.I. 133, ex. 11 at 893; *id.*, ex. 12 at 753; *id.*, ex. 13 at 635, 1134; *id.*, ex. 14 at 456) These definitions support construing "separately displaying" / "separately display" as "are each individually displayed." (D.I. 133 at 21)

For these reasons, the Court recommends that the term "separately displaying" / "separately display" be construed to mean "are each individually displayed."

D. "display on an input screen (1) at least two sample-type options that comprise concurrent display of a blood sample option and a body fluid sample option each [independently selectable]/[selectable independently] from the other on the input screen" (hereinafter, "display on an input screen")

The term "display on an input screen" appears in claims 1, 7, 16 and 24 of the '351 patent. The parties' proposed constructions are as follows:

Term	Sysmex's Proposal	BCI's Proposal
"display on an input screen"	"an input screen that displays at the same time a blood sample option and a separate body fluid sample option and allows a user to select between the blood sample option and the separate body fluid sample option"	Plain and ordinary meaning.

(D.I. 133 at 23)

The purpose of claim construction is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." *Markman*, 52 F.3d at 976. However, claim construction is required only when "the parties raise an *actual dispute* regarding the proper scope of the[] claims." *02 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (emphasis added); *see also, e.g.*, *Warner Chilcott Co. v. Mylan Inc.*, Civil Action Nos. 11-6844 (JAP), 11-7228(JAP), 2013 WL 3336872, at *3 (D.N.J. July 2, 2013) ("A court is not required to construe a claim term where there is not an actual dispute with respect to that term."). Upon review of the parties' briefing and after further probing the issue during the *Markman* hearing, it is not clear to the Court that the parties have a ripe dispute regarding the meaning of this term. Therefore, the Court finds that the term does not require construction, at least not at this time.

In the briefing, Sysmex argued that the term (pursuant to the plain language of the claims in which it is found) has two requirements: (1) the input screen must display two options (i.e., a blood sample option and a body sample fluid option) at the same time; and (2) a user must be able to select between those two sample options on the display screen. (D.I. 133 at 23) Sysmex then explained how the specification supports its construction, with Figure 8 depicting "a screen

that displays three sample options at the same time" and the specification describing how "the user can select one of these analyzer operation modes." (*Id.* at 23-24 (citing '350 patent, FIG. 8; *id.*, col. 9:11-46)) Finally, Sysmex explained how the prosecution history supports its proposed construction. (*Id.* at 24) During prosecution of a related patent application, the patentees distinguished a prior art reference ("Chow") by explaining that Chow failed to disclose "the feature of displaying a selection screen arranged to allow a user to select either the blood sample or the body fluid sample for measurement." (D.I. 132 at JA00263) Because the analyzer of Chow "only operates in a single mode[,]" the patentees explained that there was "no need" for a user to select between a blood sample or body fluid sample. (*Id.*)

Did BCI have a problem with any of that? In its briefing, the closest that BCI came to articulating a dispute was to explain that Sysmex's proposal "potentially would exclude various computer interfaces" pertaining to "two sample-type options" such as "radio buttons, checkboxes, a drop down menu, etc." (D.I. 133 at 25) During the *Markman* hearing, however, Sysmex explained that its position would not exclude such design choices. (Tr. at 115)

Then during the *Markman* hearing, BCI raised a new issue—one it had not set out in the briefing. BCI asserted that a dispute existed with respect to the requirement that each sample option be "independently selectable" (or "selectable independently") from the other. (*Id.* at 116-20) According to BCI, this requirement means that "one [option] is selected notwithstanding . . . whether the [other option] is active or not" and that the user "could select both" options. (*Id.* at 117-18, 120) In this vein, according to BCI, if the user "had to toggle between [the two options], there's a dependence between the two" and they therefore would *not* be "independently selectable." (*Id.* at 119) In BCI's view, the portion of Sysmex's construction allowing for "a

user to select between the blood sample option and the separate body fluid sample option" "is not giving [the user] the ability to independently select each of them." (*Id.* at 120)

However, because BCI did not identify this dispute in the briefing, there was no meaningful pre-*Markman* hearing discussion between the parties about the issue. And so during the hearing, Sysmex understandably responded that because this was "the first time that we've heard" BCI's position, it was "hard [] to say" what Sysmex's view was regarding the issue. (*Id.* at 120-21)

Again, claim construction is proper when there is a real, known dispute between the parties about a term's scope. Because it is not clear to the Court whether there is such a dispute with respect to "display on an input screen," (or if there is, what the nature of that dispute is), the Court declines to construe the term at this stage. *See, e.g.*, *Endoheart AG v. Edwards Lifescis. Corp.*, C.A. No. 14-1473-LPS, 2016 WL 1270127, at *4 (D. Del. Mar. 31, 2016) (declining to construe a claim term where the parties failed to "actually articulate[] a fundamental disagreement about the scope of the disputed term"); *Warner Chilcott Co.*, 2013 WL 3336872, at *3 (declining to construe a claim term where "no party has been able to adequately articulate how, based upon the claim term 'tablet,' the meaning or proper scope of any of the asserted claims is in dispute").

Accordingly, the Court recommends that "display on an input screen" be afforded its plain and ordinary meaning.

E. "a second test result screen"

The term "a second test result screen" appears in claims 1, 9 and 25 of the '351 patent. The parties' proposed constructions are as follows:

Term	Sysmex's Proposal	BCI's Proposal
"a second test result screen"	"a body fluid measuring mode test result screen not used in the blood measuring mode"	Plain and ordinary meaning.

(D.I. 133 at 28)

The crux of the dispute here is whether a "second test result screen" can be used in the blood measuring mode. (*Id.* at 29, 30 n.6; Tr. at 122-23, 125) Sysmex asserts that it cannot be, while BCI's position is that it could be. In light of the intrinsic record, the Court sides with Sysmex.

Turning first to the plain language of the claims, it is in line with Sysmex's position. (D.I. 133 at 28; Tr. at 123) Exemplary claim 1 of the '351 patent recites two test result screens: (1) in the blood measuring mode, "perform the analyzing operation . . . to: analyze blood-sample measurements of cells sensed in the introduced blood measurement sample; and display analysis results of the blood-sample measurements on a *first test result screen*; and" (2) in the body fluid measuring mode, "perform the analyzing operation . . . to: analyze body-fluid-sample measurements of the cells sensed in the introduced body fluid measurement sample; and display analysis results of the body-fluid-sample measurements on a *second test result screen*." ('351 patent, col. 17:28-33, 46-51 (emphasis added)) The claims' recitation of two test result screens—a first screen and a second screen—indicates that these are different screens; if they were (or could be) the same, there would be no reason to include the terms "first" and "second." (D.I. 133 at 28, 30; Tr. at 123); *Luminati Networks Ltd. v. Code200, UAB*, No. 2:19-cv-00396-JRG, 2021 WL 425101, at *7- 8 (E.D. Tex. Feb. 8, 2021) (explaining that the "first server[,]" the

"second server" and the "client device" were separately recited in the claims, which suggested that they were distinct components); *see also Becton, Dickinson & Co.*, 616 F.3d at 1254. Moreover, dependent claims 11, 13 and 25 of the '351 patent recite "a second test result screen" and require that measurements/results *specific to the body fluid measuring mode* are displayed on that second screen. ('351 patent, cols. 19:39-43, 19:52-56, 19:66-20:3, 22:65-67, 23:1-9) This further indicates not only that "a second test result screen" is different from a first test result screen, but also that the second screen is only to be used in the body fluid measuring mode. (D.I. 133 at 28; Tr. at 123-24)

Turning next to the specification, Figure 13 depicts a screen "showing the measurement results in the blood measurement mode[,]" while Figure 14 depicts a screen "showing the measurement results in the body fluid measurement mode[.]" ('350 patent, FIG. 13, col. 3:34-35, 3:36-37) And with respect to Figure 14, the specification explains that one region shown in that screen "includes the name of the measurement items for body fluid measurement *rather than the measurement results of the blood measurement mode*[.]" (*Id.*, col. 15:9-18 (emphasis added)) Here, the specification is strongly suggesting that "a second test result screen" is used in the body fluid measuring mode, but not the blood measuring mode. (D.I. 133 at 29)

