UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioners,

v.

MODERNA TX, INC.,
Patent Owner.

Case IPR2023-01359
Patent No. 10,933,127

PATENT OWNER'S OBJECTIONS TO EVIDENCE FILED AND SERVED WITH PETITIONER'S REPLY PURSUANT TO 37 C.F.R. § 42.64

Pursuant to 37 C.F.R. § 42.64, Patent Owner submits the following objections to evidence filed and served with Petitioner's Reply ("Reply"). Patent Owner's objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within five business days of service of evidence to which the objection is directed (August 30, 2024).

Exhibit 1159 (Declaration of Daniel O. Griffin, M.D., Ph.D.):

Patent Owner objects to Exhibit 1159 as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106, 401, 402, and 403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 43 and 463 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly and incorrectly characterize the teachings of the '127 patent;
- ¶¶ 44, 129, 145-184, 189, 191, 214-226, 229, 231-237, 239, 245-246, 249-250, 256, 267-269, 273-274, 279, 306, 308, 313, 317, 333, 347-348, 350-

351, 449-450, 454-455, and 458-460, as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the state of the art;

- ¶¶ 31-32, 53-54, 65, 97, 101-102, and 305 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the teachings of Schrum;
- ¶¶ 22, 190, 213, and 284 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the teachings of Geall;
- ¶¶ 337-338, 354, and 362 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the teachings of Yang;
- ¶¶ 389-393 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the teachings of Altmeyer.
- ¶¶ 28-32, 34-35, 39, 43, 109-110, 112, 139-141, 143, 150, 156-159, 170-171, 175, 185, 194-196, 202-206, 212, 227, 234-237, 239-240, 247, 255-256, 265, 278-279, 372, 378, 386, 389, 391, 393, 395, 419, and 425 as misleading, incomplete, and irrelevant because they lack support for the

contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Fuller.

- ¶¶ 219, 275, 435-442, 444, 463, and 467 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Krause.
- ¶¶ 453 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Moon.
- ¶¶ 209-210, 229, and 396-399 as prejudicial including because these paragraphs introduce new, untimely issues that should have been discussed in the Petition or beyond the scope of issues raised in Patent Owner's response, and are thus irrelevant. While Patent Owner believes these paragraphs of Exhibit 1159 should be struck rather than excluded, Patent Owner presents these objections to the extent the Board would prefer this issue be presented in a motion to exclude.

Patent Owner further objects to Exhibit 1159, including ¶¶ 10-18, 21-27, 32-32, 53-54, 65, 97, 129, 145-184, 189, 191, 207, 214-226, 229, 231-237, 239, 245-246, 249-250, 256, 267-269, 273-274, 279, 306, 308, 313, 317, 333, 347-348, 350-351, 449-450, 454-455, and 458-460 of Exhibit 1159, as opinions on which Dr.

Griffin is not qualified to provide, as not being based on sufficient facts or data, as not being the product of reliable principles and methods, and/or as not being a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703.

Patent Owner further objects to ¶¶ 41-42, 339, and 390 of Exhibit 1159 as opinions for which Dr. Griffin failed to apply the claim construction Petitioner advanced in the Petition and therefore are not the product of reliable principles and/or methods. *See* Fed. R. Evid. 702, 703.

Patent Owner further objects to ¶¶ 1-4, 334, 432-434, and 468-469 of Exhibit 1159 because these paragraphs are not cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401, 402.

Patent Owner further objects to ¶¶ 28, 33, 35-36, 60-127, 138-142, and 280-334 of Exhibit 1159 because these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401, 402. Petitioner includes citations in the Reply to large paragraph ranges in Exhibit 1159. *See* Reply, 5 (citing "Ex. 1159, ¶¶28-127"), 20 (citing "Ex. 1159, ¶¶138-256"), 12 (citing "Ex. 1159, ¶¶138-280"), 13 (citing "Ex. 1159, ¶¶185-237"), and 11 (citing "Ex. 1159, ¶¶281-333"). This does not moot Patent Owner's objection to ¶¶ 28, 33, 35-36, 60-127, 138-142, and 280-334 because Petitioner's wholesale citation to every paragraph in large sections of Dr. Griffin's second declaration amounts to

improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration "merely because they are cited in the Petition").

Patent Owner further objects to ¶¶ 12, 14-15, 17, 148, 156-157, 161, 166, 168, 171, 177-178, 184, 193, 200-201, 209, 212, 214-216, 222, 224, 239, 245, 250, 253, 267-269, 278, 437, 441, 444, 450, 453-454, 456-457, and 462 of Exhibit 1159, which contain citations to Exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to ¶¶ 42, 44, 59, 147-150, 152-157, 161, 163-169, 175-176-180, 183-184, 186, 191-193, 199-201, 209-210, 212, 214-223, 227, 232-236, 238-239, 245-246, 248, 250-251, 253-254, 256, 258-279, 284, 306, 350-351, 437-438, 440-441, 444-445, 449-450, 453, 456-457, 462, and 467 of Exhibit 1159, which contain citations to Exhibits that form no part of the grounds on which *inter partes* review was instituted, as irrelevant. *See* Fed. R. Evid. 402. Further, any probative value of these paragraphs is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence.

Patent Owner further objects to all paragraphs of Exhibit 1159 that cite to other Exhibits Patent Owner currently objects to, for the same reasons Patent Owner objects to these Exhibits as discussed in this paper.

Patent Owner further objects to all paragraphs of Exhibit 1159 that contain citations to Exhibits that Patent Owner has objected to in its Objections to Evidence filed on March 20, 2023, for the same reasons provided therein. *See* Paper 21.

Exhibit 1164 (Declaration of L. Ross Pierce, M.D.)

Patent Owner objects to Exhibit 1164 as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106, 401, 402, and 403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 41-42, 60-62, and 73 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and incorrectly characterize the state of the art;
- ¶¶ 2, 23, 26-28, 30, 35, 37, 39, 41-43, 46-47, 51, 56, 59, 62-64, 72, and 74-75 as misleading, incomplete, and irrelevant because they lack support for

the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Krause.

Patent Owner further objects to ¶¶ 24-75 of Exhibit 1164 as opinions on which Dr. Pierce is not qualified to provide, as not being based on sufficient facts or data, as not being the product of reliable principles and methods, and/or as not being a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703.

Patent Owner further objects to ¶¶ 1, 3-22, 24-43, 48-64, and 76 of Exhibit 1164 because these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401, 402. Petitioner includes one citation in the Reply to all paragraphs in Exhibit 1164. *See* Reply, 24 (citing "Ex. 1164, ¶¶ 1-76"). This does not moot Patent Owner's objection to ¶¶ 1, 3-22, 24-43, 48-64, and 76 because Petitioner's wholesale citation to every paragraph in Dr. Pierce's declaration amounts to improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration "merely because they are cited in the Petition").

Patent Owner further objects to ¶¶ 15-20, 32-33, and 36-38 of Exhibit 1164, which contain citations to Exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to ¶¶ 15-17, 19-21, 28, 32-33, 36-41, 44-51, 53-55, 57-67, and 69-75 of Exhibit 1164, which contain citations to Exhibits that form no part of the grounds on which *inter partes* review was instituted, as irrelevant. *See* Fed. R. Evid. 402. Further, any probative value of these paragraphs is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence.

Patent Owner further objects to all paragraphs of Exhibit 1164 that cite to other Exhibits Patent Owner currently objects to, for the same reasons Patent Owner objects to these Exhibits as discussed in this paper.

Patent Owner further objects to all paragraphs of Exhibit 1164 that contain citations to Exhibits that Patent Owner has objected to in its Objections to Evidence filed on March 20, 2023, for the same reasons provided therein. *See* Paper 21.

Exhibit 1161 (Declaration of James J. Moon, Ph.D.):

Patent Owner objects to Exhibit 1161 as misleading, incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106 and 401-403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper

incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 18, 22, 24, 25, 27, 28, 47, 59, 65, 67, 72, and 77 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of the '600 patent;
- ¶¶ 3-17, 19-20, 66, 74-75, 77-79, 82, 83-86, 88-89, 91, 96-97, and 99 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited, and improperly characterize the state of the art;
- ¶¶ 18, 21, 22-64, 65, 67-73, 76, 80-81, 87, 90, 92-95, 98 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Schrum and/or Geall;
- ¶¶ 14-17, 19-21, 23, 24, 26, 29-30, 31, 37, 39-42, 44-46, 48, 49-52, 53-58, 60-64, 66-68, 74, 78, 79-82, 83, 85-87, 90-95, and 97 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Chan;

- ¶ 98 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Fuller;

Patent Owner further objects to ¶¶ 3-99 as not being based on sufficient facts or data, the product of reliable principles and methods, and/or not reflecting a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702-703.

Patent Owner further objects to ¶¶ 7, 28, 76-78, and 99, which cite to exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to all paragraphs of Exhibit 1161 that cite to other Exhibits Patent Owner currently objects to, for the same reasons Patent Owner objects to these Exhibits as discussed in this paper.

Patent Owner further objects to all paragraphs of Exhibit 1161 that cite to Exhibits that Patent Owner has objected to in its Objections to Evidence filed on March 20, 2023, for the same reasons provided therein. *See* Paper 21.

Exhibit 1163 (Declaration of W. Christopher Bakewell):

Patent Owner objects to Exhibit 1163 as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid.

106, 401, 402, and 403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 13-21, 23, 27, 53, 62, 70, 73, 75-76, 79-80, 82-83, 85-89, 94, 96, 101-103, 109-110, 112-114, 129-130, 134-135, 139, and 150-151 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Mr. Malackowski.
- ¶¶ 13-14, 56, 60, 62, 75, 79, 82, and 112 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Krause.

To the extent ¶¶ 11, 17-18, 27, 54-62, 78-81, 88-93, 97, 102-104, 106, 110, 113, 151 are being offered to prove the truth of the matter asserted, Patent Owner objects to these paragraphs as constituting inadmissible hearsay. Patent Owner further objects to these paragraphs as opinions on which Mr. Bakewell is not qualified to provide, as not being based on sufficient facts or data, as not being the product of reliable principles and methods, and/or as not being a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702, 703.

Patent Owner further objects to ¶¶ 1-154 of Exhibit 1163 because these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401, 402. Petitioner includes one citation in the Reply to all paragraphs in Exhibit 1163. *See* Reply, 28 (citing "Ex. 1163, ¶¶1-154"). This does not moot Patent Owner's objection to ¶¶ 1-154 because Petitioner's wholesale citation to every paragraph in Mr. Bakewell's declaration amounts to improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration "merely because they are cited in the Petition").

Patent Owner further objects to ¶¶ 13, 15-19, 21-22, 26-37, 39-53, 61, 70-72, 74-80, 82, 85-86, 88, 90-92, 94, 96-98, 101-104, 106-109, 111, 113, 115-133, 135-145, and 148-150 of Exhibit 1163, which cite to exhibits that are not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to all paragraphs of Exhibit 1163 that cite to Exhibits that Patent Owner currently objects, for the same reasons Patent Owner objects to these Exhibits as discussed in this paper.

Patent Owner further objects to all paragraphs of Exhibit 1163 that cite to Exhibits that Patent Owner has objected to in its Objections to Evidence filed on March 20, 2023, for the same reasons provided therein. *See* Paper 21.

Exhibits 1098-1100, 1102-1103, 1106-1130, 1133-1151, 1153-1157, 1166-1222, 1224-1305, and 1314-1315:

Patent Owner objects to Exhibits 1098-1100, 1102-1103, 1106-1130, 1133-1151, 1153-1157, 1166-1222, 1224-1305, and 1314-1315 under Fed. R. Evid. 401, 402, and 403 as lacking relevance and because their probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, or needlessly presenting cumulative evidence. Patent Owner further objects to these exhibits under Fed. R. Evid. 401 and 402 because the exhibits are not cited in the Petition or Reply. In fact, of the 205 new exhibits filed by Petitioners with the Reply, only 12 are cited in Petitioner's Reply.

To the extent Exhibits 1103, 1106, 1108, 1109, 1100, 1112, 1114, 1115, 1116, 1117, 1119, 1121, 1123, 1124, 1129, 1130, 1133, 1134, 1136, 1138, 1139, 1140, 1141, 1142, 1143. 1151, 1153, 1154, 1156, 1166, 1168, 1169, 1170, 1171, 1172, 1174, 1176, 1181, 1182, 1183, 1185, 1187, 1188, 1189, 1190, 1191, 1192, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1203, 1204, 1207, 1208, 1210, 1211, 1214, 1215, 1216, 1217, 1218, 1224, 1225, 1226, 1227, 1228, 1229, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1244, 1246, 1248, 1249, 1250, 1251, 1254, 1256, 1257, 1258, 1259, 1262, 1263, 1264, 1265, 1266, 1267, 1268, 1269, 1270, 1271, 1274, 1275, 1277, 1278, 1279, 1280, 1281, 1282, 1285, 1286, 1289, 1290, 1291, 1292, 1293, 1294, 1296, 1297, 1298, 1299, 1300, 1301, 1302, 1303, 1305,

1314, and 1315 are being offered to prove the truth of the matter asserted, the exhibits constitute inadmissible hearsay.

Patent Owner further objects to Exhibits 1102, 1113, 1122, 1124, 1126, 1128, 1130, 1144, 1145, 1146, 1147, 1149, 1167, 1168, 1170, 1173, 1175, 1176, 1177, 1179, 1183, 1184, 1191, 1192, 1195, 1203, 1214, 1215, 1216, 1217, 1228, 1229, 1244, 1245, 1246, 1247, 1248, 1250, 1251, 1262, 1263, 1267, 1272, 1275, 1277, 1294, 1304, 1305 under Fed. R. Evid. 901 because the documents lack authentication.

Patent Owner further objects to Exhibits 1098, 1107, 1123, 1182, 1187, 1200, 1250, 1261, 1276, 1281 under Fed. R. Evid. 106 as incomplete.

Patent Owner further objects to any paragraph of Exhibits 1159, 1161, 1163, and 1164 to the extent they rely on Exhibits 1098-1100, 1102-1103, 1106-1130, 1133-1151, 1153-1157, 1166-1222, 1224-1305, or 1314-1315 for at least the reasons identified here.

Exhibits 1101 and 1132:

Patent Owner objects to Exhibits 1101 and 1132 under Fed. R. Evid. 901 because the documents lack authentication.

To the extent that Exhibits 1101 and 1132 are being offered to prove the truth of the matter asserted, the exhibits constitute inadmissible hearsay.

Patent Owner further objects to any paragraph of Exhibits 1159, 1161, 1163, and 1164 to the extent they rely on Exhibits 1101 or 1132 for at least the reasons identified here.

Exhibits 1104, 1105, and 1152:

Patent Owner objects to Exhibits 1104, 1105, and 1152 under Fed. R. Evid. 106 as incomplete and/or inaccurate transcripts of the depositions of Dr. Deborah Fuller, Dr. Philip Krause, and Dr. Warren C. W. Chan, which occurred on August 2, 2024, August 14, 2024, and July 30, 2024, respectively, because these transcripts do not include any forthcoming errata sheets. To the extent these witnesses submit errata sheets, they must in fairness be considered at the same time as the exhibit.

Respectfully submitted,

Date: September 9, 2024

By: /Emily R. Whelan/
Emily R. Whelan (Reg. No. 50,391)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6567
Email: Emily.Whelan@wilmerhale.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2024, I caused a true and correct copy of the following documents:

- Patent Owner's Objections to Evidence Pursuant to 37 C.F.R. § 42.64

to be served via e-mail, as consented to by Petitioner, upon the following:

COVIDPatentPfizer@wc.com
BioNTech-Moderna-IPR@paulhastings.com

By: /Wenli Gu /
Wenli Gu (Reg. No. 72,124)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6093
Email: Wenli.Gu@wilmerhale.com