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 **21st of January, 2020**:

Pending before the Court are motions to exclude expert testimony 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"). (D.I. 315, 328, 329, 330, 331)

Having considered the parties' briefing and related materials (*see* D.I. 316-17, 346, 348-49, 372-73, 378-79), and having heard oral argument on December 18, 2019 (*see* D.I. 392 ("Tr.")),[1]

IT IS HEREBY ORDERED that:

1. There are three distinct requirements for admissible expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the opinion must relate to the

[1] Summary judgment motions were also argued at the December 18 hearing. (*See* Tr.) Those motions will be addressed in one or more subsequent orders. The resolution of the *Daubert* motions should not be understood to imply what the outcome of the summary judgment motions will be.

facts. *See generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741-46 (3d Cir. 2000). Hence, expert testimony is admissible if it "is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). Rule 702 embodies a "liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal citations omitted). Motions to exclude evidence are committed to the Court's discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994).

2. Plaintiffs' motion seeking to preclude Defendants' expert witness John Bone (D.I. 328) from testifying regarding certain damages calculations is **DENIED**. Plaintiffs identify several issues with Mr. Bone's opinions, including the apportionment inputs for his "income approach" to determining a reasonable royalty; Mr. Bone's reliance in his "market approach" on a 2014 license agreement that resulted from a litigation settlement; and Mr. Bone's decision not to apply a "cost approach" to assess Defendants' expenses in implementing non-infringing alternatives. Plaintiffs also challenge Mr. Bone's use of a transfer price and cost of LTR primer and probe components to apportion the value of the infringing products. (*See* D.I. 328 Ex. 1 at ¶¶ 16, 166, 171-73)

Mr. Bone utilized a recognized, sufficiently reliable method. *See, e.g.*, *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015) ("A party may use the royalty rate from sufficiently comparable licenses, value the infringed features based upon comparable features in the marketplace, or value the infringed features by comparing the accused product to non-infringing alternatives."). Plaintiffs' disagreement with his inputs goes to the weight the jury may accord Mr. Bone's opinions, not their admissibility. Similarly, Mr. Bone's opinions regarding the 2014 license are sufficiently reliable and relevant to be admissible; he provided the

factual basis for his opinion that the parties had "resolved all open questions" regarding the litigation, and Defendants are free to challenge that basis at trial. Finally, Mr. Bone's choice to use the *Georgia-Pacific* factors[2] to analyze prices of non-infringing alternatives is sufficiently reliable and does not render his opinion inadmissible. Plaintiffs may challenge Mr. Bone's opinions on cross-examination and with the presentation of competing evidence.

3. Plaintiffs' motion to exclude Dr. Ehrlich's testimony (D.I. 330) is **DENIED**. What Plaintiffs characterize as Dr. Ehrlich's factual narrative will, in the Court's view, assist the jury in understanding the development of complicated assays. Further, as Defendants explain, "Dr. Ehrlich provides the underlying factual bases for his opinions relating to a central dispute between the parties – whether Gen-Probe abandoned, suppressed, or concealed its prior invention." (D.I. 348 at 1-2) His testimony is relevant, reliable, and admissible pursuant to Fed. R. Evid. 702.

4. Plaintiffs' motion to exclude certain testimony from Dr. Stephen Kunin (D.I. 329) is **DENIED** without prejudice to renew after trial, given the Court's denial without prejudice to renew motions directed to Defendants' inequitable conduct claims. (*See* D.I. 389; *see also* D.I. 391)

5. Plaintiffs' motion to exclude certain opinions of Dr. Warner Greene (D.I. 331) is **DENIED.** Dr. Greene has set forth adequate information supporting his opinion that each non-infringing alternative was available to Defendants. Because some of these alternatives were similar to assays that were commercially available from other competitors, Dr. Greene opines that Defendants had the capability to implement them. (*See* D.I. 331 Ex. 2 at ¶¶ 226-27, 232-33,

[2] *See Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

239-40, 246-47, 256-57) Although Dr. Greene did not, himself, commercially develop the non-infringing alternatives, or work at the FDA, these facts do not render him unqualified or his opinions unreliable. His opinions "are based on his extensive experience in the field of nucleic acid-based assays and his review of record evidence." (D.I. 348 at 5) Plaintiffs' criticisms go to the weight, not admissibility, of his opinions.

6. Defendants' motion to exclude Mr. Nixon's opinions and testimony (D.I. 15) is **DENIED** without prejudice to renew, for the same reasons stated above with respect to Dr. Kunin. (*See supra* ¶ 4; *see also* D.I. 389)

7. Defendants' motion to exclude Dr. Thomas Gingeras' testimony (D.I. 315) is **DENIED.** Dr. Gingeras' opinion is not inconsistent with the Court's construction of the claim term "HIV-1 genome / HIV-1 nucleic acid," which is not limited to all presently-known subtypes, and does not assume that HIV-1 subtype reactivity is a limitation of the claims. (*See, e.g.*, D.I. 317 Ex. 6 (Gingeras Rep.) at ¶¶ 189, 203) The opinions are relevant to the issues in the case, including obviousness and Defendants' § 102(g) affirmative defense (e.g., whether Defendants intentionally concealed their invention or unreasonably delayed filing for a patent). (D.I. 346 at 7) Defendants' concerns go to weight, not admissibility.

8. Defendants' motion to exclude expert testimony of Dr. Robert van Gemen (D.I. 315) is **DENIED IN PART**, and **GRANTED IN PART**.

Dr. van Gemen's analysis of the technical comparability between certain patents identified in purportedly comparable licenses and the patents-in-suit is reliable. Dr. van Gemen opines that the five patents he analyzed are representative of all patent families covered in the comparable licenses. (*See* D.I. 317 Ex. 9 at 33) Defendants' arguments regarding Dr. van Gemen's decision to analyze only a subset of the patents selected by Plaintiffs' counsel go to the

weight of the evidence, and not admissibility. Dr. van Gemen is unlike the experts in *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 496 (D. Del. 2019), who failed to provide any analysis of comparability beyond a general description of the subject matter of the purportedly comparable patents. For example, Dr. van Gemen opines why differences in the claimed technology (e.g., longer nucleotide sequences of the HIV-1 genome) do not render the patents-in-suit technically different from the comparable license patents. (*See, e.g.*, D.I. 317 Ex. 11 (van Gemen 8/28 Decl.) at ¶¶ 9-10, 13-14) He explains his opinion that the licensed patents and the patents-in-suit are comparable because they involve the specific nucleotide sequence of HIV-1. (*See* D.I. 347 Ex. 1 (van Gemen 9-10 Dep.) at 99-103)

However, Dr. van Gemen will not be permitted to offer opinions on Defendants' state of mind based on proceedings relating to the European counterparts to the patents-in-suit. (*See* D.I. 317 Ex. 11 (van Gemen Decl.) at ¶ 8; *see also* D.I. 317 Ex. 9 at 90-91) Generally, intent is not a proper topic for expert testimony. *See, e.g.*, *AstraZeneca LP v. TAP Pharma. Products*, 444 F. Supp. 2d 278, 293 (D. Del. 2006). Thus, while Dr. van Gemen may testify to Defendants' conduct, he may not proffer an opinion on how Defendants' practices speak to their intent.

9. Defendants' motion to exclude Catherine Lawton's expert testimony (D.I. 315) is **DENIED.** Ms. Lawton evaluated multiple sources in assessing the technical comparability of the licenses she considered. These sources include licenses covering HIV-1 detection technology executed by Defendants' predecessors (*see* D.I. 317 Ex. 12 (Lawton Op. Rep.) at ¶¶ 436, 450), Defendants' internal documents describing licenses with other entities for products within the same "intellectual property landscape" (D.I. 317 Ex. 12 (Lawton Op. Rep.) at ¶¶ 342-43)), an internal proposal that Plaintiff prepared for Defendants in 2005 – which included patents in the same family as the patents-in-suit (*see* D.I. 347 Ex. 2 (Lawton Reply Rep.) at ¶¶ 123-26) –

and U.S. classification codes of the patents in the licenses and the patents-in-suit (*see* D.I. 317 Ex. 12 (Lawton Op. Rep.) at Schedule 9.3.1). Ms. Lawton's apportionment analysis also analyzes the differences between the diagnostics and blood screening markets, which provides, in her view, the basis for why revenue projections from the viral load market are a "reasonable proxy" for the blood screening market of the accused products. (D.I. 346 at 20) Ms. Lawton's apportionment analysis also accounts for the accused "smallest saleable unit" containing the infringing features of the accused products. Defendants' criticisms of Ms. Lawton's opinions go to the weight to be afforded them and not their admissibility. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012).

10. Defendants' motion to exclude Dr. Roger Dodd's testimony (D.I. 315) is **DENIED**. Dr. Dodd's experience in implementing the accused products in the blood banking industry, and specifically with the American Red Cross ("ARC"), make him a qualified witness to testify on whether individuals in the blood banking industry, such as those at the ARC, have used the accused products in accordance with the labels approved by the U.S. Food and Drug Administration ("FDA"). (D.I. 346 at 22-24) Dr. Dodd's testimony may be helpful for the jury. The deficiencies that Defendants find in Dr. Dodd's opinions go to weight and not admissibility.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE