IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SYSMEX CORPORATION and SYSMEX AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 19-1642-JFB-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 BCI's Motion for Summary Judgment of Noninfringement (the "Motion"). (D.I. 412) For the reasons that follow, the Court recommends that the Motion be DENIED.

I. BACKGROUND

A. Factual Background

Sysmex alleges that BCI's DxH hematology analyzer products (the "accused products") infringe claims 1, 4, 9, 12, 18-21 and 27-28 of the '350 patent and claims 1, 4, 6, 16-17, 21 and 23-26 of the '351 patent. (D.I. 1 at ¶¶ 6, 17-56; D.I. 368; D.I. 416, ex. 11 at ¶ 5) Both patents are titled "Sample Analyzer and Computer Program Product[,]" and they issued on September 3,

2019. (D.I. 1, exs. A-B)[1] 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)[2] 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 configured to operate in both the blood measuring mode and the body fluid measuring mode. (*See generally* '350 patent, '351 patent)

Any additional facts relevant to this Report and Recommendation will be discussed in Section III below.

B. Procedural History

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)

On April 6, 2021, the Court issued a Report and Recommendation regarding claim construction (the "claim construction R&R"). (D.I. 230) On April 27, 2022, the District Court issued a Memorandum Order adopting the claim construction R&R. (D.I. 493)

BCI filed the instant Motion on November 30, 2021, (D.I. 412), and briefing was completed on January 14, 2022, (D.I. 435). The Court heard oral argument on certain portions of the Motion (as well as other summary judgment and *Daubert* motions) by video conference on

[1] 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.

[2] 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.

February 25, 2022. (D.I. 486 (hereinafter, "Tr.")) Following oral argument, the parties submitted supplemental letters with respect to the Motion. (D.I. 489; D.I. 490; D.I. 491)

II. STANDARD OF REVIEW

A. Summary Judgment

The Court incorporates by reference the standard of review for summary judgment motions set out in its prior May 6, 2022 Report and Recommendation. (D.I. 499 at 2-3)

B. Patent Infringement

The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the patent claims asserted to be infringed. *Id.* Claim construction is generally a question of law, although subsidiary factfinding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing device. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents (hereinafter, "DOE") if any differences between the claimed invention and the accused product are insubstantial. *See VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014). The patent owner has the burden of proving infringement, and must do so by a

preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

When an accused infringer moves for summary judgment of non-infringement, such relief may be granted only if at least one limitation of the asserted claim does not read on an element of the accused product, either literally or under the DOE. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) ("Summary judgment of noninfringement is [] appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial."). Therefore, the court may grant summary judgment of non-infringement only if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is covered by the claims, as construed by the Court. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

III. DISCUSSION

With its Motion, BCI seeks summary judgment of non-infringement on four independent bases. The Court will address each of those in turn below.

A. The Claimed "Controller"

Every asserted claim of the asserted patents recites a "controller programmed to" perform various functions. (*See* D.I. 230 at 5-6) BCI's first argument is that summary judgment of non-infringement should be granted with respect to Sysmex's literal infringement and DOE theories for the "controller" limitation. The Court will first consider literal infringement, and will then turn to the DOE.

1. Literal Infringement

We begin with some background. During claim construction, BCI argued that "controller" should be construed as a means-plus-function limitation pursuant to 35 U.S.C. § 112, ¶ 6. (*Id.* at 7-13) The Court then assessed whether BCI had overcome the presumption against means-plus-function treatment by showing that the term failed to recite sufficiently definite structure, or that it recited function without reciting sufficient structure for performing that function. As part of that back-and-forth, BCI did not dispute Sysmex's assertion that the term "controller," as a general matter, refers to a known class of structures. But BCI argued that the *claimed* controller "falls outside of this [known] 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 9-11 & n.4) Sysmex and its expert, meanwhile, argued that a person of ordinary skill in the art ("POSITA") would understand that the functions performed by the claimed controller are in line with those typically performed by a "controller." (*Id.*) The Court ultimately agreed with Sysmex, concluding that the claimed controller was therefore not a "black box" that must get means-plus-function treatment. (*Id.* at 10-13) Having resolved that dispute, the Court recommended that no construction was needed for the "controller" term, (*id.* at 13), a recommendation that has subsequently been adopted, (D.I. 493 at 10).

The accused products have two main components: the Specimen Processing Module (the "SPM") and the System Manager. (D.I. 418, ex. 27 at 1-5; *see also* D.I. 416, ex. 11 at ¶¶ 62-63) Sysmex contends that the System Manager component meets the "controller" claim limitations. (D.I. 416, ex. 11 at ¶ 62; *id.*, ex. 13 at ¶ 12) Additionally, Sysmex argues that the System Manager working with the SPM constitutes a group of devices that can also meet the "controller" limitations. (*Id.*, ex. 11 at ¶ 63; *id.*, ex. 13 at ¶ 12)

With that background behind us, the Court now turns to BCI's merits argument. Here, BCI asserts that, in light of the Court's claim construction decision, the claimed "controller" cannot simply amount to a general purpose computer. (D.I. 413 at 4-5; D.I. 435 at 1-3) And BCI then argues that the component of the accused products that Sysmex identifies as the "controller" (i.e., the System Manager) *is* just a general purpose computer. (D.I. 413 at 4-7) So, BCI's argument goes, summary judgment of non-infringement is warranted because BCI's System Manager is the very thing that the Court has said a "controller" cannot be (i.e., a general purpose computer). (*Id.* at 1, 7-9)

In responding, Sysmex's opening salvo is that BCI's position (i.e., that the Court previously decided that a "controller" cannot be a general purpose computer) is simply "wrong and ignores the Court's claim construction[.]" (D.I. 427 at 25) According to Sysmex: (1) the Court found that a "controller" is not a means-plus-function limitation because BCI failed to overcome the presumption against means-plus-function claiming; (2) the Court therefore did not perform additional means-plus-function analysis to determine the structure that performs the alleged recited function; and (3) it would have been only during this additional means-plus-function/structure analysis that the Court could have been making findings as to whether the disclosed structure was a general purpose computer. (*Id.*; *see also* Tr. at 59-60, 63)

But in the Court's view, it is Sysmex, not BCI, that is ignoring what happened during the claim construction proceedings in this case. (*See* D.I. 435 at 3) As the Court explained in the claim construction R&R, BCI's primary argument supporting its position that the "controller" term should be construed as a means-plus-function limitation was that the claimed "controller" did not fall into the known class of "controller" structures; instead, BCI argued that it "f[ell] outside of th[at] 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)." (D.I. 230 at 9-10)[3] To rebut this argument and demonstrate that the "controller" term *was not* a means-plus-function term, Sysmex clearly asserted, *inter alia*, that the claimed controller "is not a general purpose computer." (D.I. 133 at 50; *see also* D.I. 146 at 50, 52 (Sysmex's counsel arguing that with respect to the claimed controller, "[y]ou've got a pre-established microcomputer here . . . . This isn't a general purpose computer. . . . [It is a much more specifically-programmed computer] designed in a certain way.")) Likewise, Sysmex's expert Dr. Vijay Madisetti, in a portion of his expert declaration submitted with the claim construction briefing, laid out his arguments for why the "controller programmed to" is not a means-plus-function limitation, (D.I. 133, ex. 18 at 11-15); in that portion of his declaration, Dr. Madisetti clearly stated that "'controller' in the context of the '350 and '351 patents is a known class of structures, not a general purpose computer[,]" (*id.* at ¶ 56 (*cited in* D.I. 133 at 54; D.I. 146 at 62; D.I. 230 at 11 n.4)). And in ultimately agreeing with Sysmex that "controller" should not get means-plus-function treatment, the Court considered and accepted these arguments. (D.I. 230 at 11-13 & n.4) In other words, Sysmex's arguments persuaded the Court that the claimed "controller" refers to a known class of structures, *and* that this known class of structures did not simply amount to general purpose computers. (*Id.*; *see also, e.g.*, D.I. 133, ex. 18 at ¶ 56) Thus, the Court agrees with BCI that Sysmex cannot now point to a component of the accused products that is simply a general purpose computer—

[3] (*See also, e.g.*, D.I. 133 at 38 ("'Controller Programmed To' Is A Placeholder For A General Purpose Computer") (emphasis omitted); *id*. at 42 ("[A] skilled artisan would not have understood the claimed controller to refer to a known class, but instead to refer to a general purpose computer."); D.I. 146 at 12 ("[O]ur contention is that the controller that is claimed in the [asserted] patent[s] . . . refers to nothing more than [] general purpose computing equipment or a general purpose computer."))

nothing more—and then assert that this satisfies the "controller" claim limitation. *See, e.g.*, *Oleksy v. Gen. Elec. Co*., No. 06 C 1245, 2015 WL 5714208, at *5 (N.D. Ill. Sept. 29, 2015); *Stairmaster Sports/Med. Prods., Inc. v. Groupe Procycle, Inc.*, 25 F. Supp. 2d 270, 279-80 (D. Del. 1998).

Sysmex's alternative position is that even if the Court's claim construction for the "controller" term does exclude a general purpose computer, Sysmex has nevertheless put forward evidence creating a fact issue as to whether the System Manager is a "controller." (D.I. 427 at 28-31) On this front, the Court agrees with Sysmex.

In arguing to the contrary, BCI contends that the System Manager is simply a general purpose computer that: (1) runs Windows applications; (2) uses routine Windows functionality; (3) includes standard applications such as Paint, Solitaire, Word, Excel, WordPad and Explorer; and (4) includes a Windows operating system that controls the conventional personal computer components, such as the keyboard and applications (including the System Manager application). (D.I. 413 at 5-6 (citing D.I. 418, ex. 27 at 1-5 (DxH series operator manual explaining that the System Manager "[i]ncludes . . . a computer with CD/DVD RW drive running Microsoft® Windows®"))) Thus, BCI argues that the System Manager includes functionality beyond that implemented by a "controller" belonging to the "known class of structures" discussed in the claim construction R&R. (*Id.* at 6-7; D.I. 418, ex. 34 at ¶ 39) With Sysmex having accused a general purpose computer as meeting the "controller" limitation—instead of a "controller" from the known class of structures—BCI argues that its products do not contain the claimed "controller" and therefore that summary judgment of non-infringement is warranted. (D.I. 413 at 8-9)

But Sysmex has countered with evidence sufficient to defeat summary judgment—evidence indicating that the System Manager is more than just a general purpose computer (and instead meets the definition of a "controller" from the known class of structures). (D.I. 427 at 23, 28, 29; Tr. at 61-62, 79-80) This view of the claimed "controller" is consistent with Sysmex's arguments during claim construction that the microcomputer disclosed in the patent specification is an embodiment of the claimed controller, and that the microcomputer is a "much more specifically programmed computer. . . . designed in certain way." (D.I. 146 at 52; Tr. at 61, 82); *see also, e.g.*, *Sound View Innovations, LLC v. Facebook, Inc.*, No. 16-cv-116 (RGA), 2017 WL 2221177, at *5 (D. Del. May 19, 2017) (explaining that a controller "may be implemented in software, firmware, hardware, or some suitable combination of at least two of the three"); *Goss Int'l Ams., Inc. v. Graphic Mgmt. Assocs., Inc.*, 739 F. Supp. 2d 1089, 1100 (N.D. Ill. 2010) ("[A] controller is a known structure that is a type of special purpose computer.") (*cited in* D.I. 133 at 50). Sysmex first points to the operator manual for the accused product, which explains that the System Manager "[c]ontrols processes, such as analysis and diagnostic procedures[,]" "[p]roduces test results" and "[m]anages data, such as test ordering, results review, results release, quality control, LIS interface, logging, and report generation." (D.I. 418, ex. 27 at 1-5 (*cited in* D.I. 427 at 23, 29)) Further, Sysmex's expert, Dr. Madisetti, opines that the System Manager is not a general purpose computer since it: (1) "serves a specialized predetermined function" in controlling processes; and (2) includes DxH software, which causes the System Manager to be a special purpose computer, as the software is associated with the control function provided by the System Manager and is not something that would be included on a general purpose computer. (D.I. 416, ex. 13 at ¶¶ 13, 22; *see also* D.I. 418, ex. 27 at 1-5 (noting that the System Manager includes a computer with "DxH software"); D.I. 427 at

30; Tr. at 82 ("The DxH [product] does not just use any computer lying around. It uses the [S]ystem [M]anager, which is sold as part of the DxH product."), 86)

BCI has four primary responses to Sysmex's proffered evidence. None are availing.

First, BCI argues that Sysmex's position (i.e., that the System Manager is not just a general purpose computer, but instead is a special purpose computer running particularized software) is simply irrelevant here, because an inquiry as to whether a device is a "special purpose computer" is only relevant in one context: when a claim has been construed to include a means-plus-function limitation. (D.I. 413 at 7-8; D.I. 435 at 6; Tr. at 20-21) Now, it is true that in the means-plus-function context, when the claim discloses a computer that is not capable of performing the relevant function absent specialized software, then the requisite structure is typically understood to be a "special purpose computer" that is programmed to perform the disclosed algorithm. *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999); *see also Rain Comput., Inc. v. Samsung Elecs. Am., Inc.*, 989 F.3d 1002, 1007 (Fed. Cir. 2021). Yet while that is an example of how the term "special purpose computer" can have relevance with regard to means-plus-function claiming, it does not mean that the term cannot also be pertinent regarding other types of infringement inquiries. (Tr. at 87-88); *see, e.g.*, *Nuance Commc'ns, Inc. v. MModal LLC*, C.A. No. 17-1484 (MN), 2020 WL 6384204, at *1 (D. Del. Oct. 30, 2020) (noting that the parties' agreed-upon construction for "speech recognition system" was "device or combination of devices, which could include general-purpose computers, special purpose computers, or dedicated hardware circuits, and the software thereon, that recognize speech"). And since BCI is asserting here that the "controller" cannot be a general purpose computer, then it only makes sense that Sysmex should be free to point to evidence demonstrating why the System Manager *is not* a general purpose computer (and instead is a

"special purpose computer"). *Uniloc USA, Inc. v. E-MDS*, CASE NO. 6:14-cv-625, 2016 WL 3049143, at *5 (E.D. Tex. May 31, 2016).

Second, BCI argues that even outside of the means-plus-function context, a "general purpose computer loaded with software [i.e., how BCI characterizes the System Manager] is still a general purpose computer." (D.I. 435 at 2, 4; *see also* D.I. 413 at 7) However, its opening brief cited to nothing in support of this notion. (D.I. 413 at 7; *see also* D.I. 427 at 30) In its reply brief, BCI cited to *Eon Corp. IP Holdings LLC v. AT & T Mobility LLC*, 785 F.3d 616 (Fed. Cir. 2015) in support of the proposition (specifically, to the *Eon* Court's notation that "[a] general purpose computer is flexible—it can do anything it is programmed to do"). (D.I. 435 at 2-3, 4 (citing *Eon*, 785 F.3d at 623)) But the Court is not persuaded by this citation. (Tr. at 86) The *Eon* Court otherwise explains that a general purpose computer programmed to carry out functionality that is not coextensive with a general purpose computer becomes a new machine—a special purpose computer. 785 F.3d at 622-23.

BCI's third counter-argument is that, during claim construction, Sysmex asserted that the claimed "controller" does not amount to software running on a general purpose computer—and that Sysmex is now estopped from taking a contrary position. (D.I. 435 at 2-3, 6) On that front, one portion of the patents' specification states:

> A fourth aspect of the present invention is a computer program product, comprising: a computer readable medium; and instructions, on the computer readable medium, adapted to enable *a general purpose computer* to perform operations[.]

('350 patent, col. 2:56-60 (*cited in* D.I. 146 at 51) (emphasis added)) In contrast, the specification also describes a "first aspect of the present invention" as constituting a "sample analyzer" that comprises, *inter alia*, control means. (*Id.*, col. 2:1-14) During the *Markman*

hearing, Sysmex's counsel distinguished these two embodiments in support of Sysmex's position that the claimed "controller" was not a means-plus-function limitation. (D.I. 146 at 51) That is, Sysmex noted that the patentees knew how to use the term "general purpose computer," but emphasized that the patentees did not say that a "microcomputer as used in the patent is a general purpose computer. Instead, they talked about a microcomputer in a sample analyzer[—]not a software for a general purpose computer here. . . . [the claimed invention] involves a pre-established microcomputer" that is "a much more specifically programmed computer" than a general purpose computer. (*Id.* at 51-52; *see also* D.I. 133 at 52 (explaining that the "fourth aspect of the present invention" is an "embodiment of a computer readable medium for use with a general purpose computer that is not claimed in the asserted patents"); D.I. 133, ex. 18 at ¶ 57)

BCI did not squarely raise this argument until its reply brief.[4] And so Sysmex did not have the opportunity to fairly respond to the argument in its answering brief. BCI's failure here is particularly important, because it is asking the Court to grant summary judgment in its favor on a case-dispositive issue when the Court does not have the benefit of good, full briefing on that issue—and the reason for that *is BCI's fault*. BCI's failure to clearly raise this estoppel-type argument in its opening brief means that it has waived the argument at the summary judgment

[4] BCI's opening brief did confront Sysmex's argument that the System Manager application running on the general purpose computer makes it a special purpose computer (and it cited the paragraph of Dr. Madisetti's report in which Dr. Madisetti opined that the DxH "software causes [the System Manager] to be a special[-]purpose computer"). (D.I. 413 at 7-8 (citing D.I. 416, ex. 13 at ¶ 22)) But in that opening brief, BCI did not mention Sysmex's above-referenced comments during the claim construction hearing, nor say anything about how those comments might impact the decision on the "controller" issue. Instead, it was not until BCI's reply brief that BCI put forward the argument that Sysmex's non-infringement position here "is directly contrary to [Sysmex's] counsel's argument" during the claim construction process that "the claimed controller 'is not a general purpose computer' running 'software[.]'" (D.I. 435 at 1-2 (internal citations omitted))

stage. *See, e.g.*, *EIS, Inc. v. WOW Tech Int'l GmbH*, C.A. No. 19-1227-LPS, 2020 WL 7027528, at *7 (D. Del. Nov. 30, 2020); *Perrigo Co. v. Int'l Vitamin Co.*, No. 1:17-CV-01778, 2019 WL 359991, at *2 n.22 (D. Del. Jan. 29, 2019).

BCI's fourth counter-argument was also raised for the first time in its BCI's reply brief. Here, BCI argued that: (1) the Court's claim construction requires that the claimed "controller" be "'electrically connected to the detectors as depicted in Figure 2 of the ['350] patent'"; (2) and Sysmex advances no argument that BCI's System Manager satisfies this requirement. (D.I. 435 at 1 (citing D.I. 230 at 12 n.5); *see also* Tr. at 74) Here again, because the argument could have been included in BCI's opening brief, but was not, it is waived. And further, Sysmex pointed out during oral argument that BCI's own opening brief described the System Manager as being connected to the SPM, which houses the detectors. (Tr. at 74-76 (citing D.I. 413 at 4-6); *see also* D.I. 419, ex. 35 at BCID231292; Sysmex's Summary Judgment Presentation, Slide 11) Thus, even absent waiver, Sysmex has demonstrated a material issue of fact on this point.

For the foregoing reasons, the Court recommends that this portion of BCI's Motion be denied.

2. DOE

BCI also argues that Sysmex cannot contend that the System Manager can be combined with a separate device (the SPM) for DOE purposes, because the claims require that a *single* controller be programmed to perform the requisite functions. (D.I. 413 at 10)[5] In support of this argument, BCI relies on the claim language (which recites "*a* controller"), as well as on the

[5] BCI additionally asserted that Sysmex cannot accuse a general purpose computer of being the claimed "controller" under the DOE. (D.I. 413 at 9) However, this argument is moot because Sysmex did not advance a DOE theory involving a general purpose computer. (D.I. 427 at 31; D.I. 435 at 7)

prosecution history of a parent application to the asserted patents. (*Id.* at 10-11) With regard to that latter prosecution history issue, the original claims of that patent recited a "first control means" and a "second control means[.]" (D.I. 420, ex. 36 at SYSMEXUS0000776-77) Certain dependent claims recited a "blank measurement controlling means," "a comparison means," and "a wash controlling means[.]" (*Id.* at SYSMEXUS0000778) The Examiner rejected the claims as being anticipated by a prior art reference known as "Hirayama" that taught an analyzer comprising, *inter alia,* various control means. (*Id.* at SYSMEXUS0000765-66) The patentee subsequently amended the claims to recite "a controller configured to [control/compare][.]" (*Id.* at SYSMEXUS0000776-78) In light of this, BCI contends that prosecution history estoppel applies to prevent Sysmex from asserting that the use of multiple devices can be equivalent to a single "controller[.]" (D.I. 413 at 11 (citing *Traxcell Techs., LLC v. Nokia Sols. & Networks Oy*, 15 F.4th 1136, 1145 (Fed. Cir. 2021))[6]

The Court disagrees with BCI that summary judgment is warranted here. As an initial matter, the Court notes that Sysmex has put forward evidence demonstrating that a POSITA

[6] Prosecution history estoppel prevents a patentee from using the DOE to recapture subject matter surrendered from the literal scope of a claim during prosecution. *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013). When presented with a narrowing amendment that was made for a substantial reason related to patentability, the Court must "presum[e] that prosecution history estoppel applies." *EMD Millipore Corp. v. AllPure Techs., Inc.*, 768 F.3d 1196, 1203 (Fed. Cir. 2014). The patentee may rebut the presumption by establishing one of three exceptions to estoppel: "[t]he equivalent [was] unforeseeable at the time of the application; the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question; or there [was] some other reason suggesting that the patentee could not reasonably be expected to have described the [equivalent]." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740-41 (2002). Whether prosecution history estoppel applies, and therefore whether a patentee may assert the DOE for a particular claim limitation, is a question of law. *Spectrum Pharms., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015); *Intellectual Ventures I LLC v. T–Mobile USA, Inc.*, C.A. No. 13-1632-LPS, 2017 WL 3723934, at *5 (D. Del. Aug. 29, 2017).

would understand that a "controller" could constitute a singular device *or* multiple devices—such that multiple controller devices working together could literally meet the "controller" limitation. (D.I. 427 at 32; Tr. at 80-81; *see also, e.g.*, D.I. 133, ex. 6 at 217; D.I. 230 at 10; D.I. 416, ex. 11 at ¶ 68) And with regard to BCI's prosecution history estoppel argument, it does not appear that the amendments in question had anything to do with whether multiple devices could work together in order to meet the "controller" limitation. (D.I. 427 at 32-33)[7] Instead, it seems as if by removing the "first control means" and "second control means" language from the claims during prosecution, the patentees were simply intending to eliminate means-plus-function claim limitations—not making a point about whether multiple controllers could satisfy the "controller" requirement. (*Id.*); *see also, e.g.*, *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1331-32 (Fed. Cir. 2019).[8] Indeed, BCI does not substantively reply to Sysmex's arguments in this regard. (*See* D.I. 435 at 7 n.1) As a result, Sysmex's DOE argument is viable.

For these reasons, the Court recommends that this DOE-related portion of BCI's Motion regarding the "controller" limitation also be denied.

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[7] With respect to the Examiner's rejection of the claims as anticipated by Hirayama, Sysmex did not argue in response that Hirayama disclosed multiple controllers while the claims only required a single controller. (*See* D.I. 427 at 33) Rather, Sysmex argued that Hirayama did not disclose "a controller" that was configured to operate in the manner required by the claims. (D.I. 420, ex. 36 at SYSMEXUS0000780)

[8] The facts here are much different than in *Traxcell Techs., LLC v. Nokia Sols. & Networks Oy*, 15 F.4th 1136 (Fed. Cir. 2021), a case cited by BCI. (D.I. 413 at 10) In *Traxcell*, the patentee had distinguished a prior art reference during prosecution because that reference disclosed multiple computers, noting clearly and explicitly (and repeatedly) that its claimed invention used just one. 15 F.4th at 1144. The *Traxcell* Court found that this conduct disclaimed the use of multiple computers, and that prosecution history estoppel therefore foreclosed Traxcell's multiple-computer DOE theory. *Id*. at 1144, 1146. The patentee's intent in editing the claims here during prosecution to avoid the Hirayama reference simply is nowhere near as clear as the situation in *Traxcell*.

B. Multi-Mode Detectors

Independent claims 1, 12 and 19 of the '350 patent and independent claims 1, 16 and 24 of the '351 patent recite "multi-mode detectors configured to operate in both the blood measuring mode and the body fluid measuring mode" (the "multi-mode detectors limitation"). (*See* D.I. 413 at 12) This term was not presented as a disputed term during the claim construction process.

However, with its Motion, BCI now contends that these claims explicitly require two separate, different configurations (i.e., one configuration for the blood measuring mode, and a separate, different configuration for the body fluid measuring mode). (*Id.* at 12-14; D.I. 435 at 7-8; *see also* D.I. 409, ex. 41 at ¶ 38 (BCI's expert Mr. Roche opining that BCI does not infringe certain claims because the detectors in its products "are not configured to operate differently in a blood measuring mode as compared to a body fluid measuring mode, and they are not configured to operate in separate modes for blood and body fluid")) With BCI's accused products having only one configuration for both the blood measuring mode and the body fluid measuring mode, BCI argues that they cannot infringe these claims. (D.I. 413 at 13-14 (BCI noting that its detectors cannot infringe because they "are configured to operate *identically*, with no dependence on whether a blood measuring mode or body fluid measuring mode has been selected") (emphasis added); D.I. 435 at 8)

Sysmex, for its part, retorts that the plain and ordinary meaning of the multi-mode detectors limitation does not require that the detectors necessarily be configured separately or differently. Instead it argues that the multi-mode detectors limitation means multi-mode detectors "that *can operate* in both the blood measuring mode and the body fluid measuring mode[.]" (D.I. 427 at 34-36 (emphasis added); *see also* D.I. 413 at 12; D.I. 416, ex. 11 at ¶ 86; D.I. 417, ex. 21 at 252)

The Court recommends that this portion of BCI's Motion be denied, as it is not persuaded that BCI's proposed construction of the multi-mode detectors limitation is correct. (D.I. 427 at 34) Instead, it adopts Sysmex's proposed construction of the term. This is because the claims and the specification support Sysmex's position. Claim 1 of the '350 patent, for example, demonstrates that the patentees knew how to use the word "different" or variants thereof when they wanted to; indeed, they used "different" just a few lines before the multi-mode detectors limitation, when explaining that the "sensing operation performed in the body fluid measuring mode [must be] *different*, at least partially, from the sensing operation performed in the blood measuring mode[.]" ('350 patent, col. 16:62-65 (emphasis added)) Yet the patentees did not draft the multi-mode detectors limitation to read "one or more multi-mode detectors configured to operate *differently* in . . . the blood measuring mode and the body fluid measuring mode"—instead, they left the word "differently" out of the claim language there. (*Id*., cols. 16:66-17:2; *see also* Sysmex's Summary Judgment Presentation, Slides 33-34) Furthermore, the specification seems to support the idea that a detector can be configured so that it is used in both the blood measurement mode and the body fluid measurement mode. ('350 patent, FIG. 3, cols. 9:47-60, 12:13-20; D.I. 427 at 34; Sysmex's Summary Judgment Presentation, Slide 35)

Having adopted Sysmex's proposed construction, the Court concludes that there is a genuine issue of material fact as to whether the accused products meet the multi-mode detectors limitation. (D.I. 427 at 35-36) This is because, at a minimum, Sysmex's expert opines that: (1) the accused products have a blood measuring mode and a body fluid measuring mode; (2) the electrical detectors of the accused products sense cells in both blood samples and body fluid samples; and (3) even assuming that both modes "call the same [source code] files to operate the detectors, that does not mean that the two separate modes are in fact one mode"; as (4) the body

fluid mode includes a prewashing step that is not included in the blood measuring mode. (D.I. 416, ex. 13 at ¶ 43; *id.*, ex. 15 at ¶ 38) Thus, there is a dispute of fact as to whether the accused products include detectors that can operate in both the blood measuring mode and the body fluid measuring mode.

For these reasons, the Court recommends that BCI's Motion be denied with respect to the multi-mode detectors limitation.

C. Poly-nucleated Cells

BCI next moves for summary judgment of non-infringement with respect to the "poly-nucleated cells" limitation. This term appears in claims 9, 20 and 21 of the '350 patent and in claims 24-26 of the '351 patent, which generally require that the amount/count of poly-nucleated cells be calculated and displayed. (*See* D.I. 413 at 14)

This was a disputed term during the claim construction process. BCI had proposed that "poly-nucleated cells" be limited to three types of white blood cells: "neutrophils, eosinophils and basophils." (D.I. 230 at 28) Meanwhile, Sysmex argued that: (1) the term included, but was not limited to, those particular three types of blood cells and could further include anomalous particles (i.e., nucleated cells such as tumor cells, macrophages and mesothelial cells); and (2) the term should be construed in accordance with its plain and ordinary meaning, i.e., "cells with two or more nuclei." (*Id.* at 28-29) With it being undisputed that the plain and ordinary meaning of "poly-nucleated cells" is "cells with two or more nuclei[,]" and with nothing in the intrinsic record limiting the term in the manner that BCI suggested, the Court recommended that the term be construed to mean "cells with two or more nuclei." (*Id.* at 28, 33)

The Court now turns to BCI's non-infringement argument. In that regard, there is no dispute that the accused products count only polymorphonuclear cells. (D.I. 413 at 15; D.I. 418,

ex. 28 at 1-1; D.I. 418, ex. 31 at ¶¶ 40-42) There is also no dispute that: (1) polymorphonuclear cells have two or more nuclei segments or lobes; and (2) neutrophils, eosinophils and basophils are examples of polymorphonuclear cells. (D.I. 413 at 15; D.I. 417, ex. 17 at ¶¶ 34-35) Nor is there any dispute that certain non-polymorphonuclear cells, such as tumor cells, macrophages and mesothelial cells, all contain multiple nuclei. (D.I. 230 at 28-29; D.I. 418, ex. 31 at ¶ 41) BCI's position here is that polymorphonuclear cells should be understood as having only *one* (albeit multi-lobed) nucleus, and thus do not have "two or more nuclei"; as a result, BCI asserts that it cannot infringe the asserted claims. (D.I. 413 at 15-16) Again, the Court disagrees with BCI.

BCI's current position—that counting "poly-nucleated cells" cannot encompass counting polymorphonuclear cells like neutrophils, eosinophils and basophils, (D.I. 435 at 8)—stands in stark contrast to BCI's position during the claim construction process. There, as noted above, BCI proposed that "poly-nucleated cells" *be construed to mean* "neutrophils, eosinophils and basophils[.]" (D.I. 230 at 28, 30) Moreover, in its briefing here, BCI argues that summary judgment of non-infringement is warranted because, during claim construction, Sysmex successfully argued "*against* a construction that equated counting 'poly-nucleated' cells with counting neutrophils, eosinophils, and basophils." (D.I. 435 at 8 (emphasis added)) But that point too is wrong. In fact, during claim construction, Sysmex *did not dispute* that "poly-nucleated cells" include neutrophils, eosinophils and basophils; rather, its position was that the term *should not be limited* to those types of white blood cells. (D.I. 230 at 28-30; D.I. 427 at 36) In sum, as to this term, BCI is now both: (1) taking a position that is antithetical to the arguments it made during claim construction; and (2) wrongly accusing Sysmex of doing the same thing.

Indeed, the parties' agreement during the claim construction process that poly-nucleated cells include neutrophils, eosinophils and basophils makes good sense, in light of the asserted patents' specification. The specification uses the terms "polymorphonuclear" and "polynuclear" interchangeably, and it also makes clear that poly-nucleated cells/polymorphonuclear cells include neutrophils, eosinophils and basophils. ('350 patent, cols. 12:55, 12:59-60, 13:47; 13:55, 13:58, 15:14, 15:16-17; *see also* D.I. 230 at 30-31; D.I. 427 at 36-37) And Sysmex's expert opines that the POSITA would have the same understanding—pointing to both the intrinsic record as well as to extrinsic evidence. (D.I. 417, ex. 17 at ¶ 35; D.I. 428, ex. 66 at ex. C, at 1; D.I. 428, ex. 66 at ex. E, at 3)

Once it is understood that "poly-nucleated cells" include polymorphonuclear cells like neutrophils, eosinophils and basophils, then it is clear that this portion of BCI's Motion should be denied. Sysmex's expert opines that the accused products count and display the count of cells including neutrophils, eosinophils and basophils. (D.I. 417, ex. 17 at ¶¶ 36-37) To the extent that BCI disagrees, this presents a genuine issue of material fact, and summary judgment of non-infringement is not warranted. *See, e.g.*, *TQ Delta, LLC v. 2Wire, Inc.*, Civil Action No. 13-1835-RGA, 2021 WL 3375900, at *4 (D. Del. Aug. 3, 2021).

BCI additionally asserts that summary judgment of non-infringement is warranted with respect to the "poly-nucleated cells" limitation under the DOE, for two reasons. (D.I. 413 at 16; D.I. 435 at 9) It first recycles its argument that Sysmex's infringement theory (i.e., that counting neutrophils, eosinophils and basophils is the equivalent to counting "poly-nucleated cells") contradicts Sysmex's claim construction positions. (D.I. 413 at 16) But as discussed above, BCI is wrong on that front. Second, BCI contends that the "disclosure-dedication doctrine" prohibits Sysmex's reliance on the DOE, because while the specification discloses counting both

polymorphonuclear cells and poly-nucleated cells, Sysmex only claimed the latter. (*Id.*; D.I. 435 at 9)[9] This position is unpersuasive because as Sysmex points out, BCI does not identify any instance where Sysmex disclaimed poly-nucleated cells as *excluding* polymorphonuclear cells (or neutrophils, eosinophils and basophils). (D.I. 427 at 37 & n.20 (citing *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1176 (Fed. Cir. 2020))[10]

The Court therefore recommends that BCI's Motion be denied here as well.

D. Installed Base

Finally, BCI seeks summary judgment of no liability with respect to products sold prior to issuance of the asserted patents (i.e., September 3, 2019) (the "installed base"). BCI has sold the accused products continuously since 2008. (D.I. 413 at 16) It is undisputed that BCI's sales of the accused products prior to September 3, 2019 do not directly infringe the asserted patents. (D.I. 413 at 17; D.I. 427 at 38; D.I. 435 at 9); *see also Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 304 (Fed. Cir. 1995) ("[A patentee] may of course obtain damages only for acts of infringement after the issuance of the . . . patent[.]"). However, Sysmex contends that BCI indirectly infringes the asserted patents with respect to the installed base (i.e., equipment that may have been itself sold prior to patent issuance)—in that BCI's activities after September

[9] The disclosure-dedication rule precludes a finding of infringement that is based on subject matter disclosed in the written description but not claimed. *Eli Lilly & Co.*, 933 F.3d at 1334; *ViiV Healthcare Co. v. Gilead Scis., Inc.*, 437 F. Supp. 3d 395, 399 (D. Del. 2020). Such unclaimed subject matter is dedicated to the public. *Eli Lilly*, 933 F.3d at 1334; *ViiV Healthcare*, 437 F. Supp. 3d at 399. "The reason for the doctrine is that members of the public reading a disclosure of particular subject matter are entitled, absent a claim to it, to assume that it is not patented and therefore dedicated to the public (unless, for example, claimed in a continuation or other application based on the disclosure)." *Eli Lilly*, 933 F.3d at 1334.

[10] To the extent that BCI does not dispute that the accused products count and display the count of neutrophils, eosinophils and basophils, (i.e., if BCI concedes that they do), then the Court does not see how Sysmex would even need to resort to the DOE as to this infringement issue.

3, 2019, such as BCI's actions in providing training and instruction manuals to customers, purportedly induced its customers to then infringe the asserted patents. (D.I. 427 at 38; *see also* D.I. 416, ex. 11 at ¶ 43; D.I. 417, ex. 19 at ¶ 108)

With its Motion, BCI argues that Sysmex's induced infringement claim in this regard is legally incorrect. BCI asserts that if its sale of the installed base was itself free from liability, then any later use of that same equipment by BCI's customers must also be free from liability (either as to its customers pursuant to a direct infringement rationale, or as to BCI pursuant to an induced infringement rationale). (D.I. 413 at 17; D.I. 435 at 9-10)

BCI relies heavily on *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543 (Fed. Cir. 1997) in support of its position. (D.I. 413 at 17; D.I. 435 at 9-10) In that case, an asserted patent covered a technique for using an MRI scanner in a certain manner. *Fonar*, 107 F.3d at 1546. The district court overturned a jury verdict finding that the defendant induced infringement of that patent. *Id.* at 1547. The patentee appealed, arguing that it put forward substantial evidence that the defendant induced infringement by continuing to service scanners that it sold prior to receiving notice of the asserted patent. *Id.* at 1554. For its part, the defendant contended that the patentee failed to mark the scanners that are the subject of the inducement claim, and that there is no liability for induced infringement where the original buyer had a right to repair and service the scanners. *Id.* The United States Court of Appeals for the Federal Circuit affirmed the district court's grant of the defendant's motion for judgment as a matter of law of no induced infringement. *Id.* at 1555. After considering the marking statute, the Federal Circuit noted that because the scanners in question were not marked, the patentee could not recover damages before notice was given. *Id.* Further, it reasoned that "[i]f a machine was sold under

circumstances that did not subject its seller to damages, then subsequent repair cannot subject it to damages. One is entitled to repair that which is sold free of liability for infringement." *Id.*

The Court is not persuaded that *Fonar* warrants the grant of BCI's Motion with respect to the installed base. (D.I. 427 at 38) It is important to first consider that pursuant to 35 U.S.C. § 271, "whoever *without authority* makes, uses, offers to sell, or sells any patented invention within the United States . . . infringes the patent." 35 U.S.C. § 271(a) (emphasis added). And after *Fonar*, in *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509 (Fed. Cir. 2012), the Federal Circuit characterized the *Fonar* decision in a less expansive—rather than a more expansive—way. More specifically, the *ePlus* Court made a point to note that in *Fonar*, because the patentee *had failed to mark* relevant products, that is why the defendant's sale of the scanners "was authorized and free of liability." *ePlus*, 700 F.3d at 522. And as *ePlus* and other courts examining *Fonar* have emphasized, this meant that such authorized sales carried with them an implied license to use the scanner—i.e., that the defendant had the plaintiff's authority to make and sell the plaintiff's equipment to its customers; thus, when the defendant serviced these same machines for its customers, it "could not induce any infringement of the patent because the customers were not directly infringing the patent through unauthorized use." *ePlus, Inc. v. Lawson Software, Inc.*, Civil No. 3:09cv620, 2011 WL 2119410, at *21 (E.D. Va. May 23, 2011); *see also, e.g.*, *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1272-73 (Fed. Cir. 1999) (affirming the district court's holding that machines sold during a laches period were "free from liability from infringement, and thus acquired an implied license allowing their service and repair").

Here, in contrast, there is no marking issue, so it cannot be said that Sysmex's failure to mark its own patented product somehow gave BCI or its customers an implied license to use

Sysmex's patented technology. And the Court is not convinced that the circumstances here—i.e., that a BCI customer purchased an accused product before the patents-in-suit issued—amounts to the type of implied license to infringe those patents thereafter that is being discussed in a case like *Fonar*. In light of this, the relevant inquiry on this issue should simply be: (1) did BCI's customers use the patented technology after the date of patent issuance (i.e., did they directly infringe); and (2) if so, did BCI knowingly induce those customers to take those infringing actions (i.e., did it induce infringement) in that same relevant time period. *Cf. GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Civil Action No. 14-878-LPS-CJB, 2016 WL 3946770, at *10-11 (D. Del. July 20, 2016), *report and recommendation adopted*, 2017 WL 1050574 (D. Del. Mar. 20, 2017); *CreAgri, Inc. v. Pinnaclife Inc.*, Case No. 5:11-CV-06635-LHK, 2013 WL 3958379, at *4-5 (N.D. Cal. July 29, 2013).[11]

In sum, the Court is not persuaded that *Fonar* dictates that BCI is entitled to summary judgment of no liability with respect to the installed base as a matter of law. (*See* D.I. 435 at 10)

IV. CONCLUSION

For all of the above reasons, the Court recommends that BCI's Motion be DENIED.

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 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*,

[11] Following oral argument on the Motion, BCI filed a letter asserting that the Federal Circuit's recent decision *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F. 4th 1109 (Fed. Cir. 2022) "directly supports" its argument that it cannot infringe the asserted patents based on its activity associated with the installed base. (D.I. 489) The Court does not agree. In *Roche*, the Federal Circuit reversed the jury's verdict of induced infringement where all of the acts of inducement occurred *before* the damages period began to run. *Roche*, 30 F.4th at 1119-20. Here, in contrast, Sysmex seeks damages for acts of inducement that occurred after the damages period began to run.

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 March 7, 2022, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov. Objections to this Report and Recommendation are due by **May 31, 2022**. Responses to any such objections are due by **June 6, 2022**.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **May 31, 2022** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: May 26, 2022

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE