IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROCHE DIAGNOSTICS CORP.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-189-LPS-CJB
	:	
MESO SCALE DIAGNOSTICS, LLC.,	:	
	:	
Defendants.	:	
MESO SCALE DIAGNOSTICS, LLC,	:	
	:	
Counterclaim Plaintiff	:	
	:	
v.	:	
	:	
ROCHE DIAGNOSTICS CORP. and BIOVERIS CORPORATION	:	
	:	
Counterclaim Defendants	:	

MEMORANDUM ORDER

Pending before the Court is Roche Diagnostic Corp.'s ("Roche") motion for summary judgment.[1] (D.I. 170) The motion asks the Court to hold that Meso Scale Diagnostics, LLC ("Meso") is foreclosed from: (1) asserting direct and indirect infringement for sales to Roche's dual-use customers; (2) arguing that Roche's ProCell reagent is part of a "kit;" (3) arguing that a

[1] The Court provided a detailed summary of the background of this case, the relationship between the parties, and the legal standard for summary judgment in its prior Memorandum Opinion, which is incorporated herein by reference. (D.I. 153)

claimed Y-Linker element refers to a pre-bound linker; and (4) arguing that Roche's electrodes are "disposable."

Having considered the parties' briefing (D.I. 171, 192, 204) and related materials, and having heard oral argument on July 23 ("Tr."),[2] **IT IS HEREBY ORDERED** that Roche's motion (D.I. 170) will be **GRANTED IN PART** and **DENIED IN PART**. Certain issues presented in the motion will also remain under advisement, pending the Court's review of supplemental briefing being ordered, as explained below.

1. The parties' dispute with respect to direct infringement for dual-use customers turns on the meaning of a 2003 License Agreement ("2003 Agreement") between IGEN and Roche,[3] in which Roche was granted "only for use in the Field[4], an irrevocable, perpetual, Non-Exclusive . . . license under the Licensed ECL Technology." (D.I. 175-1 Ex. 30 at A-1133, § 2.1) Stated differently, Roche was permitted to sell products covered by IGEN's patents for certain "in-field" use, but not for "out-of-field" use. (*Id.* at A-1133) It is undisputed that some of Roche's sales were to customers who used the product both in-field ***and*** out-of-field. (D.I. 171 at 9-10) The parties refer to such customers as dual-use customers.

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[2] Daubert motions were also argued at the July 23 hearing. The Court will issue one or more additional orders addressing those motions.

[3] To briefly summarize the relationship of the parties, IGEN was the original owner of certain patents covering ECL technology. In 1995, IGEN and another Meso entity ("MST") entered into a Joint Venture Agreement ("JVA"), wherein Meso obtained an exclusive license to IGEN's ECL technology for certain purposes. IGEN also granted a series of non-exclusive licenses to Roche (or its predecessors) for the same technology in fields not covered by Meso's license. In 2003, BioVeris acquired IGEN's ECL technology business, and, in 2007, Roche acquired BioVeris. Thus, Roche is now the owner of the ECL patents, subject to Meso's exclusive license. (*See* D.I. 153 at 1-4)

[4] "Field" is defined as "the analyzing of specimens taken from the human body," and does not include "(A) life science research and/or development . . . , (B) patient self testing use; (C) drug discovery and/or drug development . . . , or (D) veterinary, food, water, or environmental testing or use." (D.I. 175-1 Ex. 30 at A-1131, § 1.7(a)-(b))

The issue presented by the motion is whether Roche is liable for sales to dual-use customers. The 2003 Agreement, in defining "Field," provides in pertinent part:

> in the event a Product that has been sold or placed solely for the [in-field] uses specified [] above, ***is incidentally used outside those specified uses without the knowledge or consent*** of LLC or any of its Affiliate Sublicensees (***without a duty to inquire or investigate***), then such incidental use shall be considered inside the Field and such sale or placement shall not retroactively be considered outside the Field.

(*Id.* at A-1131-32, § 1.7(c)) (emphasis added) It is undisputed that Roche consented to the 2003 Agreement, including this definition of "Field." (*Id.* at A-1153)

In earlier litigation (involving the same parties here) in the Delaware Court of Chancery, Vice Chancellor Parsons had this to say about the "Field" provision of the 2003 Agreement: "Meso conceivably may have viable [patent] infringement or other claims against Roche for its actions since 2007, when it allegedly began operating ***deliberately*** outside of the Field." *Meso Scale Diagnostics, LLC v. Roche Diagnostics GmbH*, 2014 WL 2919333, at *28 (Del. Ch. June 25, 2014), *aff'd*, 116 A.3d 1244 (Del. 2015) (emphasis added). The Vice Chancellor's statement was dicta. *See id.* ("The question of whether Roche infringed on Meso's ECL-related intellectual property rights, however, ***is distinct from, and has no bearing on***, the breach of contract claim that Meso pursued at trial in this litigation.") (emphasis added). Still, Roche now seizes on this language to argue that is liable only for ***deliberate*** out-of-field sales – and, therefore, not for dual-use customers (as their out-of-field use was incidental and not known by or consented to by Roche). (D.I. 171 at 14-16)

This Court is not bound by the Chancery Court's interpretation of the Field provision. Nevertheless, having undertaken an independent review of the 2003 Agreement, the Court (consistent with the view of Vice Chancellor Parsons) concludes that, due to the "Field" provision, Roche may be liable only for deliberate out-of-field sales, where "deliberate" is

defined as "non-incidental, and with knowledge or consent." (D.I. 175-1 Ex. 30 at A-1131-32) Thus, Meso cannot prove infringement merely by pointing to sales to dual-use customers; it must also show that Roche ***knew***, at the time of sale, those dual-use customers would non-incidentally use the product out-of-field. Otherwise, the sale cannot be the basis for a finding of patent infringement. (*Id.* at A-1131-32)

In opposing this conclusion, Meso faults Roche's reliance on § 2.5 of the Agreement – an enforcement mechanism whereby 65% of out-of-field sales would be paid to IGEN – a provision to which Meso asserts it did not consent. (D.I. 192 at 8-10) Even assuming *arguendo* that Meso did not consent to § 2.5, Meso indisputably consented to § 2.1 (the license rights) (D.I. 192 at 9), which incorporates the definition of "Field" from § 1.7. In this way, through § 2.1, Meso in effect "grant[ed] Roche a[] license to make non-deliberate out-of-field sales." (D.I. 192 at 9)

Meso also argues that a second license agreement between IGEN and Roche in 2007 ("2007 Agreement") superseded the 2003 Agreement. (D.I. 192 at 10) However, the section of the 2007 Agreement upon which Meso relies is no more than an integration clause. (D.I. 192-1 Ex. 6 at 14, § 13.10) More pertinent is Section 13.8 of the 2007 Agreement, which expressly states "the terms of this Agreement ***do not amend or supersede***, and shall not be used to interpret, the terms of ***the Existing License*** . . . dated as of July 24, 2003 [i.e., the 2003 Agreement]." (*Id.*) (emphasis added) Based on this explicit language, the Court concludes that the 2007 Agreement did not supersede the 2003 Agreement.

Based on the briefing to date and oral argument, it is unclear how Meso believes the record contains evidence from which a reasonable fact finder could find that Roche had knowledge of non-incidental out-of-field use by dual-use customers. Meso will be provided a

limited, final opportunity to brief this point. The schedule and length for such briefing is included at the end of this Order.

2. Roche's motion for summary judgment directed at inducing infringement by dual-use customers is DENIED.

"In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement," and "second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). The principal dispute here relates to how the rights granted under the 2003 Agreement to Roche interact with what Meso must show to prove Roche met the intent element of induced infringement. (*Compare* D.I. 171 at 18-19 *with* D.I. 192 at 13) Roche contends that Meso must prove that Roche intended to encourage dual-use customers' out-of-field use. Meso counters that, because the asserted claims do not have a field-of-use limitation, that limitation (even if present in the 2003 Agreement) does not impact the intent element.

The Court agrees with Roche. If all of the acts that Roche induced were licensed under the 2003 Agreement – so those acts could not give rise to liability for patent infringement – then Roche lacked a specific intent to induce acts constituting patent infringement. *See generally Commil USA, LLC v. Cisco Sys., Inc.*, 135 S.Ct. 1920, 1926, (2015) (stating that liability for inducement "can only attach if the defendant knew of the patent and knew as well that the induced acts constitute patent infringement") (internal quotation marks omitted); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990) ("It must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement."). It is not enough for

Meso to show that Roche encouraged customers to use its products, generally, and that some customers incidentally used the products out-of-field, because that incidental out-of-field use would not constitute patent infringement under the 2003 Agreement. (D.I. 175-1 Ex. 30 at A-1133, § 1.7(c); *see also* 35 U.S.C. § 271(a) ("[W]hoever ***without authority*** makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.") (emphasis added); *McCoy v. Mitsuboshi Cutlery, Inc.*, 67 F.3d 917, 920 (Fed. Cir. 1995) ("A licensee, of course, has an affirmative defense to a claim of patent infringement."). Instead, Meso must provide evidence that Roche specifically intended to encourage customers' non-incidental out-of-field use, in violation of the 2003 Agreement.

Despite agreeing with Roche's view of what Meso must prove, the Court concludes that the evidence in the record, taken in the light most favorable to Meso, is sufficient to permit a reasonable factfinder to find that Meso has proven Roche acted with the requisite intent. (*See, e.g.*, D.I. 192 at 15-16) (citing evidence) The specific intent element "requires that the alleged infringer knew or ***should have known*** his actions would induce actual infringement." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (internal quotation marks omitted; emphasis added). Therefore, summary judgment with respect to induced infringement is denied.

3. Roche's motion for summary judgment directed at contributory infringement by dual-use customers is GRANTED.

To establish liability for contributory infringement, "the patent owner must show . . . : 1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) that ***the component has no substantial noninfringing uses***, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir.

2010) (emphasis added). Meso's contributory infringement claim is based on Roche's use and sale of "ECL machines and ECLIA kits." (D.I. 10 at ¶¶ 36, 48, 59, 72, 85, 98, 111, 122, 134) However, a reasonable factfinder could find only that those ECL machines and kits have a substantial noninfringing use: in-field (licensed) use. (D.I. 175-1 Ex. 30 at A-1131-33, § 1.7, 2.1) Therefore, summary judgment is granted.

4. Roche's motion for summary judgment directed at Meso's construction of kit is DENIED.

The parties dispute whether Roche's ProCell reagent is part of a "kit" (D.I. 171 at 22-23; D.I. 192 at 17-19), which the Court construed as "a set of materials packaged to be used together" (D.I. 114 at 5). To be clear, the Court has already rejected Meso's view – articulated in, for instance, D.I. 192 at 18 – that placing all of the reagents in Roche's ECL instrument necessarily renders the reagents a "kit" (D.I. 114 at 5-6). There is, however, a genuine dispute of fact as to whether packaging and shipping ProCell separately nonetheless makes the accused product a "kit" if ProCell is intended to be used with other reagents. That is, a reasonable factfinder could find that the accused product constitutes a set of materials packaged to be used together. Thus, summary judgment is denied.

5. Roche's motion with respect to the Y-Linker element turns on whether claim 10 of the '607 Patent refers to (1) a pre-bound form of the Y component (Meso's view) or (2) the Y component as it exists when bound to the X and Z component (Roche's view).[5] Roche argues

[5] The relevant portion of claim 10 provides:

> A compound having the structure: X-Y-Z
>
> Wherein X represents one or more analytes of interest of analogues of the analytes of interest. . . ; Y comprises a linker group attached to and positioned between X and Z at a 4 position of a 4'-methyl substituted bipyridal group of Z. . . wherein Y is selected from . . . $-CH_2-(CH_2)_n-COOH$.

that its Y component is $-CH_2-(CH_2)_n-C=0-$ (a carbonyl), which is distinct from the claimed -COOH (a carboxylic acid). (D.I. 171 at 25) Meso responds, and Roche concedes, that a POSA would know that a -COOH would almost never exist after being covalently bonded to an analyte (the X and Z). (D.I. 192 at 19) Meso then argues that one skilled in the art would know that claim 10 refers to the ***pre-bound*** form of the linker. (*Id.*)

During oral argument, Meso claimed that Roche had admitted its products are covered by claim 10, but the reference Meso cited does not reveal such an admission. (Tr. at 62 (citing Meso Scale Exhibit 22 at 22); *see also* D.I. 192-1 Ex. 22 at 22 (***Meso's expert*** stating that POSA would read Y-linker as pre-bound form); D.I. 192-1 Ex. 21 at 23 (Roche denying its products have claimed linker group)) The Court will require additional briefing (as explained further below) to resolve what appears to be a claim construction dispute. (*See* Tr. at 30, 62)

6. Roche's motion for summary judgment directed at Meso's construction of disposable electrodes is **DENIED**.

The parties dispute whether Roche's platinum electrodes, which can be used 50,000-100,000 times, are nonetheless "disposable" within the meaning of the IGEN/Meso JVA.[6] (D.I. 171 at 26) It is uncontested that Roche's electrodes are reusable. Still, Meso contends that because Roche's electrodes may be replaced during the lifetime of the ECL instrument, the reusable electrodes may still be found to be disposable. (D.I. 192 at 22-23)[7]

(D.I. 174-1 Ex. 68 at A02102)

[6] Meso's exclusive license is controlled by the JVA, which limits Meso's rights to "disposable electrodes." (D.I. 173-3 Ex. 19 at A-615) Meso does not have an exclusive right to use ECL systems that utilize "non-disposable" (e.g., permanent) electrodes. (*Id.*)

[7] Roche contends that Meso is judicially estopped from making this argument because, in a prior case in the District of Maryland, Meso distinguished its product from IGEN's by pointing to its electrode's disposability. (D.I. 171 at 26-27) The Court disagrees. The District of Maryland Special Master did not define what constitutes "permanent" and "disposable" electrodes. (*See*

The record contains evidence pertaining to the intent of the parties to the JVA – Meso and IGEN – when they used "disposable" in their agreement. (*See, e.g.*, D.I. 192 at 24) (citing evidence) "Determining the intent of the parties [in a contract] is a question of fact." *Delaware Bay Surgical Services, P.C. v. Swier*, 900 A.2d 646, 650 (Del. 2006); *see also* D.I. 173-1 Ex. 3 at § 8) (stating Delaware law applies to JVA). A reasonable factfinder could find that the parties intended "disposable" in the JVA to include an electrode used up to 100,000 times (or more) as long as it might be replaced during the lifetime of the ECL instrument with which it was used. Therefore, summary judgment is denied.

IT IS FURTHER ORDERED that the parties shall submit supplemental letter briefs addressing the outstanding issues identified in paragraphs (1) and (5) above, as follows: (a) simultaneous opening briefs, not to exceed five pages (i.e., a single letter per side of no more than five pages addressing both of the outstanding issues), due **September 20**; (b) simultaneous answering briefs, not to exceed five pages, due **September 25**; and (c) simultaneous reply briefs, not to exceed three pages, due **September 27**.

IT IS FURTHER ORDERED that the parties shall meet and confer and, no later than **September 16**, submit a proposed redacted version of this Order, should they believe they can satisfy the standard for redacting any portion of the Order. Thereafter, the Court will issue a public version of this Order.

September 13, 2019
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

D.I. 173-2 Ex. 11 at A-418) ("MSD's use of the multi-array technology has focused on the [] use of . . . ***disposable*** electrodes . . . . In contrast, the ECL technology exploited by Igen . . . measures each sample sequentially, through a flow cell using a ***permanently*** installed electrode.")