While BCI, for its part, asserts that "a second test results screen" is not "mutually exclusive of other screens[,]" it does not cite to anything in the patent in support of its claim that the second test result screen could also be used in the blood measuring mode. (*Id.* at 29-30) When pressed by the Court during the *Markman* hearing about whether any portion of the patent depicts or describes "a second test result screen" being used in the blood measuring mode, BCI's counsel responded that "the patent is directed primarily to screens which are developed in the body fluid measuring mode, so it does not show the various screens that would be available in a

blood measuring mode in terms of the display of the screens." (Tr. at 126-27) But as Sysmex's counsel then retorted, Figure 13 *does* show a screen that is utilized for the blood measurement mode. (*Id*.) And, as noted above, it is a separate screen from that used for the body fluid measuring mode (*Id.*) Therefore, BCI's unsupported position is not persuasive.

For these reasons, the Court recommends that the term "a second test result screen" be construed to mean "a body fluid measuring mode test result screen not used in the blood measuring mode."

F. "electrical detector" and "optical detector"

The terms "electrical detector" and "optical detector" appear in independent claim 7 of the '351 patent. Claim 7 recites a sample analyzer comprising, among other components:

> [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[.]

('351 patent, col. 18:14-24 (emphasis added)) The parties' proposed constructions are as follows:

Term	**Sysmex's Proposal**	**BCI's Proposal**
"electrical detector"	Plain and ordinary meaning, no construction necessary. Alternatively, "a detector that measures one or more electrical parameters."	"detector that measures electrical properties of blood and body fluid, rather than optical properties"
"optical detector"	Plain and ordinary meaning, no construction necessary.	"detector that measures optical properties of blood and body

	Alternatively, "a detector that measures one or more optical parameters."	fluid, rather than electrical properties"

(D.I. 133 at 63)

The crux of the dispute here is whether an "electrical detector" and an "optical detector" refer to different detectors (BCI's position) or whether they may refer to the same detector (as Sysmex proposes). (D.I. 133 at 66, 67; Tr. at 129)[10] For the two reasons set forth below, the Court agrees with BCI.

First, the plain language of claim 7 is consistent with BCI's position. (D.I. 133 at 67; Tr. at 129) The claim requires "a *plurality* of detectors" that comprise "at least one optical detector" and "at least one electrical detector[.]" ('351 patent, col. 18:15-17 (emphasis added)) This use of the word "plurality" strongly suggests that what is intended is that the two detectors that are listed thereafter are *different* detectors, not the same detector. (*Cf*. D.I. 133 at 67); *see also Becton, Dickinson & Co.*, 616 F.3d at 1254.

Second, the specification distinguishes between electrical detectors and optical detectors, which further demonstrates that claim 7 is referring to different detectors. (D.I. 133 at 67-68; Tr. at 129) The specification identifies three different types of detectors: a white blood cell detection unit, an RBC/PLT detection unit, and an HGB detection unit. (Tr. at 129-30) And in

[10] In the briefing, the parties also presented a dispute with respect to whether the recited detectors could "be used only with blood or body fluid" (with Sysmex asserting that BCI's proposed construction improperly limits the detectors to ones that can be used only with blood or body fluid). (D.I. 133 at 63-70) During the *Markman* hearing, however, the parties appeared to reach agreement that there was no longer a dispute regarding that issue, with BCI confirming that its proposed construction is not meant to "preclude the possibility of [the claimed detectors] measuring something other than blood or body fluid." (Tr. at 132-33) Therefore, the Court will not include "of blood and body fluid" in its recommended constructions for these terms.

doing so, the specification describes them as separate units and "exclusively as either electrical detectors or optical detectors[.]" (*Id.*) To that end, the specification explains that the detection device in the sample analyzer:

> is provided with a white blood cell detection unit **41** for detecting white blood cells. The white blood cell detection unit **41** is also used to detect nucleated red blood cells and reticulocytes. *In addition to the white blood cell detection unit*, the detection device **4** is also provided with an RBC/PLT detection unit **42** for measuring the number of red blood cells and the number of platelets, and an HGB detection unit **43** for measuring the amount of pigment in the blood.

