

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENE COMPANY PTY LTD,
Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,
Patent Owner.

Case IPR2024-00313
U.S. Patent No. RE47,045

**PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED WITH
PETITIONER'S REPLY**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner, The Trustees of Columbia University in the City of New York (“Columbia”), submits the following objections to evidence served with Petitioner Gene Company PTY LTD’s (“Gene”) Reply in *Inter Partes* Review of U.S. Patent No. RE47,045 (Paper No. 31) (“Pet. Rep.”).

Exhibit 1065: Objections to Exhibit 1065 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Del Priore. EX1069 at 58:25-59:4. Columbia objects to Exhibit 1065 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1065 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because there is no evidence establishing that it was publicly available before the earliest possible priority date of the patent at issue. *See* EX1065 at 1 (“2022”). Columbia also objects to Exhibit 1065 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.*, Pet. Rep. at 2. Exhibit 1065 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibit 1066: Objections to Exhibit 1066 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Del Priore. EX1069 at 218:20-219:9. Columbia objects to Exhibit 1066 as lacking authentication under FRE 901. This

exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1066 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because there is no evidence establishing that it was publicly available before the earliest possible priority date of the patent at issue. *See* EX1066 at 1 (“2021”). Columbia also objects to Exhibit 1066 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.*, Pet. Rep. at 19, 21. Exhibit 1066 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807. Columbia further objects to Petitioner’s reliance on Exhibit 1066 as an incomplete statement (FRE 106). *See, e.g.*, Pet. Rep. at 19-21.

Exhibit 1067: Objections to Exhibit 1067 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Del Priore. EX1069 at 243:16-20. Columbia objects to Exhibit 1067 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1067 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because Exhibit 1067 is not cited in any

substantive pleading and because there is no evidence establishing that it was publicly available before the earliest possible priority date of the patent at issue. *See* EX1067 at 1 (“2023”). Columbia also objects to Exhibit 1067 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. Exhibit 1067 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibit 1068: Objections to Exhibit 1068 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Del Priore. EX1069 at 255:25-256:2. Columbia objects to Exhibit 1068 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1068 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because there is no evidence establishing that it was publicly available before the earliest possible priority date of the patent at issue. *See* EX1068 at 1 (“2019”). Columbia also objects to Exhibit 1068 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.,* Pet. Rep. at 20. Exhibit 1068 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibit 1072: Objections to Exhibit 1072 were preserved under 37

C.F.R. § 42.64(a) during the deposition of Dr. Saad. EX1079 at 162:17-22. Columbia objects to Exhibit 1072 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1072 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403. Columbia also objects to Exhibit 1072 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.*, Pet. Rep. at 28. Exhibit 1072 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibit 1073: Objections to Exhibit 1073 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Saad. EX1079 at 164:8-10. Columbia objects to Exhibit 1073 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1073 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403. Columbia also objects to Exhibit 1073 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.*, Pet. Rep. at 28. Exhibit 1073 does not fall

under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibits 1074-1078: Objections to Exhibits 1074-1078 were preserved under 37 C.F.R. § 42.64(a) during the deposition of Dr. Saad. EX1079 at 183:20-23 (EX1074), 190:8-12 (EX1075), 193:22-24 (EX1076), 197:11-13 (EX1077), 200:22-24 (EX1078). Columbia objects to each of Exhibits 1074-1078 as lacking authentication under FRE 901. These exhibits are not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of these exhibits, and accordingly fails to provide sufficient information regarding their authenticity. Columbia also objects to each of Exhibits 1074-1078 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because they are not cited in Petitioner's Reply. Columbia also objects to each of Exhibits 1074-1078 under FRE 801 and 802 as containing inadmissible hearsay because Petitioner improperly relies on the exhibit for the truth of the matter asserted. The exhibits do not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Exhibit 1080: Columbia objects to each of paragraphs 5-8 of Exhibit 1080 under FRE 401, 402, and 403 as not relevant and not helpful to the trier of fact because they are not cited in any substantive pleading.

Columbia also objects to each of paragraphs 16-20, 22, 25, 31, 32, 37-39, 40, 48, 51-59, 63, 65, 66, 75-78 of Exhibit 1080 because these paragraphs rely on

evidence that is inadmissible under at least FRE 402, 403, 901, 1002, and/or 1003 as described herein (Exhibit 1065) and in Patent Owner's Objections to Evidence submitted with Petition for *Inter Partes Review* (Paper 2) (to Exhibits 1006, 1008, 1010, 1011, 1015, 1016, 1022, 1035, 1050).

Columbia also objects to each of paragraphs 11-12, 17-23, 31-32, 36-40, 42-45, 48, 51-60, 63-66, 75-78 of Exhibit 1080 under FRE 702-703 as improper expert testimony. For example, Dr. Guengerich does not provide citations or support from the prior art for the statements in these paragraphs and thus fails to disclose the underlying facts or data for his purported expert opinions. *See also* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Based on the current record, there is insufficient information to establish that the opinions expressed in these paragraphs are the product of sufficient facts and data; whether the opinions are the product of reliable principles and methods; or whether Dr. Guengerich has reliably applied the principles and methods to the facts, as required by FRE 702(b)-(d). Columbia further objects to these paragraphs as improper lay testimony under FRE 602 because they are not rationally based on Dr. Guengerich's own personal and percipient knowledge. Columbia further objects to these paragraphs because the probative value of Dr. Guengerich's testimony is substantially outweighed by unfair prejudice and confusion of the issues (FRE 401-

403).

Columbia also objects to paragraphs 5-14, 21-36, 38-77 of Exhibit 1080 as improper expert testimony under FRE 702-703. For example, these paragraphs contain opinions outside the scope of Dr. Guengerich's purported knowledge, skill, experience, training, and/or education. Based on the current record, there is insufficient information to establish that the opinions expressed in these paragraphs are the product of sufficient facts and data; whether the opinions are the product of reliable principles and methods; or whether Dr. Guengerich has reliably applied the principles and methods to the facts, as required by FRE 702(b)-(d). *See also* 37 C.F.R. § 42.65. Columbia further objects to these paragraphs as improper lay testimony under FRE 602 because they are not rationally based on Dr. Guengerich's own personal and percipient knowledge. Columbia further objects to these paragraphs because the probative value of Dr. Guengerich's testimony is substantially outweighed by unfair prejudice and confusion of the issues (FRE 401-403).

Exhibit 1083: Columbia objects to Exhibit 1083 as lacking authentication under FRE 901. This exhibit is not a self-authenticating document under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibit, and accordingly fails to provide sufficient information regarding its authenticity. Columbia also objects to Exhibit 1083 as inadmissible hearsay (FRE

802) to the extent it is offered or relied upon for the truth of the matter asserted therein. *See, e.g.*, Pet. Rep. at 2. Exhibit 1083 does not fall under any of the hearsay exceptions, e.g., FRE 803, 804, 805, and 807.

Date: December 31, 2024

Respectfully submitted,

/Drew D. Christie/

Drew D. Christie
Counsel for Patent Owner The Trustees of
Columbia University in the City of New
York

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Objections to Evidence Submitted with Petitioner's Reply** was served electronically via email on December 31, 2024, in its entirety on the following:

Jad A. Mills
Michael T. Rosato
Wilson, Sonsini, Goodrich & Rosati
701 Fifth Avenue, Suite 5100
Seattle, WA 98104-7036
jmills@wsgr.com
mrosato@wsgr.com

Matthew Bresnahan
Wilson, Sonsini, Goodrich & Rosati
12235 El Camino Real
San Diego, CA 82130-3002
mbresnahan@wsgr.com

Petitioner has consented to service by electronic mail.

Dated: December 31, 2024

/William Esper/
William Esper
Legal Assistant and PTAB Coordinator
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP