

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL  
BOARD

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GENE COMPANY PTY LTD  
Petitioner,

v.

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

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Case IPR2024-00312  
U.S. Patent No. 9,486,432

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE**

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”) Petition for *Inter Partes* Review of U.S. Patent No. 9,486,432 (Paper No. 2).

**Exhibit 1008:** Columbia objects to Exhibit 1008 as lacking authentication under FRE 901. The 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 1008 for failing to comply with 37 C.F.R. § 42.63(b). Exhibit 1008 purports to be an English translation of a foreign language document, and Gene has not provided a translation of the document into English with a qualifying affidavit or declaration attesting to the accuracy of the translation. Columbia also objects to Exhibit 1008 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. Exhibit 1008 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

**Exhibit 1015:** Columbia objects to Exhibit 1015 as lacking authentication under FRE 901. The 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 1015 for failing to comply with 37 C.F.R. § 42.63(b). Exhibit 1015 purports to be an English translation of a foreign language document and Gene has not provided a translation of the document into English with a qualifying affidavit or declaration attesting to the accuracy of the translation. Columbia also objects to Exhibit 1015 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. Exhibit 1015 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

**Exhibits 1006, 1007, 1010, 1011, 1012, 1013, 1014, 1016, 1018, 1019, 1020, 1021, 1025, 1026, 1027, 1028, 1029, 1030, 1033, 1034, 1035, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1050, 1051, 1053, 1054, 1055, 1056, and 1058:** Columbia objects to Exhibits 1006, 1007, 1010, 1011, 1012, 1013, 1014, 1016, 1018, 1019, 1020, 1021, 1025, 1026, 1027, 1028, 1029, 1030, 1033, 1034, 1035, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1050, 1051, 1053, 1054, 1055, 1056, and 1058 as lacking authentication under FRE 901. The exhibits are not self-authenticating documents under FRE 902. Gene fails to provide sufficient evidence indicating the origin or publication of the exhibits, and accordingly fails to provide sufficient information regarding the exhibits' authenticity. Columbia also objects to Exhibits 1006, 1007, 1010, 1011, 1012, 1013, 1014, 1016, 1018, 1019, 1020, 1021, 1025, 1026, 1027, 1028, 1029,

1030, 1033, 1034, 1035, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1050, 1051, 1053, 1054, 1055, 1056, and 1058 as inadmissible hearsay (FRE 802) to the extent they are offered or relied upon for the truth of the matter asserted therein. These exhibits do not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

**Exhibit 1017:** Columbia objects to Exhibit 1017 under FRE 403 because it is an incomplete document, with only select portions of the whole presented as exhibits. Exhibit 1017 purports to be an excerpt from a multi-chapter book. Columbia further objects to Exhibit 1017 as incomplete under FRE 106. Columbia submits that, in fairness, the complete document should be produced for Columbia's consideration. Columbia also objects to Exhibit 1017 under FRE 901 as lacking authenticity. The 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 objects to Exhibit 1017 as inadmissible hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. Exhibit 1017 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

**Exhibit 1022:** Columbia objects to Exhibit 1022 as lacking authentication under FRE 901. The 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. Gene identifies Exhibit 1022 as “Age-Related Eye Disease Study Research Group, A Randomized, Placebo-controlled, Clinical Trial of High-dose Supplementation with Vitamins C and E, Beta Carotene, and Zinc for Age-related Macular Degeneration and Vision Loss: AREDS report no. 8. *Archives of Ophthalmology*, 119(10), 1417-1436 (2001).” See Paper 2 at 75. On its face, Exhibit 1022 states that it is an “Author Manuscript,” distinct from the document identified by Gene. No evidence therefore establishes that Exhibit 1022 is what Gene claims it is. Columbia also objects to Exhibit 1022 as hearsay (FRE 802) to the extent it is offered or relied upon for the truth of the matter asserted therein. Exhibit 1022 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807. Columbia also objects to Exhibit 1022 as not relevant and not helpful to the trier of fact under FRE 401, 402, and 403, at least because it is not what Gene purports it to be.

**Exhibit 1023:** Exhibit 1023 purports to be the declaration of Irina Hinrichs. Columbia objects to Exhibit 1023 as lacking authentication under FRE 901. The exhibit is not a self-authenticating document under FRE 902. Exhibit 1023 appears to have been executed without the United States yet does not contain the required language under 28 U.S.C. § 1746. See EX1023 at 2 (“Executed on October 17, 2023 at Niš (Serbia)”) (emphasis added)). Columbia also objects to Exhibit 1023 under

FRE 801 and 802 as inadmissible hearsay. Exhibit 1023 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807. Columbia further objects to Exhibit 1023 under FRE 702 as Gene's declarant has not been qualified as an expert, and Exhibit 1023 fails to establish that the witness is qualified to perform the translation as required by FRE 702. For instance, Exhibit 1023 does not state that the witness is fluent in both English and German. Columbia further objects under FRE 701 to the extent Gene's declarant is proffered as a fact witness, including because this testimony is not rationally based on the declarant's perception and is based on specialized knowledge within the scope of FRE 702. Further, for at least the same reasons described for Exhibit 1008, *supra*, Columbia also objects to pages 16–26 of Exhibit 1023 as lacking authentication under FRE 901, for failure to comply with 37 C.F.R. § 42.63(b), and as hearsay under FRE 801.

**Exhibit 1024:** Exhibit 1024 purports to be the second declaration of Irina Hinrichs. Columbia objects to Exhibit 1024 as lacking authentication under FRE 901. The exhibit is not a self-authenticating document under FRE 902. Exhibit 1024 appears to have been executed without the United States yet does not contain the required language under 28 U.S.C. § 1746. *See* EX1024 at 2 (“Executed on November 13, 2023 *at Niš (Serbia)*”) (emphasis added)). Columbia also objects to Exhibit 1024 under FRE 801 and 802 as inadmissible hearsay. Exhibit 1024 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

Columbia further objects to Exhibit 1024 under FRE 702 as Gene's declarant has not been qualified as an expert, and Exhibit 1024 fails to establish that the witness is qualified to perform the translation as required by FRE 702. For instance, Exhibit 1024 does not state that the witness is fluent in both English and German. Columbia further objects under FRE 701 to the extent Gene's declarant is proffered as a fact witness, including because this testimony is not rationally based on the declarant's perception and is based on specialized knowledge within the scope of FRE 702. Further, for at least the same reasons described for Exhibit 1015, *supra*, Columbia also objects to pages 16–26 of Exhibit 1024 as lacking authentication under FRE 901, failure to comply with 37 C.F.R. § 42.63(b), and as hearsay under FRE 801.

**Exhibits 1031 and 1032:** Exhibits 1031 and 1032 purport to be excerpts from the File Histories of U.S. Patent Nos. 8,877,809 (Exhibit 1031) and 9,486,432 (Exhibit 1032). Columbia objects to these Exhibits under FRE 403 because they are incomplete documents, with only select portions of the whole presented as exhibits. Columbia also objects to these exhibits under FRE 901 as lacking authenticity. These excerpts are incomplete documents and none of the excerpts is a certified copy of the file history. Columbia also objects to these Exhibits under FRE 1002 because none are the original file history documents. For the same reason, Columbia also objects to these Exhibits under FRE 1003 because none are duplicates of the original file history documents. Columbia further objects to Exhibits 1031 and 1032 as

incomplete under FRE 106. Columbia submits that, in fairness, the complete documents should be produced for Columbia's consideration.

**Exhibit 1049:** Columbia objects to Exhibit 1049 as lacking authentication under FRE 901. The exhibit is not a self-authenticating document under FRE 902. Gene identifies Exhibit 1049 as "Bull E. What is a Nutraceutical? *Pharm J.* 265:57-58 (2000)." Paper 2 at 77. On its face, however, Exhibit 1049 states that it was "last updated 22 March 2021." EX1049 at 5. 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 1049 under FRE 801 and 802 as inadmissible hearsay. Exhibit 1049 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803, 804, 805, and 807.

Date: July 9, 2024

Respectfully submitted,

/Drew D. Christie/  
Drew D. Christie, Reg. No. 78,004  
Counsel for Patent Owner The Trustees of  
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York

**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the foregoing **Patent Owner's Objections to Evidence** was served electronically via email on July 9, 2024, in its entirety on the following:

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Petitioner has consented to service by electronic mail.

Dated: July 9, 2024

/William Esper/  
William Esper  
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