('350 patent, cols. 5:62-6:3 (emphasis added)) The specification then goes on to teach that the "[t]he white blood cell detection unit **41** is configured as an optical detection unit[.]" (*Id.*, col. 6:4-5) It also describes the HGB detection unit 43 as one that measures optical properties of the sample. (*Id.*, cols. 7:56-8:19) And it then discusses the third detection unit, the RBC/PLT detecting unit 42, as measuring electrical properties of the sample. (*Id.*, col. 7:7-40) This all leads to the same conclusion: an electrical detector and an optical detector are different things.

Sysmex's only retort is that "[t]here is nothing in the intrinsic evidence to require the electrical detector to be capable of detecting electrical parameters, but not optical parameters as BCI argues; or requiring that an optical detector to be incapable of detecting both optical and electrical parameters." (D.I. 133 at 69-70) But Sysmex cites to nothing in support of its position. (*Id.* at 70) And, as described above, the intrinsic record in fact does provide significant evidence to indicate that BCI is correct here.

For these reasons, the Court recommends that the term "electrical detector" be construed to mean "detector that measures electrical properties, rather than optical properties" and the term

"optical detector" be construed to mean "detector that measures optical properties, rather than electrical properties."

G. "mono-nucleated cells" and "poly-nucleated cells"

The terms "mono-nucleated cells" and "poly-nucleated cells" appear in claims 8, 9, 20 and 21 of the '350 patent, as well as in independent claim 7 of the '351 patent. The parties' proposed constructions are as follows:

Term	**Sysmex's Proposal**	**BCI's Proposal**
"mono-nucleated cells" and "poly-nucleated cells"	mono-nucleated cells Plain and ordinary meaning, no construction necessary. Alternatively, "cells with a single nucleus." poly-nucleated cells Plain and ordinary meaning, no construction necessary. Alternatively, "cells with two or more nuclei."	mono-nucleated cells "lymphocytes and monocytes" poly-nucleated cells "neutrophils, eosinophils and basophils"

(D.I. 133 at 71, 73)

The parties' dispute here is whether "mono-nucleated cells" and "poly-nucleated cells" should be limited to five types of white blood cells (i.e., lymphocytes, monocytes, neutrophils, eosinophils and basophils), as BCI asserts, or whether these cells may include more than those five types of white blood cells, as Sysmex contends. (*Id.* at 71, 73, 74) More specifically, BCI argues that the term "mono-nucleated cells" is limited to lymphocytes and monocytes, while the term "poly-nucleated cells" is limited to neutrophils, eosinophils and basophils. (*Id.* at 73) Meanwhile, Sysmex contends that: (1) the terms are inclusive of, but are not limited to, those five types of white blood cells; and (2) can further include anomalous particles (i.e., nucleated

cells such as tumor cells, macrophages and mesothelial cells). (*Id.* at 71, 75) The Court sides with Sysmex here.

As an initial matter, BCI does not appear to dispute that the plain and ordinary meaning of "mono-nucleated cells" is "cells with a single nucleus" and that the plain and ordinary meaning of the term "poly-nucleated cells" is "cells with two or more nuclei." (*Id.* at 74 (BCI noting that the "literal meaning" of the terms at issue is as Sysmex suggests)) Indeed, BCI's Instructions for Use for certain of its accused products include a glossary, in which it defines "mononuclear" as "[h]aving only one nucleus" and "polynuclear" as "[h]aving many nuclei." (*Id.*, ex. 9 at BCI0034556, BCI0034560; ex. 10 at BCI0330501, BCI0330505 (*cited in* D.I. 133 at 73)) The Court is mindful that "[a]bsent lexicography or disavowal," it should "not depart from the plain meaning of the claims[.]" *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016).

Turning to the claims themselves, their language is at least somewhat helpful to Sysmex's position. For one thing, BCI does not point to any instance where the claims limit mono-nucleated cells and poly-nucleated cells to a particular type of such cells (such as the five types of white blood cells referenced above). (*See* D.I. 133 at 71, 74) Indeed, certain claim language suggests that the terms are not so limited. That language is found in claim 20 of the '350 patent which, as was previously noted above, requires a controller programmed to:

> perform the sequence of operations in the blood measuring mode to: analyze blood-sample measurements of cells in the blood sample; count each of *five types of white blood cells* in the blood sample; and separately display in a screen a count of each of said *five types of white blood cells*; and
>
> perform the sequence of operations in the body fluid measuring mode to: analyze body-fluid-sample measurements of cells in the body fluid sample; count *mono-nucleated cells and poly-nucleated*

> *cells* in the body fluid sample; and separately display in a screen a count of the *mono-nucleated cells* and a count of the *poly-nucleated cells*.

('350 patent, col. 20:22-34 (emphasis added)) The way that claim 20 separately references "mono-nucleated cells" and "poly-nucleated cells" on the one hand, and "each of five types of white blood cells" on the other hand, can be read to suggest that those are different groupings that do not entirely overlap (and that the scope of the former terms may be broader than the scope of the latter term). (D.I. 133 at 72); *cf. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996) ("If the terms 'pusher assembly' and 'pusher bar' described a single element, one would expect the claim to consistently refer to this element as *either* a 'pusher bar' or a 'pusher assembly[,]' but not both[.]") (emphasis in original).[11]

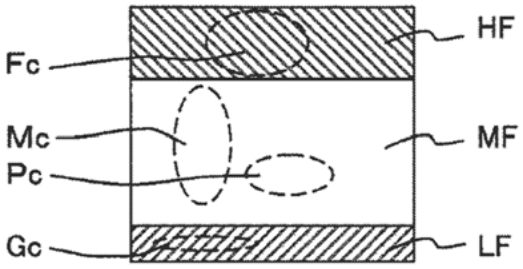
The Court turns next to the specification. As BCI notes, the specification certainly does make clear that mono-nucleated cells include lymphocytes and monocytes, and that poly-nucleated cells include neutrophils, eosinophils and basophils (a point that is not in dispute). In that vein, the specification explains that:

> In the analysis processing of the blood measurement mode, the DIFF scattergram and the like are analyzed, and information is calculated for five types of white blood cell subclasses (NEUT:

[11] BCI attempts to explain away claim 20's usage of the terms "mono-nucleated cells," "poly-nucleated cells," and "five types of white blood cells" by asserting that "claim differentiation need not be applied" to claim 20 because that claim was recently added to the asserted patent. (D.I. 133 at 74) But as Sysmex replies, (*id*. at 75 n.13), the doctrine of claim differentiation really is not in play here, since the terms at issue were all used in the *same claim*. Put differently, regardless of when claim 20 was added, the content of that claim suggests that the patentees did not view "mono-nucleated cells" and "poly-nucleated cells" as together meaning the exact same thing as "five types of white blood cells[.]" *S. Snow Mfg. Co. v. SnoWizard Holdings, Inc.*, Civil Action No. 06-9170, 2013 WL 12229039, at *7 (E.D. La. Jan. 2, 2013) ("Notwithstanding the doctrine of claim differentiation, which SnoWizard notes requires that 'each claim in a patent must be interpreted to have a different scope than every other claim,'[] the terms and phrases within a single claim can and should modify the scope and meaning of that particular claim.") (citation omitted).

> neutrophil, LYMPH: lymphocyte, MONO: monocyte, EO: eosinophil, and BASO: basophil), whereas in the analysis processing of the body fluid measurement mode, two subclasses (MN: mononuclear cell, PMN: polymorphonuclear cell) are classified in a partially integrated form because there are a lesser number of blood cells and these cells are sometimes damaged. *The lymphocytes and monocytes belong to mononuclear cells, and neutrophils, eosinophils, and basophils belong to polymorphonuclear cells.*

('350 patent, col. 12:48-60 (emphasis added); *see also id.*, col. 15:9-17 (explaining that the field "MN#" shows "mononuclear cell count (lymphocytes+monocytes)[,]" the field "PMN#" shows "polymorphonuclear cell count (neutrophils+basophils+eosinophils)[,]" the field "MN %" shows the "ratio of mononuclear cells among white blood cells" and the field "PMN %" shows the "ratio of polymorphonuclear cells among white blood cells")) Additionally, Figure 10, shown below, depicts a scattergram derived from measurements of a sample prepared from body fluid. (*Id.*, col. 3:25-27) The scattergram shows three regions, including the MF region in which "*mononuclear white blood cells Mc* and *polynuclear white blood cells Pc* are distributed[.]" (*Id.*, col. 13:47-48 (emphasis added))



And the specification goes on to note that anomalous particles in the regions Fc and Gc (found in the regions HF and LF, respectively) are intentionally excluded "in order to obtain a high precision classification of blood cells within the body fluid[.]" (*Id.*, col. 13:24-26 (*cited in* D.I. 133 at 74)) It explains that "[w]hite blood cells in body fluid can be measured with greater precision based on the new knowledge tha[t] anomalous particles appear in the top part of the

DIFF scattergram produced by this blood cell analyzer of the present invention." (*Id.*, col. 13:27-31)

However, the Court is not persuaded that the above portions of the specification serve to redefine the terms "mono-nucleated cells" and "poly-nucleated cells" such that they should be limited to only the five types of white blood cells. That is because, as Sysmex points out, (D.I. 133 at 72), the specification *also* indicates that these terms may include more than just the five types of white blood cells. It notes that in the MF region in the above-referenced scattergram from Figure 10, "[l]ymphocytes and monocytes are included in mononuclear white blood cells" and "neutrophils, basophils, and eosinophils are included in polynuclear white blood cells." ('350 patent, col. 13:52-55) And it goes on to teach that:

> *Anomalous particles (nucleated cells such as tumor cells, macrophages, mesothelial cells) other than blood cells* may also be present in body fluid. Although it is rare for such anomalous cells to be present in cerebrospinal fluid, such cells appear comparatively frequently in abdominal and thoracic fluids. In the scattergram of FIG. **10**, such *nucleated cells other than white blood cells* are distributed in region HF. In the present embodiment, it is possible to determine accurate white blood cells counts even in body fluid which contains such *nucleated cells other than white blood cells* since *nucleated cells other than white blood cells* can be identified. *The degree of occurrence of anomalous cells can be determined by counting the cells which appear in region HF.*

(*Id.*, cols. 13:60-14:6 (emphasis added)) This excerpt demonstrates that anomalous particles are clearly "nucleated cells." And it also shows that these anomalous cells can be detected by the sample analyzer. (*See* D.I. 133 at 72) Indeed, the sample analyzer described in the preferred embodiment can provide a scattergram analysis that distinguishes between white blood cells and anomalous cells. ('350 patent, col. 14:10-24) Thus, when considering the specification as a

whole, the Court does not see how it clearly limits "mono-nucleated cells" and "poly-nucleated cells" to only the five types of white blood cells.

Accordingly, the Court recommends that "mono-nucleated cells" be construed to mean "cells with a single nucleus" and "poly-nucleated cells" be construed to mean "cells with two or more nuclei."

H. "total [count] of nucleated cells"

The term "total [count] of nucleated cells" appears in dependent claim 10 of the '350 patent, as well as in dependent claims 8, 13, and 25 of the '351 patent. The parties' proposed constructions are as follows:

Term	**Sysmex's Proposal**	**BCI's Proposal**
"total [count] of nucleated cells"	Plain and ordinary meaning, no construction necessary. Alternatively, "a total [count] of cells having one or more nucleus."	"total [count] of mono-nucleated and poly-nucleated white blood cells"

(D.I. 133 at 76)

The parties' dispute here mirrors the dispute that they had for the above terms "mono-nucleated cells" and "poly-nucleated cells." That is, BCI contends that the term "total [count] of nucleated cells" only includes white blood cells, while other cell types (such as anomalous cells) are excluded from the total count. (*Id.* at 77) Meanwhile, Sysmex asserts that the total count of cells can include the five types of white blood cells as well as anomalous nucleated cells. (*Id.*)

Here again, the Court sides with Sysmex. It does so in part because it finds BCI's position wanting "for the same reasons it was wrong to try to limit the construction of the prior term [i.e., 'mono-nucleated cells' and 'poly-nucleated cells'] to five types of white blood cells."

(*Id.*) But below, the Court will also set out a few additional reasons why Sysmex has the better position with respect to this term.

First, the claim language supports Sysmex's view. For example, claim 8 of the '351 patent recites:

> **8.** The sample analyzer according to claim **7**, wherein the analyzing operation performed in the blood measuring mode comprises operations to obtain a *total count of the white blood cells* sensed in the introduced blood measurement sample and display the total count of the white blood cells, and the analyzing operation performed in the body fluid measuring mode comprises operations to obtain a *total count of nucleated cells* sensed in the introduced body fluid measurement sample and display the total count of the nucleated cells.

('351 patent, col. 19:26-35 (emphasis added)) If "total count of nucleated cells" means the same thing as "total count of white blood cells," then presumably the claim would use the same term to represent this, instead of using two different terms. The fact that the patentees did not do so is some indication that these terms mean different things. (D.I. 133 at 77); *Ethicon Endo-Surgery, Inc.*, 93 F.3d at 1579.

As for the specification, here again, BCI contends that it supports its position. More specifically, BCI points to Figure 14—i.e., the figure depicting "a display screen showing the measurement results in the body fluid measurement mode[.]" ('350 patent, col. 3:36-37) Figure 14 displays a white blood cell count for a body fluid sample ("WBC-BF") of 6.180. (*Id.*, FIG. 14 & col. 15:9-12) It also displays a mononuclear cell count ("MN#") of 2.369 and a polymorphonuclear cell count ("PMN#") of 3.811, which totaled together equals the WBC-BF count. (*See id.*, FIG. 14; D.I. 133 at 77) According to BCI, these numbers illustrate that the total count of nucleated cells equals the count of mononuclear and polymorphonuclear white blood cells (and that if MN# and PMN# included any cells other than white blood cells, such as

anomalous particles, WBC-BF would be less than (not equal to) the sum of MN# and PMN#). (D.I. 133 at 78)

In reply, however, Sysmex points to Figure 15. (*Id.* at 79) That figure also depicts "a display screen showing the measurement results in the body fluid measurement mode[.]" ('350 patent, col. 3:38-39) This screen displays, *inter alia*, the: (1) number of particles in the HF region of the scattergram shown in Figure 10 (which consist of anomalous particles), denoted as "HF-BF#"; and (2) the combined number of particles in both the HF region and the MF region (which consist of white blood cells), denoted as "TC-BF#[.]" (*Id.*, FIG. 15 & col. 15:24-35) On its face, then, TC-BF represents the total number of nucleated cells and is comprised of something other than just white blood cells. (D.I. 133 at 78-79) This portion of the specification is helpful to Sysmex's case, and overall, the specification certainly does not provide enough support for the Court to divert from the plain and ordinary meaning of the term at issue.

Thus, the Court recommends that "total [count] of nucleated cells" be construed to mean "total [count] of cells having one or more nucleus."

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. No construction is needed for "controller programmed to."

2. "a blood measuring mode" should be construed to mean "a sample analyzer operation mode, different from the body fluid measuring mode, used for measuring cells in a blood sample" and "a body fluid measuring mode" should be construed to mean "a sample analyzer operation mode, different from the blood measuring mode, used for measuring cells in a body fluid sample"

3. "separately displaying" / "separately display" should be construed to mean "are each individually displayed"

4. "display on an input screen" should be afforded its plain and ordinary meaning

5. "a second test result screen" should be construed to mean "a body fluid measuring mode test result screen not used in the blood measuring mode"

6. "electrical detector" should be construed to mean "detector that measures electrical properties, rather than optical properties" and "optical detector" should be construed to mean "detector that measures optical properties, rather than electrical properties"

7. "mono-nucleated cells" should be construed to mean "cells with a single nucleus" and "poly-nucleated cells" should be construed to mean "cells with two or more nuclei"

8. "total [count] of nucleated cells" should be construed to mean "total [count] of cells having one or more nucleus"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: April 6, 2021

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE