

**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 Sysmex’s Motion for Partial Summary Judgment of no inequitable conduct (the “Motion”). (D.I. 406)<sup>1</sup> For the reasons that follow, the Court recommends that the Motion be DENIED.

**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 filed the instant Motion on November 30, 2021, (D.I. 406), and briefing was completed on January 14, 2022, (D.I. 436). The Court heard oral argument on the Motion (as

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<sup>1</sup> Sysmex’s Motion also moves for partial summary judgment on additional grounds that will be addressed in forthcoming opinions.

well as on other summary judgment and *Daubert* motions) by videoconference on February 25, 2022. (D.I. 486 (hereinafter, “Tr.”)) Following oral argument, the parties submitted supplemental letters with respect to the Motion. (D.I. 480; D.I. 484; D.I. 487)

The Court writes here primarily for the parties, and so any facts relevant to this Report and Recommendation will be discussed in Section III below.

## **II. STANDARD OF REVIEW**

### **A. Summary Judgment**

A grant of summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). If the moving party meets this burden, the nonmovant must then “come forward with specific facts showing that there is a *genuine issue for trial*.” *Id.* at 587 (emphasis in original) (internal quotation marks and citation omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, the Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

However, in order to defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586. The “mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the

requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are “material,” and a factual dispute is “genuine” only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. “If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted).

A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials”; or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B).

## **B. Inequitable Conduct**

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.” *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1352 (Fed. Cir. 2016) (internal quotation marks and citation omitted). “A finding of inequitable conduct as to any single claim renders the entire patent unenforceable[.]” *Id.* (internal quotation marks and citation omitted).

To prevail on an inequitable conduct allegation, “the accused infringer must prove that the patentee acted with the specific intent to deceive the [United States Patent and Trademark Office (‘PTO’)].” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). “In a case involving nondisclosure of information, clear and convincing evidence must

show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Id.* (emphasis in original) (internal quotation marks and citation omitted). While a court may infer intent from indirect and circumstantial evidence, “to meet the clear and convincing evidence standard, the specific intent to deceive must be the ‘single most reasonable inference able to be drawn from the evidence.’” *Id.* (quoting *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). That is, the evidence must be sufficient to “*require* a finding of deceitful intent in light of all of the circumstances.” *Id.* (emphasis in original) (internal quotation marks and citation omitted). Thus, if there are “multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 1290-91. Inequitable conduct also requires a finding of but-for materiality; prior art is “but-for material” if the PTO would not have granted the patent had it been aware of that art. *Id.* at 1291.

### **III. DISCUSSION**

In BCI’s operative Second Amended Answer and Counterclaims, it asserts an inequitable conduct counterclaim and affirmative defense with respect to the asserted patents based on a theory of nondisclosure. (D.I. 302 at 11, 13-38, 41) On this front, BCI alleges that Sysmex’s prosecuting attorney Tadashi Horie (“Horie”) and two inventors of the asserted patents, Takaaki Nagai (“Nagai”) and Noriyuki Narisada (“Narisada”), purposely withheld three types of material information relating to Sysmex’s XE-2100 hematology analyzer during prosecution of the asserted patents: (1) the XE-2100 with Body Fluid Application; (2) the XE-2100 Main Unit Manual; and (3) XE-2100 IPU Manual (collectively, the “withheld information”). (*Id.* at 14-15, at ¶¶ 11-13; Tr. at 139-40)

Sysmex’s XE-2100 device was first sold in 1999. (D.I. 302 at 19, at ¶ 24; D.I. 467 at ¶ 24) In March 2004, the United States Food and Drug Administration approved the Body Fluid

Application for the XE-2100. (D.I. 302 at 20, at ¶ 26; D.I. 416, ex. 2; D.I. 467 at ¶ 26) The XE-2100 IPU Manual and the XE-2100 Main Unit Manual were published in 2004 and 2005, respectively. (D.I. 416, ex. 8 at 1; D.I. 430, ex. 45 at BCID002229) The XE-2100 IPU Manual contains Appendix C, which covers the XE-2100's Body Fluid Application. (*See, e.g.*, D.I. 416, ex. 8 at SCorp-Del00257530; *see also* D.I. 302 at 20, at ¶ 28)

Many years later, the applications for the '350 and '351 patents were filed. The applications were filed on December 10, 2018 and March 25, 2019, respectively, and both asserted patents issued on September 3, 2019. (D.I. 1, exs. A-B;<sup>2</sup> *see also* D.I. 407 at 4; D.I. 429 at 4 n.3) 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)

With the instant Motion, Sysmex contends that it is entitled to summary judgment of no inequitable conduct because BCI has presented no evidence demonstrating that the single most reasonable inference is that Horie, Nagai and Narisada knew of the withheld information during prosecution of the asserted patents and withheld it from the PTO with an intent to deceive. (D.I. 407 at 4; Tr. at 101, 170; *see also* Sysmex's Summary Judgment Presentation, Slide 58 ("Specific Intent to Deceive Must Be the Single Most Reasonable Inference")) According to Sysmex, while deceptive intent could be a reasonable inference, there is another equally reasonable or more reasonable inference that can be drawn from the facts: that these individuals did not have knowledge of the withheld information during prosecution of the asserted patents, and did not have an intent to deceive the PTO. (D.I. 407 at 4; D.I. 407 at 9 (Sysmex stating that

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<sup>2</sup> 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.

an “equally reasonable, if not more reasonable, inference is that Horie did not have knowledge” of the withheld information, and thus did not have deceptive intent during prosecution of the asserted patents); *id.* at 13-14 (same with respect to Nagai); *id.* at 16-17 (same with respect to Narisada); Tr. at 170 (Sysmex’s counsel asserting that in light of all the evidence, “there is more than one reasonable inference available here. There’s multiple reasonable inferences.”)<sup>3</sup> Thus, according to Sysmex, BCI’s inequitable conduct defense must fail as a matter of law under the applicable legal standard with respect to deceptive intent. (D.I. 436 at 1)

For its part, BCI counters that: (1) Sysmex’s Motion gets the applicable legal standard wrong, and that (2) multiple factual disputes regarding the knowledge and intent of Horie, Nagai and Narisada during prosecution preclude summary judgment of no inequitable conduct. (D.I. 429 at 5-6; Tr. at 138, 164) The Court will address these two issues in turn.

#### **A. The Correct Legal Standard**

The Court assesses the legal standard-related dispute first. In that regard, BCI acknowledges that at trial, it must prove that deceptive intent is the single most reasonable inference to be drawn from the evidence. (D.I. 429 at 6; Tr. at 138) At the summary judgment stage, however, BCI contends that it need not *prove* that there are no other more reasonable or equally reasonable inferences. (Tr. at 138) Rather, BCI asserts that the proper inquiry here is whether, drawing all justifiable inferences in its favor, a reasonable fact finder *could find* that deceptive intent is the single most reasonable inference from the evidence. (D.I. 429 at 6; Tr. at 138-39; BCI’s Summary Judgment Presentation, Slide 117)

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<sup>3</sup> Sysmex’s Motion does not challenge the materiality of the withheld references, but instead focuses on the specific intent element of inequitable conduct. (*See* D.I. 429 at 3; D.I. 436 at 1) Thus, for purposes of this Motion, the Court can infer but-for materiality. (Tr. at 137-38)

The parties' dispute as to this issue (i.e., about how the applicable legal standard regarding deceptive intent at the summary judgment stage is properly framed) is an understandable one, as the caselaw is not in uniformity. On Sysmex's side, for example, there are cases where district courts have, at summary judgment: (1) assessed whether deceptive intent is the single most reasonable inference to draw from the evidence; (2) decided that it was not; and then (3) granted summary judgment of no inequitable conduct as a result. *See, e.g., Baxter Int'l, Inc. v. CareFusion Corp.*, No. 15 C 9986, 2022 WL 981115, at \*8 (N.D. Ill. Mar. 31, 2022) (explaining that post-*Therasense*, it is "no longer the case" that "summary judgment motions for no inequitable conduct are rarely granted[,] as summary judgment "is appropriate where the evidence does not support a finding that deceptive intent is the single most reasonable inference to be drawn therefrom"); *Lear Corp. v. NHK Seating of Am. Inc.*, Case No. 13-12937, 2022 WL 876021, at \*10 (E.D. Mich. Mar. 23, 2022) (granting summary judgment of no inequitable conduct where the evidence bearing on deceptive intent was "mixed" and there were multiple reasonable inferences that may be drawn, precluding a required finding of deceptive intent); *Illumina, Inc. v. BGI Genomics, Co.*, — F. Supp. 3d —, 2021 WL 4126005, at \*15 (N.D. Cal. Sept. 9, 2021) ("Given this record, drawing all reasonable inferences in [the non-movant's] favor, I cannot reasonably conclude that the single most reasonable inference for the failure to disclose [a] reference to the PTO was to intentionally deceive the PTO."); *Bal Seal Eng'g, Inc. v. Nelson Prods., Inc.*, Case No. 8:13-cv-01880-JLS-KESx, 2018 WL 4697255, at \*11-12 (C.D. Cal. Aug. 3, 2018) (granting motion for summary judgment of no inequitable conduct because "to survive summary judgment, [the non-movant] must show that 'the single most reasonable inference to be drawn from the evidence' is that [the inventor and patent counsel] had a specific intent to deceive the PTO in omitting the prior art[,] but that "inferences of negligence or

carelessness could be drawn by a reasonable factfinder [which means that the non-movant] cannot, under the *Therasense* standard, show intent to deceive”) (citing *Therasense*, 649 F.3d at 1290); *Exergen Corp. v. Brooklands Inc.*, 290 F. Supp. 3d 113, 129 (D. Mass. 2018) (granting a motion for summary judgment of no inequitable conduct where “[o]verall, there are multiple inferences that can be drawn from each of the withheld pieces of information. Brooklands does not present evidence to make deceptive intent the single most likely inference. Indeed, deceptive intent seems to the least likely of inferences”); *Navico Inc. v. Garmin Int’l, Inc.*, NO. 2:16-CV-00190-JRG-RSP, 2017 WL 3701189, at \*2 (E.D. Tex. Aug. 7, 2017) (recommending that the patentee’s motion for summary judgment of no inequitable conduct be granted where the Court “concludes there are multiple reasonable inferences [for non-disclosure], no single one of which is the ‘single most reasonable[.]’ [and therefore] as a matter of law, [the defendant] cannot show a ‘specific intent’ to deceive”) (citation omitted), *report and recommendation adopted*, 2017 WL 3676787 (E.D. Tex. Aug. 25, 2017).

Nevertheless, in the Court’s view, BCI’s position regarding the applicable legal standard at the summary judgment stage must be the correct one. As noted above, it is undisputed that in order to prove inequitable conduct *at a trial*, BCI must demonstrate that specific intent to deceive is the single most reasonable inference that can be drawn from the evidence. *Therasense*, 649 F.3d at 1290; *see also, e.g., Alcon Rsch., Ltd. v. Apotex, Inc.*, No. 1:09-cv-102-RLY-TAB, 2013 WL 2244338, at \*8 (S.D. Ind. May 21, 2013) (noting that *Therasense* “was an appeal from a bench trial, and sets forth the standard for *proving* inequitable conduct at trial”) (emphasis in original). But we are not yet at the trial stage of this case; rather, we are at the summary judgment stage. So BCI should not be required to prove its case now—i.e., it should not have to actually demonstrate that deceptive intent *is* the single most reasonable inference. The focus



instead should simply be on whether BCI has mustered sufficient evidence such that, at the trial stage, a factfinder *could reasonably conclude* that deceptive intent is the single most reasonable inference. *See Alcon Rsch.*, 2013 WL 2244338, at \*8 (“To prevail [on a motion for summary judgment of no inequitable conduct], [p]laintiffs have the burden of establishing the absence of an essential element of [d]efendants’ case in accordance with the applicable standard of review.”); *Unwired Planet, LLC v. Apple Inc.*, Case No. 13-cv-04134-VC, 2017 WL 1175379, at \*3 (N.D. Cal. Feb. 14, 2017) (explaining that “for the purpose of getting past a motion for summary judgment against [inequitable conduct], the test is necessarily somewhat less demanding” than proving that specific intent to deceive is the single most reasonable inference able to be drawn from the evidence).

Accordingly, the Court agrees with BCI that at this stage, “the inquiry is whether, viewing the evidence in the light most favorable to [BCI], no reasonable trier of fact could find the Applicants acted with the specific intent to deceive the PTO.” *Alcon Rsch.*, 2013 WL 2244338, at \*8; *see also, e.g., Unwired Planet*, 2017 WL 1175379, at \*3 (explaining that “for the purpose of getting past a motion for summary judgment against [inequitable conduct] . . . [t]he question is not whether [defendant’s] circumstantial evidence *requires* an inference of deceptive intent, but whether [the patentee’s] presentation is sufficient to preclude a reasonable trier of fact from reaching that conclusion”) (emphasis added). Put another way, summary judgment of no inequitable conduct should be denied if, drawing all reasonable inferences in favor of BCI, a reasonable factfinder *could reasonably find* that intent to deceive is the single most reasonable inference. *Sprint Commc’ns Co. LP v. Charter Commc’ns, Inc.*, C.A. No. 17-1734-RGA, 2021 WL 982728, at \*4-5 (D. Del. Mar. 16, 2021); *CliniComp Int’l, Inc. v. Athenahealth, Inc.*, CAUSE NO. A-18-CV-00425-LY, 2020 WL 7011769, at \*5 (W.D. Tex. Nov. 10, 2020); *Helios*

*Software, LLC v. Awareness Techs., Inc.*, C.A. No. 11-1259-LPS, 2015 WL 12806482, at \*13 (D. Del. Apr. 13, 2015).

## **B. Applying the Correct Legal Standard to the Evidence**

In the Court's view, once the correct legal standard is applied to the facts, Sysmex's Motion should be denied. To that end, the Court will briefly summarize the evidence that BCI has put forward to create a triable issue of fact with respect to knowledge/deceptive intent on the part of Horie, Nagai and Narisada.

With regard to Horie, BCI points to the following evidence as sufficient to enable the trier of fact to determine that the single most reasonable inference is that Horie knowingly and intentionally deceived the PTO by failing to disclose the withheld information during prosecution of the asserted patents, (D.I. 429 at 4, 6-9; BCI's Summary Judgment Presentation, Slide 122):

- Horie is intimately familiar with Sysmex, Sysmex's patents and patent applications and hematology analyzers, he prosecuted over 400 patents for Sysmex since 2004, and he collaborated with Narisada in drafting the claims for at least the '350 patent. (D.I. 302 at 32, at ¶ 56; D.I. 430, ex. 46 at PRIV0551, 0552, 1056, 1118, 1121; D.I. 430, ex. 47 at 74-75);<sup>4</sup>
- In 2015 and 2016, during prosecution of a different Sysmex patent application, Horie argued patentability over a 2007 publication of Chapter 7 of the XE-2100 Main Unit Manual. (D.I. 302 at 33, at ¶ 57; D.I. 430, ex. 48);
- During prosecution of the asserted patents, Horie submitted a reference known as the Kresie reference, which mentions the XE-2100's ability to analyze body fluids but does not contain details regarding the structure and operation of the XE-2100. Horie also submitted a European version of the XE-2100 Instructions for Use, which does not describe the device's

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<sup>4</sup> Horie did not draft the specification of the asserted patents. (D.I. 437, exs. 92-93)

functionality relating to body fluids. (D.I. 302 at 33, at ¶ 59; '350 patent at 4; D.I. 430, ex. 49 at SYSMEXUS0005832, - 5848; D.I. 430, ex. 50 at SCorp-Del00128194);

- Some sections of the specifications for the asserted patents are identical to material in the XE-2100 IPU Manual, such as the choice of measuring modes for body fluids and the instruction to run a background check and auto rinse before analyzing body fluid samples. (D.I. 302 at 23-24, at ¶ 37; D.I. 416, ex. 8 at SCorp-Del00257798);
- Several figures of the asserted patents are similar to or identical to figures contained in the XE-2100 Main Unit Manual. ('350 patent at Figs. 1, 2, 4, 5, 8; D.I. 430, ex. 45 at BCID002254, BCID002294, BCID002445, BCID002446, BCID002467);
- Horie had a motive to obtain patents for Sysmex that would cover BCI's products, so that Sysmex could prosecute an infringement case against BCI following BCI's patent infringement suit against Sysmex in the United States District Court for the Northern District of Illinois. (D.I. 302 at ¶¶ 68-69); and
- While Horie denied knowledge of the withheld information, he did not answer several questions relating to his familiarity with the XE-2100 during his deposition, in light of his counsel's invocation of attorney-client privilege/work product. (*See, e.g.*, D.I. 430, ex. 51 at 131-39) So it is not as if the substance of Horie's testimony on this issue is detail-laden.

As for Nagai and Narisada, BCI points to the following evidence as sufficient to enable the trier of fact to determine that deceptive intent is the single most reasonable inference for their non-disclosure of the withheld information, (D.I. 429 at 4-5, 9-11; BCI's Summary Judgment Presentation, Slide 123):

- Nagai was involved in the development of the hardware and software for the XE-2100. (D.I. 416, ex. 10 at 43);<sup>5</sup>

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<sup>5</sup> Sysmex asserts (and BCI does not dispute) that at the time when Nagai was involved in the development of the XE-2100, the device did not yet have an approved body fluid application. (D.I. 436 at 4 (citations omitted))

- Narisada was involved in the development of the software for the XE-2100. (D.I. 430, ex. 47 at 29);
- Nagai was copied on a March 2004 e-mail attaching a draft of Appendix C of the XE-2100 IPU Manual, and he was one of the recipients of another March 2004 e-mail requesting a meeting to discuss the “North American Body-Fluid Specifications[,]” (D.I. 430, ex. 52T);
- In May 2004, Narisada both received an e-mail containing a draft of Appendix C, and e-mailed Appendix C to another individual. (*Id.*, exs. 53, 54);
- In June 2004, Narisada e-mailed Appendix C to another individual and requested that a change be made to the document. (*Id.*, exs. 55, 55T; *see also* D.I. 408, ex. 9 at 137 (Narisada stating, while examining Appendix C, that “I was involved in the design change”));<sup>6</sup>
- Nagai and Narisada had significant experience in dealing with the PTO, as Nagai is a named inventor of 50 United States patents, (*id.*, ex. 56), and Narisada is a named inventor of 17 United States patents, (*id.*, ex. 57);
- Narisada collaborated with Horie in drafting the claims for at least the '350 patent, and was involved in the prosecution of Sysmex’s patent applications in the United States. (*Id.*, ex. 47 at 75; *id.*, ex. 59 at PRIV2283, -2338, -2352, -2389); and
- Nagai and Narisada signed 37 C.F.R. § 1.63 declarations during prosecution of the asserted patents affirming their duty of candor and good faith dealing with the PTO. (*Id.*, exs. 49, 58).<sup>7</sup>

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<sup>6</sup> Narisada testified that he did not know whether he was involved in editing Appendix C. (D.I. 408, ex. 9 at 137, 141, 145)

<sup>7</sup> As further evidence of inequitable conduct, BCI also contends that Nagai and Narisada were aware of market demands for a device that could analyze body fluid (to match the Bayer Advia 120 and BCI’s own device) in the 2004-2006 timeframe, and that third parties communicated to the inventors that the XE-2100 could be modified to include a body fluid measuring mode. (D.I. 429 at 10-11; Tr. at 156-57) To this, Sysmex responds that BCI should not be able to rely on these facts because it did not include this theory in its pleading, even though the theory seems to be premised on documents that had been produced long before BCI’s Second Amended Counterclaim for inequitable conduct was filed. (D.I. 436 at 6 n.6) The Court

This evidence withstands Sysmex's Motion. Below, the Court explains why this is so.

With regard to Horie, a factfinder could reasonably infer that during prosecution of the asserted patents, he was familiar with his long-standing client's hematology products, including the XE-2100 with Body Fluid Application (and, relatedly, that he was familiar with the XE-2100 IPU Manual and the XE-2100 Main Unit Manual). (D.I. 429 at 6-9) Indeed, as noted above, just a few years prior to prosecution of the asserted patents, Horie had distinguished another Sysmex patent over a 2007 publication of Chapter 7 of the XE-2100 Main Unit Manual.<sup>8</sup> Moreover, during prosecution of the asserted patents, Horie cited to references that discussed the XE-2100 and its body fluid application, including the Kresie reference (although those references did not go into great detail about the device's body fluid application). If there is good evidence that Horie had real familiarity with the XE-2100 as of the relevant timeframe, then a factfinder could infer that Horie also was familiar with *all of the relevant characteristics of that device* (including the details relating to its body fluid measuring mode) at that time.

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declines to resolve this issue, as it need not consider these facts to determine that the Motion should be denied.

<sup>8</sup> It appears to be undisputed that Chapter 7 did not include a reference to the XE-2100's body fluid application. (D.I. 436 at 2; Tr. at 165) Nevertheless, the factfinder could infer from this evidence that Horie gained knowledge of the XE-2100 at least a few years before prosecution of the asserted patents. Sysmex attempts to argue that this 2007 manual is irrelevant to inequitable conduct because it is not prior art, (D.I. 436 at 2; Tr. at 113, 116), citing to a decision in which the United States Court of Appeals for the Federal Circuit affirmed a district court's ruling that the patentee did not commit inequitable conduct by not disclosing a device that was not prior art to the patent examiner, *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940 (Fed. Cir. 1990). That argument is not persuasive here because BCI is not attempting to argue that the 2007 manual is itself prior art. Rather, BCI's point is that Horie's argument about the patentability of another Sysmex patent over the Chapter 7 Manual is evidence that Horie was aware of the XE-2100 (and aware of the fact that there were certain manuals that described how that device worked).

Likewise, a factfinder could reasonably infer that Nagai and Narisada had the relevant knowledge of the withheld information in the relevant timeframe. After all, the two were *themselves involved in developing* the XE-2100. Now, to be sure, they developed the device long before the patent applications at issue here were filed. But in the Court's view, the simple fact that these two individuals were centrally involved in creating the XE-2100 is pretty important. (Tr. at 130) It seems a fair inference that if the two developed the device in the first instance, then they would have continued to be familiar with the device's progression over the years (including its addition in 2004 of a body fluid application, and the fact that there were related manuals that described that device). (D.I. 429 at 9-11; Tr. at 130-31) This inference could be further bolstered by the fact that both Nagai and Narisada were copied on e-mails in 2004 containing drafts of the XE-2100 IPU Manual. This is especially so as to Narisada, who appeared to be involved in the editing of Appendix C of that manual (which specifically covers the XE-2100's body fluid application). And the inference could further be amplified by the fact that from the time when they developed the XE-2100 (1997-2000) through to when the relevant patent applications were filed (2018-2019), Nagai and Narisada continued to work at Sysmex (in a similar subject matter field to that of the XE-2100). (Tr. at 130-31, 133, 159-60)

A factfinder could also infer that Horie, Nagai and Narisada, who were well aware of the disclosure obligations of a patent applicant, *intended* to conceal the withheld information, while submitting less detailed information regarding the XE-2100 to the PTO during prosecution of the asserted patents. (D.I. 429 at 6-11) It could be fairly inferred that, as Defendant argues, the three individuals withheld the material in order to enable their employer, Sysmex, to obtain patent protection in an area that would be beneficial to it (and perhaps detrimental to BCI). *See, e.g., Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1190-91 (Fed. Cir. 2014)

(affirming the district court’s judgment of inequitable conduct where the applicant provided a limited disclosure regarding a prior art system without providing its operational details, in order to allow “his patent application [to] succeed[.]”); *Unwired Planet*, 2017 WL 1175379, at \*3 (concluding that the defendant has “supplied enough evidence to create a triable question of fact on deceptive intent” where the evidence, *inter alia*, “suggest[ed] that the inventors were intimately familiar with the undisclosed prior art [and] knowledgeable about their responsibilities to the PTO”).

Systemex suggests that the deposition testimony of Horie, Nagai and Narisada—in which the three individuals all claim to have no memory of the XE-2100 and/or its body fluid application, and no knowledge about the withheld information during prosecution of the asserted patents—should prevent any inference of knowledge and deceptive intent.<sup>9</sup> (D.I. 407 at 4-5; D.I. 436 at 4-6; Tr. at 111; *see also, e.g.*, D.I. 408, ex. 6 at 104-06, 109-10, 131-33; *id.*, ex. 8 at 78, 81-82; *id.*, ex. 9 at 109, 124, 137, 141, 145; D.I. 437, ex. 76 at 171-72) Of course, this is helpful evidence for Systemex. And it is certainly possible that a factfinder could ultimately decide that what the three are saying is, in fact, accurate.<sup>10</sup> However, with BCI pointing to evidence that could enable a contrary reasonable inference of knowledge and deceptive intent, material disputed issues of fact remain. *See, e.g., Neev v. Alcon LenSx, Inc.*, SACV 15-01538 JVS(JCGx), 2017 WL 6886670, at \*26 (C.D. Cal. June 30, 2017) (finding that a genuine dispute

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<sup>9</sup> Narisada testified that he remembered the FDA’s approval of the body fluid application for the XE-2100, but did not remember when he was aware of that. (D.I. 408, ex. 9 at 167-68)

<sup>10</sup> Witness credibility might be a big factor here—i.e., how these three individuals look and sound when they are making these denials. That is something that is not available to the Court at the summary judgment stage, but would be available to the District Judge at a trial.

of material fact regarding deceptive intent precluded summary judgment of no inequitable conduct, where, *inter alia*, the factfinder “is best suited to hear testimony and make the requisite credibility determinations”); *Unwired Planet*, 2017 WL 1175379, at \*3 (finding that inventors’ declarations regarding their lack of deceptive intent did not resolve the factual dispute, because “if the inventors’ self-reported state of mind were, as a rule, enough for summary judgment of no inequitable conduct, there would be little reason to allow fact-finders to draw inferences from indirect evidence in the first place”).<sup>11</sup>

To be sure, proving inequitable conduct requires an uphill climb. And these allegations (especially if Horie, Nagai and Narisada’s denials appear credible to the factfinder) may well not ultimately pass muster after a trial. But for the reasons set out above, the Court concludes that there are sufficient material disputes of fact to at least warrant a trial. *See Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, No. 6:10-cv-812-Orl-28KRS, 2012 WL 4336208, at \*4 (M.D. Fla. Sept. 21, 2012) (noting, in a case where the manager and patent agent accused of inequitable conduct denied intending to deceive the PTO, that “GE will face a tough task in meeting the ‘single most reasonable inference’ standard set forth in *Therasense*, but [concluding that] because credibility may be crucial[,] this question cannot be determined on summary judgment”); *see also CliniComp Int’l, Inc.*, 2020 WL 7011769, at \*5. And so it recommends that Sysmex’s Motion be denied.

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<sup>11</sup> The Court also notes that Sysmex’s key cases, (D.I. 407 at 6-7; Sysmex’s Summary Judgment Presentation, Slide 57), were decided post-trial, not at the summary judgment stage, *see, e.g., Barry v. Medtronic, Inc.*, 245 F. Supp. 3d 793, 796-97 (E.D. Tex. 2017); *Otsuka Pharm. Co. v. Sandoz, Inc.*, Consolidated Civil Action No. 3:07-cv-010000 (MLC), 2010 WL 11636594, at \*2, \*26-30 (D.N.J. Dec. 15, 2010); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 723 F. Supp. 2d 1284, 1288, 1341 (S.D. Cal. 2010); *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 34 F. Supp. 2d 1208, 1210 (C.D. Cal. 1998).



#### IV. CONCLUSION

For all of the above reasons, the Court recommends that the District Court DENY Sysmex's Motion.

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*, 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 11, 2022**. Responses to any objections are due by **May 16, 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 11, 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 6, 2022

*Christopher J. Burke*  
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Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE