IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BIOMÉRIEUX, S.A. and BIOMÉRIEUX, INC.,

Plaintiffs,

v.

C.A. No. 18-21-LPS

HOLOGIC, INC., GRIFOLS S.A., and GRIFOLS DIAGNOSTIC SOLUTIONS INC.,

Defendants.

MEMORANDUM ORDER

At Wilmington this 6th of February, 2020:

Having reviewed the proposed final pretrial order (D.I. 396) ("PTO") filed by Plaintiffs bioMérieux, S.A. and bioMérieux, Inc. (together, "Plaintiffs") and by Defendants Hologic, Inc. ("Hologic"), Grifols Diagnostic Solutions Inc. ("GDS"), and Grifols, S.A. ("GSA") (together, "Defendants"),

IT IS HEREBY ORDERED that:

1. Plaintiffs' motion in limine ("MIL") #1, seeking to exclude evidence and argument relating to inequitable conduct, is **GRANTED** to the extent that: (a) evidence that is solely relevant to inequitable conduct (which will be the subject of a subsequent bench trial) and to no other issue in the case will not be admitted; and (b) there shall be no evidence, argument, or suggestion that anyone intentionally withheld material information from the Patent and Trademark Office ("PTO") or had (and violated) a duty of candor to the PTO. "Defendants do not intend to introduce at the jury trial evidence relating to intent to deceive or the duty of candor" (D.I. 396-2 Ex. 7P at p.8 of 259) However, Defendants will be permitted to reference

experimental data that is also a basis for their inequitable conduct claim, as it is relevant at least to obviousness, including secondary considerations (e.g., unexpected results). See, e.g., W.L. Gore & Associates, Inc. v. C.R. Bard, Inc., C.A. No. 11-515-LPS D.I. 473 at 2-3 (D. Del. Nov. 24, 2015). The probative value of such data, and the fact it was not before the PTO (without any reference or suggestion to whether it should have been), is not substantially outweighed by the risk of unfair prejudice, confusion, or any other concerns of Federal Rule of Evidence 403 ("Rule 403").

2. Plaintiffs' MIL #2, seeking to preclude Defendants from relying on a laboratory notebook that third-party Ortho Clinical Diagnostics ("Ortho") produced ("Ortho notebook"), is **DENIED.** There is sufficient evidence from which the Ortho notebook could be found authentic pursuant to Fed. R. Evid. 901(b)(4); if authentic, it qualifies as an ancient document under Fed. R. Evid. 803(16); and it has probative value that is not substantially outweighed by any risk of unfair prejudice. Authentication may be supported by circumstantial evidence, including a document's source, appearance, content, substance, internal pattern, distinctive characteristics, and age. See, e.g., LG Display Co. v. AU Optronics Corp., 265 F.R.D. 189, 196 (D. Del. 2010). The Ortho notebook was produced in response to a subpoena; moreover, the content, appearance, and substance of the notebook support what Defendants purport it to be: a lab notebook underlying the work leading to the invention described in U.S. Patent No. 6,001,558 ("the Backus patent"). The notebook's pages are signed by the named inventor, John Backus, contain primer data disclosed in the Backus patent, and are microfilmed consistent with the standard operating procedure for lab notebooks. (D.I. 396-2 Ex. 7P at p.41-241, 253-254) Thus, the produced lab notebook meets the authentication requirements under Fed. R. Evid. 901(b)(4). It also qualifies under the "ancient documents" exception to the rule against hearsay because it is a

statement in a document that was prepared before January 1, 1998, and whose authenticity is established. Fed. R. Evid. 803(16). Finally, the probative value of the Ortho notebook outweighs any purported prejudice. The Ortho notebook is probative of simultaneous invention, consistent with a disclosed opinion of Defendants' expert, Dr. Ehrlich, and any risk that the jury might be confused it is being offered as §102(g) prior art can be handled by appropriate instructions to counsel, witnesses, and the jury. A lab notebook is the type of information a technical expert in this field would reasonably rely on. See, e.g., Endo Pharm. Inc. v. Actavis Inc., 2017 WL 3731001, at *4 (D. Del. Aug. 30, 2017).

3. Plaintiffs' MIL #3, seeking to preclude Defendants from presenting evidence or testimony regarding Defendants' Indented Bills of Materials ("IBOMs"), is **DENIED**. Plaintiffs have not addressed or satisfied the applicable test for exclusion of evidence based on its purported untimeliness. See Meyers v. Pennypack Woods Home Ownership Assn., 559 F.2d 894, 905 (3d Cir. 1977) (describing exclusion of evidence as "extreme sanction"). Plaintiffs never raised (with Defendants or the Court) any objection to the adequacy of the preparation of Defendants' Rule 30(b)(6) witness, at or after the deposition, including in the six months between service of Mr. Bone's expert report (relying on IBOMs) on August 1, 2019 and the filing of the MIL (complaining that Defendants 30(b)(6) witness had not been prepared to discuss IBOMs) on January 31, 2020. Plaintiffs should not be surprised by Defendants' use of the IBOMs, as the documents appear on both parties' exhibit lists and both relevant experts have opined on them; the timing with which Plaintiffs have raised this issue leaves suggests it is not prejudicial and certainly not to the degree that would persuade the Court to order a late additional deposition or move the trial date; and there is no evidence of bad faith or willfulness by Defendants.

- 4. Defendants' MIL #1, seeking to exclude reference to or use of any other proceedings regarding the patents-in-suit or related foreign patents, will be argued at the pretrial conference ("PTC") tomorrow.
- 5. Defendants' MIL #2, seeking to preclude Plaintiffs from arguing a conception or reduction to practice date earlier than June 23, 1997, is **DENIED**. Plaintiffs have confirmed that they will not assert that the patents-in-suit are entitled a priority date before June 23, 1997. (See D.I. 396-4 Ex. 7D at p. 198 of 373) The probative value of Plaintiffs' evidence related to research underlying the patents-in-suit, including as helpful background about the technology, outweighs the potential for unfair prejudice. Any risk that the jury might mistakenly conclude that Plaintiffs are proposing a priority date earlier than June 23, 1997 can be addressed by a jury instruction, should any party propose one.
- 6. Defendants' MIL #3, to exclude reference to irrelevant and prejudicial financial and corporate information, is **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs will not be permitted to introduce evidence of Defendants' overall financial state or revenues not tied to the accused products and not tied to Plaintiffs' expert opinion regarding a reasonable royalty calculation. (*See* D.I. 396-4 Ex. 7D at p.206-07 of 373) The minimal probative value of such evidence to issues actually being decided by the jury is substantially outweighed by the risk of unfair prejudice to Defendants. Similarly, evidence of Defendants' economic and corporate issues unrelated to any claim or defense will also be excluded. For example, documents describing Defendants' executive turnover and a potential sale of the company could unfairly prejudice Defendants as "chronic bad actors." (*See* D.I. 396-4 Ex. 7D p.208 of 373) Plaintiffs' expert, Ms. Lawton, did not base any of her opinions on this evidence, including her opinion as to the parties' positions in a hypothetical negotiation. The Court will not, however, exclude

exhibits such as Defendants' SEC filings and presentations to investors provided they are used for a proper purpose (such as describing Defendants' diagnostics business or the revenues associated with the accused products) and provided that the parties meet and confer on appropriate redactions (of irrelevant and/or unfairly prejudicial information). Documents that are offered merely to show the purported "public perception of the state of Hologic in January 2014" (D.I. 396-4 at p.214 of 373) will be excluded. Their minimal probative value (as supposedly showing a weakened negotiation position at the time of the hypothetical negotiation) is substantially outweighed by the risk of misleading and confusing the jury and unfairly prejudicing Defendants.

- 7. Considering the issues that will be the subject of the trial, and given the Court's procedures for counting time, the Court does not believe the parties require their requested twenty (20) hours per side. (See PTO at ¶ 59) Instead, the Court believes that no more than fifteen (15) hours per side is necessary. The parties shall be prepared to address at tomorrow's PTC whether they continue to request more than 15 hours and, if so, the basis for such a request.
- 8. Given the Court's other commitments, the trial will take place at some or all of the following times, subject to the overall time limits for trial presentations (as noted above and to be discussed further tomorrow):

Tuesday, February 18:

8:30 a.m. - 5:00 p.m.

Wednesday, February 19:

8:30 a.m. – 3:00 p.m.

Thursday, February 20:

8:30 a.m. - 5:00 p.m.

Friday, February 21:

8:30 a.m. – 5:00 p.m.

Monday, February 24:

8:30 a.m. - 5:00 p.m.

Tuesday, February 25: 8:30 a.m. – 5:00 p.m.

Wednesday, February 26: 8:30 a.m. – 12:00 p.m.

Thursday, February 27: 8:30 a.m. – 5:00 p.m.

HONORABLE LEONARD P. STARK UNITED STATES DISTRICT JUDGE