

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 No. IPR2024-00313
Patent No. RE47,045

PETITIONER'S OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Gene Company Pty Ltd. (“Petitioner”) submits the following objections to the Exhibits enumerated below that were submitted by The Trustees of Columbia University in the City of New York (“Patent Owner”) with its Patent Owner Response, and any reference to or reliance by the Patent Owner on the same. Petitioner’s objections are made pursuant to the Code of Federal Regulations (“C.F.R.”) governing this proceeding, including without limitation 37 C.F.R. §§ 42.61-42.65 and § 42.6(a)(3). As required by 37 C.F.R. § 42.62, Petitioner’s objections below apply the Federal Rules of Evidence (“F.R.E.”).

II. OBJECTIONS

A. Objections to EX2052, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401-403, 602, 701-703, 705, 37 C.F.R. § 42.65, and PTAB Consolidated Trial Practice Guide November 2019.

Petitioner objects to EX2052 to the extent Dr. Prestwich’s testimony is not rationally based on his own personal and percipient knowledge (F.R.E. 602, 701) and to the extent his testimony is not providing an opinion within Dr. Prestwich’s knowledge, skill, experience, training, or education that is based on sufficient facts or data and is the product of reliable principles and methods reliably applied to the facts of this case (F.R.E. 702-703; 37 C.F.R. §42.65). Petitioner objects to EX2052

to the extent that Dr. Prestwich relies on facts or data that are not the kinds of facts or data an expert in Dr. Prestwich's particular field would rely on in forming an opinion on the subject. Petitioner also objects to EX2052 to the extent Dr. Prestwich's testimony is cumulative and to the extent its probative value is substantially outweighed by unfair prejudice and confusion of the issues (F.R.E. 401-403). This includes any reliance on any portion of EX2052 that is cited for a different purpose than that for which it is relied on in the Patent Owner Response.

Petitioner additionally objects to any portions of Dr. Prestwich's declaration that are not cited in the Patent Owner Response as an improper incorporation by reference. F.R.E. 401-403; 37 C.F.R. §42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide November 2019, 35.

Furthermore, Petitioner objects to any portions of Dr. Prestwich's declaration applying an incorrect standard for evaluating the field from the perspective of a person of ordinary skill in the art or which are conclusory and unsupported. 37 C.F.R. § 42.65; *see also* PTAB Consolidated Trial Practice Guide November 2019, 40-41, F.R.E. 705.

B. Objections to Exhibits 2056 and 2057, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 106, 401-403, 602, 801-802, and 901.

Petitioner objects to each of Exhibits 2056 and 2057, which do not purport to be available prior to the critical date, to be publicly available, or to be a

complete record of the correspondence between ktrisler@asbmb.org and iw2101@columbia.edu (neither one of which has provided testimony in this case). Petitioner objects that Patent Owner did not authenticate its source for the documents (F.R.E. 602, 901) or provide the complete record (F.R.E. 106). Patent Owner also fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent these exhibits are hearsay or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

C. Objections to Exhibit 2068, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2068 because Patent Owner did not authenticate it as a prior art publication (F.R.E. 602, 901), and thereby fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2068 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2068 must be restricted to its proper scope. F.R.E. 105.

D. Objections to Exhibit 2077, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 106, 401-403, 1002.

Petitioner objects to Exhibit 2077 as being illegible and therefore incomplete. F.R.E. 106, 1002. Patent Owner thereby fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Even if admissible for some purpose, Exhibit 2077 must be restricted to its proper scope. F.R.E. 105.

E. Objections to Exhibit 2084, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2084 because Patent Owner did not authenticate it as a prior art publication (F.R.E. 602, 901), and thereby fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2084 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2084 must be restricted to its proper scope. F.R.E. 105.

F. Objections to Exhibit 2089, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 106, 401-403, 602, 801-802.

Petitioner objects to each of Exhibits 2089, which purports to be a post-critical date Alkeus submission that was not available prior to the critical date.

Patent Owner fails to demonstrate that this post-critical date document is prior art and, to that extent, fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to Exhibit 2089 as lacking foundation (F.R.E. 602) and lacking completeness (F.R.E. 106), and to the extent it is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2089 must be restricted to its proper scope. F.R.E. 105.

G. Objections to Exhibit 2107, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Petitioner objects to Exhibit 2107 for lack of foundation (F.R.E. 602), and for failing to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2107 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2107 must be restricted to its proper scope. F.R.E. 105.

H. Objections to Exhibit 2111, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2111 because Patent Owner did not authenticate it as a prior art publication (F.R.E. 602, 901), and thereby fails to demonstrate it is

relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2111 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2111 must be restricted to its proper scope. F.R.E. 105.

I. Objections to Exhibit 2118, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2118 because Patent Owner did not authenticate it as a prior art publication (F.R.E. 602, 901), and thereby fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2118 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2118 must be restricted to its proper scope. F.R.E. 105.

J. Objections to Exhibits 2149 and 2183, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Petitioner objects to each of Exhibits 2149 and 2183 for lack of foundation (F.R.E. 602), and for failing to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibits 2149 and 2183 are

hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibits 2149 and 2183 must each be restricted to its proper scope. F.R.E. 105.

K. Objections to Exhibit 2172, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2172 because Patent Owner did not authenticate it as a prior art publication (F.R.E. 602, 901), and thereby fails to demonstrate it is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2172 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2172 must be restricted to its proper scope. F.R.E. 105.

L. Objections to Exhibit 2190, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, and 901.

Petitioner objects to Exhibit 2190 for lack of foundation and demonstration of authenticity (F.R.E. 602, 901). Patent Owner also fails to demonstrate Exhibit 2190 is relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to the extent Exhibit 2190 is hearsay or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, Exhibit 2190 must be restricted to its proper scope. F.R.E. 105.

M. Objections to EX2191, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401-403, 602, 701-703, 705, 801-802, 37 C.F.R. § 42.65, and PTAB Consolidated Trial Practice Guide November 2019.

Petitioner objects to EX2191 to the extent Dr. Saad's testimony is not rationally based on his own personal and percipient knowledge (F.R.E. 602, 701) and to the extent he purports to provide any expert opinions or rely on hearsay. F.R.E. 702-703, 705, 801-802; 37 C.F.R. §42.65. Petitioner also objects to EX2191 to the extent its probative value is substantially outweighed by unfair prejudice and confusion of the issues (F.R.E. 401-403). This includes any reliance on any portion of EX2191 that is cited for a different purpose than that for which it is relied on in the Patent Owner Response.

Petitioner additionally objects to any portions of Dr. Saad's declaration that are not cited in the Patent Owner Response as an improper incorporation by reference. F.R.E. 401-403; 37 C.F.R. §42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide November 2019, 35.

N. Objections to EX2192, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401-403, 602, 701-703, 705, 37 C.F.R. § 42.65, and PTAB Consolidated Trial Practice Guide November 2019.

Petitioner objects to EX2192 to the extent Dr. Del Priore's testimony is not rationally based on his own personal and percipient knowledge (F.R.E. 602, 701)

and to the extent his testimony is not providing an opinion within Dr. Del Priore's knowledge, skill, experience, training, or education that is based on sufficient facts or data and is the product of reliable principles and methods reliably applied to the facts of this case (F.R.E. 702-703; 37 C.F.R. §42.65). Petitioner objects to EX2192 to the extent that Dr. Del Priore relies on facts or data that are not the kinds of facts or data an expert in Dr. Del Priore's particular field would rely on in forming an opinion on the subject. Petitioner also objects to EX2192 to the extent the probative value of Dr. Del Priore's testimony is substantially outweighed by unfair prejudice and confusion of the issues (F.R.E. 401-403). This includes any reliance on any portion of EX2192 that is cited for a different purpose than that for which it is relied on in the Patent Owner Response.

Petitioner additionally objects to any portions of Dr. Del Priore's declaration that are not cited in the Patent Owner Response as an improper incorporation by reference. F.R.E. 401-403; 37 C.F.R. §42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide November 2019, 35.

Furthermore, Petitioner objects to any portions of Dr. Del Priore's declaration applying an incorrect standard for evaluating the field from the perspective of a person of ordinary skill in the art or which are conclusory and unsupported. 37 C.F.R. § 42.65; *see also* PTAB Consolidated Trial Practice Guide November 2019, 40-41, F.R.E. 705.

O. Objections to Post-Critical Date Documents, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, and 801-802.

Petitioner objects to each of Exhibits 2054, 2061, 2070, 2071, 2075, 2100, 2101, 2102, 2117, 2134, 2135, 2144, 2145, 2149, 2159, 2160, 2161, 2165, 2166, 2167, 2171, 2174, 2176, 2179, 2180, 2181, 2185, 2187, 2188, and 2189, which are exhibits that do not purport to be available prior to the critical date. Patent Owner fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to each of these exhibits as lacking foundation (F.R.E. 602) and to the extent they are hearsay or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

P. Objections to Post-Critical Date Partial Web Printouts, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 106, 401-403, 602, and 801-802.

Petitioner objects to each of Exhibits 2086, 2087, 2088, 2090, 2157, 2177, and 2186, which are post-critical date, partial printouts that do not purport to be available prior to the critical date. Patent Owner fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they

are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to each of these exhibits as lacking foundation (F.R.E. 602) and lacking completeness (F.R.E. 106), and to the extent they are hearsay or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

Q. Objections to Post-Critical Date Alkeus Documents, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, and 801-802.

Petitioner objects to each of Exhibits 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2108, and 2182, which are post-critical date, Alkeus documents that do not purport to be available prior to the critical date. Patent Owner fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to each of these exhibits as lacking foundation (F.R.E. 602), and to the extent they are hearsay or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

R. Objections to Post-Critical Date Web Printouts, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, and 801-802.

Petitioner objects to each of Exhibits 2098, 2099, 2105, 2106, 2168, 2169, 2170, 2175, and 2178, which are post-critical date printouts that do not purport to be available prior to the critical date. Patent Owner fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to each of these exhibits as lacking foundation (F.R.E. 602), and to the extent they are hearsay or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

S. Objections to Post-Critical Date “Wayback” Documents, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, and 801-802.

Petitioner objects to each of Exhibits 2123, 2124, 2125, and 2131, which are post-critical date printouts that do not purport to be available prior to the critical date. Patent Owner fails to demonstrate that the post-critical date documents are prior art and, to that extent, fails to demonstrate they are relevant, and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Petitioner also objects to each of these exhibits as lacking

foundation (F.R.E. 602), and to the extent they are hearsay or contain hearsay.

F.R.E. 801-802. Even if admissible for some purpose, each of these exhibits must be restricted to its proper scope. F.R.E. 105.

III. **CONCLUSION**

The aforementioned exhibits were filed together with the Patent Owner's Response. These objections are made within 5 business days of service of the Patent Owner Response pursuant to 37 C.F.R. § 42.64.

Respectfully submitted,

Dated: September 30, 2024

/Jad A. Mills/
Jad A. Mills, Lead Counsel
Reg. No. 63,344

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Objections to Evidence was served on September 30, 2024, at the following electronic service addresses:

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Respectfully submitted,

Dated: September 30, 2024

/Jad A. Mills/
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