

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ROCHE DIAGNOSTICS CORP., :
 :
 :
 Plaintiff, :
 :
 :
 v. :
 :
 MESO SCALE DIAGNOSTICS, LLC., :
 :
 :
 Defendants. :

C.A. No. 17-189-LPS-CJB

REDACTED

MESO SCALE DIAGNOSTICS, LLC, :
 :
 :
 Counterclaim Plaintiff :
 :
 :
 v. :
 :
 :
 ROCHE DIAGNOSTICS CORP. :
 and BIOVERIS CORPORATION :
 :
 :
 Counterclaim Defendants :

MEMORANDUM ORDER

Pending before the Court is Roche’s motion for summary judgment.¹ (D.I. 170) In its September 13 Memorandum Order, the Court answered certain questions and required the parties to submit additional briefing on two remaining issues: (1) whether evidence exists as to Roche’s knowledge of out-of-field use by dual-use customers; and (2) each party’s construction of the claimed “Y-Linker” element. (D.I. 219) Having reviewed the parties’ letter briefs (D.I. 221-24,

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

228-29) and related materials, as well as all other previously-filed materials and the parties' statements at oral argument, **IT IS HEREBY ORDERED** that:

1. Roche's motion for summary judgment (D.I. 170) as to direct infringement for sales to dual-use customer is **DENIED**.

Having rejected Meso's view of the 2003 License Agreement, the Court gave Meso one final opportunity to identify any disputed facts as to Roche's knowledge of out-of-field use by dual-use customers. (D.I. 219 at 2-5) In response, Meso cites: (1) Mr. Griffin's Rule 30(b)(6) testimony on behalf of Roche; (2) Roche's desire to enable out-of-field sales by acquiring BioVeris (including a 2013 Request for Proposal presentation that references clinical trials, an out-of-field use); and (3) Roche's removal of field restrictions from its labels. (*See* D.I. 221)

No reasonable juror could conclude, based on Mr. Griffin's testimony or Roche's desires alone,² that Roche *knew* of (or consented to) deliberate out-of-field use by particular dual-use customers at the time the sale was made.³ At most, this testimony constitutes circumstantial evidence that Roche *suspected* that dual-use customers may be using the products out-of-field, or wished to make such sales. (D.I. 221-1 Ex. 2 at 82-84, 171-73 (Mr. Griffin testifying he knew certain customers (e.g., LabCorp, Quest Diagnostics) conducted clinical trials and were immunoassay customers of Roche, and hence "*believe[d]*" Roche immunoassays "ha[d] been used in their clinical trial activities.") (emphasis added); D.I. 221-1 Ex. 3-7 (providing circumstantial evidence that Roche sought or expected to make out-of-field sales)) Suspicious

² For reasons discussed below, and as Meso argued in its Reply letter (D.I. 228 at 3), knowledge or suspicions of (incidental) out-of-field use, combined with continued sales, may constitute implied consent. This presents a genuine dispute of material fact to be resolved by the jury.

³ The Court asked the parties to identify *facts* that raise a genuine dispute as to direct infringement of dual-use customers, not to rehash arguments already presented or introduce entirely new ones. (*See* D.I. 219) To the extent the parties provided such arguments in addition to what was requested, those arguments have not been considered.

and inclinations, however, are not enough. (D.I. 175-1 Ex. 30 at A-1131-32, § 1.7(c)) (stating Roche has no “duty to inquire or investigate”); *see also Am. Contl. Ins. Co. v. Marion Meml. Hosp.*, 773 F. Supp. 1148, 1152-53 (S.D. Ill. 1991) (noting difference between expectation and knowledge). In the Court’s view, § 1.7 implicitly granted Roche the right to “bur[y] its head in the sand” (D.I. 221 at 4), so long as it did not know or consent to the out-of-field use at the time of sale (D.I. 175-1 Ex. 30 at A-1131-32, § 1.7(c)).

That said, some of Roche’s actions suggest more than innocent ignorance. Viewing the facts in the light most favorable to Meso, it would not be unreasonable for a juror to find that Roche *implicitly* consented to out-of-field uses by dual-use customers by: (1) continuing to make sales to customers it knew or suspected of undertaking out-of-field use; and/or (2) removing the field restrictions from its labels. (D.I. 221 at 3-4; *see also* D.I. 221-1 Ex. 6) Thus, summary judgment will be denied. Meso will have an opportunity to prove at trial that Roche consented (implicitly or otherwise) to out-of-field use by at least one specific dual-use customer.

2. Roche’s motion for summary judgment (D.I. 170) with respect to the Y-Linker element is **DENIED**. Claim 10 shall be construed as referring to a pre-bound form of the linker element, consistent with Meso’s proposed construction.

Roche conceded that [REDACTED] of its products are covered by claim 10. (*See, e.g.*, D.I. 192-1 Ex. 20 at 21-22) (“The Accused Reagent Packs . . . are covered by Claim 10 of the ‘607 Patent . . . : [REDACTED].”) The Court is not persuaded by Roche’s arguments that dropping these three products from its summary judgment motion negates that admission, or that Roche admitted to infringement only because those products were already covered by claim 6. (D.I. 222 at 4) Roche also argues the [REDACTED] products have different structures, but does not identify how those differences manifest as to the Y-Linker. (*See* D.I. 222

at 4; D.I. 223 at 5) In the Court's view, a POSA, reading claim 10 in light of claims 6, 14, and 16, would conclude that all four claims refer to the linker element in the same pre-bound form. (*See id.*) For these reasons (and the others stated by Meso in its supplemental letter briefs), the Court will adopt Meso's construction and summary judgment will be denied.

IT IS FURTHER ORDERED that the parties shall meet and confer and, no later than **October 21**, 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.

October 17, 2019
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE