

Paper No. _____
Filed: March 4, 2025

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 MOTION TO EXCLUDE
37 C.F.R. §42.64(c)

I. INTRODUCTION

Petitioner (Gene Company) respectfully requests exclusion of Patent Owner (PO)'s exhibits 2001-2002, 2004-2005, 2007, 2010-2013, 2015, 2018, 2020-2021, 2024-2026, 2033, 2036-2037, 2077, and 2192, for violation of the Federal Rules of Evidence (FRE).

II. LEGAL STANDARD

The Federal Rules of Evidence (FRE) govern the admissibility of evidence submitted during an *inter partes* trial before the PTAB. 37 C.F.R. §42.62(a). The PTAB thus will exclude evidence from consideration when the proponent of that evidence fails to demonstrate its compliance with the FRE. *See* 37 C.F.R. §42.64(c).

III. THE SESSLER DECLARATION AND OTHER EXHIBITS NOT CITED POST-INSTITUTION (EXHIBITS 2001, 2002, 2004, 2005, 2007, 2010-2013, 2018, 2020, 2021, 2024-2026, 2033, 2036, AND 2037)

Exhibits 2036 and 2037 are the declaration and curriculum vitae of Dr. Jonathan L. Sessler, which was filed with Patent Owner's Preliminary Response (POPR). Upon institution, Petitioner timely objected to Dr. Sessler's declaration on grounds including relevance (FRE 401-403). Paper 17 at 5-6. Under FRE 401, evidence is relevant only if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. Irrelevant evidence is not

admissible. Fed. R. Evid. 402. For example, exhibits not cited by the parties in the documents governing an IPR trial have “no bearing on any fact that is of consequence in determining the outcome of the proceeding.” *One World Techs., Inc. v. The Chamberlain Grp., Inc.*, IPR2017-00126, Paper 56 at 16-17 (P.T.A.B. Oct. 24, 2018); *see also In re Nuvasive, Inc.*, 842 F. 3d 1376, 1380 (Fed. Cir. 2016) (preliminary response arguments waived unless argued in POR); Paper 14 at 9 (same). Under FRE 403, the Board may exclude even relevant evidence if its probative value is substantially outweighed by danger of unfair prejudice, confuses the issues, is misleading, or wastes time. Fed. R. Evid. 403.

On October 14, 2024, counsel for PO confirmed via email that PO was withdrawing Dr. Sessler’s testimony. PO has not cited Dr. Sessler’s declaration or CV post-institution, nor has PO cited, post-institution, numerous exhibits relied on as supporting evidence in Dr. Sessler’s declaration, including exhibits 2007, 2020, 2021, 2024, and 2025.

Exhibits 2001, 2002, 2004, 2005, 2010-2013, 2018, 2026, and 2033 are further exhibits not cited by PO in any post-institution briefing. Petitioner timely objected to each of these exhibits on various grounds, including under FRE 401-403. Paper 17 at 2-3, 7-8.

Additionally, none of exhibits 2001, 2002, 2004, 2005, 2007, 2010-2013, 2018, 2020, 2021, 2024-2026, 2033, 2036, and 2037 was cited in any expert

declarations filed with the POR. *See generally* EX2052, EX2191; EX2192.

As none of these exhibits have been cited by PO in any post-institution briefing, none has been shown to be relevant to any fact of consequence in these proceedings. Fed. R. Evid. 401-402. Moreover, any consideration of these exhibits would be unfairly prejudicial, as well as improper under the rules of these proceedings, including the APA. *See Nike, Inc. v. Adidas AG*, 955 F.3d 45, 52-53 (Fed. Cir. 2023); 5 U.S.C. §§ 554(b)(3), 554(c)(1), 706; Fed. R. Evid. 403. Accordingly, each of exhibits 2001, 2002, 2004, 2005, 2007, 2010-2013, 2018, 2020, 2021, 2024-2026, 2033, 2036, and 2037 should be excluded.

IV. HUSSEIN (EX2015)

Exhibit 2015 is a document filed with PO's Preliminary Response and identified in PO's exhibit list as "Rehan M. Hussain et al., *Stargardt macular dystrophy and evolving therapies, published in final edited form in* 18(10) Expert Opinion on Biological Therapy 1049-59 (2018)." Paper 10 at 2. PO provided no testimony regarding the source of EX2015, and Petitioner objected to EX2015 on authenticity grounds. PO did not serve supplemental evidence regarding EX2015.

To meet the authenticity requirement for admissibility, the proponent must "produce evidence sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901. The proponent, PO, claims that EX2015 is a paper published in 2018. *See* Paper 38 at 2; *see also* EX2052, ¶229 (citing

EX2015 as “Hussain 2018”). However, no witness testimony has been provided to establish this proposition or otherwise provide the source of EX2015. Nor has any other evidence been advanced by PO to satisfy the authenticity requirement for EX2015. Because PO has not met its burden to authenticate EX2015, it should be excluded at least for failing to meet the requirements of FRE 901.

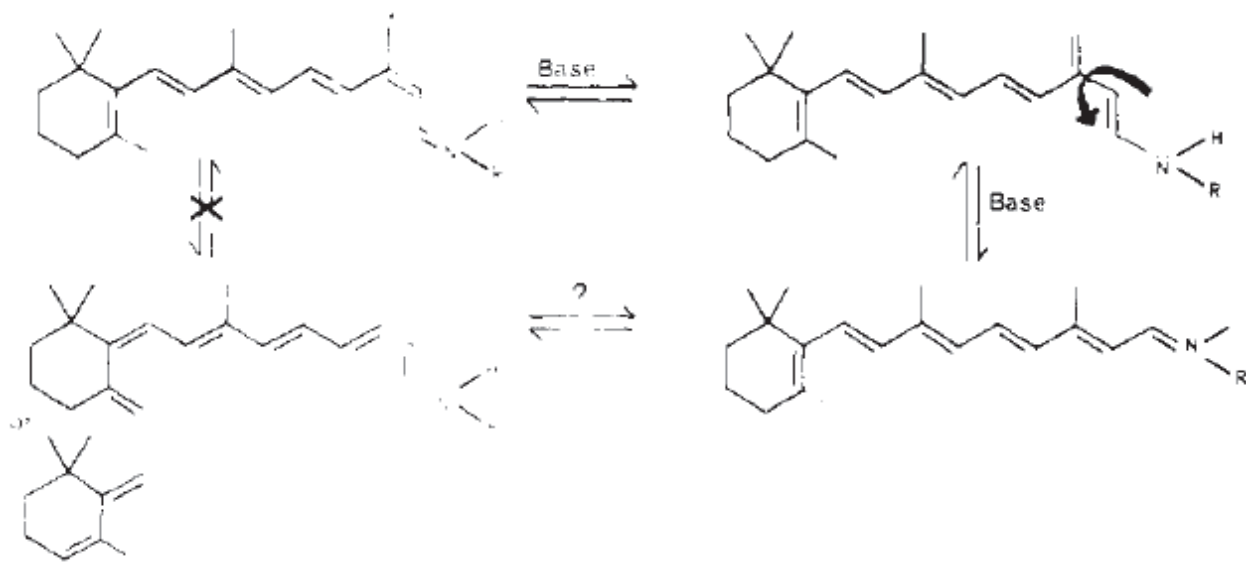
V. MOWERY (EX2077)

Exhibit 2077, filed with PO’s Response, is identified as a copy of a paper by Mowery et al. Petitioner objected to EX2077 under FRE 105, 106, 401-403, and 1002 as incomplete and illegible. Paper 25 at 2. For example, on page 3 of EX2077, Fig. 5 shows parts of chemical structures, but the structures are illegible and incomplete. In response to Petitioner’s objections, PO served EX2203 as supplemental evidence; however, the corresponding figure in EX2203 is also illegible.

An illegible copy of an original document should be excluded under F.R.E. 1002 and also for lack relevance, confusion, and unfair prejudice (FRE 401-403). Rule 1002 provides that an “original writing...is required in order to prove its content.” Fed. R. Evid. 1002. While FRE 1003 provides that a duplicate may be “admissible to the same extent as the original,” it is not admissible if “a genuine question is raised about the original’s authenticity or the circumstances make it unfair to admit the duplicate.” Fed. R. Evid. 1003. Where a copy includes defects

rendering it illegible, it is proper for the copy to be excluded, as admitting the illegible copy would be unfair. *See Lozano v. Ashcroft*, 258 F.3d 1160, 1166 (10th Cir. 2001) (photocopy inadmissible where “key information contained therein was barely legible”); *cf. Fountain v. United States*, 384 F.2d 624, 630 (5th Cir. 1967) (copy of tape not admitted where “it could not be accurately determined whether the copy in fact accurately reproduced” the original). Moreover, where a record contains ambiguous disclosure that invites speculation, it may be excluded under FRE 403. *See, e.g., Petrocelli v. Gallison*, 679 F.2d 286, 292 n.6 (1st Cir. 1982).

Here, Fig. 5 of EX2077 is illegible. Figure 5, reproduced below, is so faint that substantial portions of the depicted chemical structures are not discernable.



EX2077, Fig. 5. As further noted above, PO has not served supplemental evidence curing the deficiencies of EX2077. PO has thus failed to satisfy the requirements to admit EX2077 as a copy of an original document under Rules 1002-1003, as well

as the requirements of Rule 403 barring evidence where unfair prejudice substantially outweighs any probative value. Thus, EX2077 should be excluded, or at minimum consideration of it limited to exclude any reliance upon Fig. 5. Fed. R. Evid. 105.

VI. DEL PRIORE DECLARATION (EX2192)

Exhibit 2192 is a declaration by Dr. Lucian V. Del Priore filed with the POR. Petitioner timely objected to EX2192 as improper lay or expert testimony under FRE 602, 701-703, and 705, as well as objecting to EX2192 as irrelevant, unduly prejudicial, and confusing under FRE 401-403.

FRE 702 requires that a purported expert is sufficiently qualified by knowledge such that the testimony “will help the trier of fact to understand the evidence or to determine a fact in issue”; that “the testimony is based on sufficient facts or data”; that “the testimony is the product of reliable principles and methods”; and that “the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702. The proponent of expert testimony must demonstrate its admissibility by a preponderance of the evidence. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 n.10 (1993). Where an expert testifies “beyond the scope of his expertise as a technical witness,” his testimony is properly excluded. *Applied Med. Res. Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1381 (Fed. Cir. 1998).

In EX2192, Dr. Del Priore proffered opinions regarding enzyme reaction kinetics. *See* EX2192, ¶62. Subsequently, at deposition, when asked whether he was “an expert in enzyme kinetics,” Dr. Del Priore admitted that he was not an expert in enzyme kinetics. EX1069, 22:16-19 (“I have some knowledge, but would not hold myself out as an expert.”); *see also, e.g.*, EX2192, ¶¶109, 175, 179, 210-11, 216, 221 (citing section VI.B, including discussion of enzyme kinetics in paragraph 62, as underpinning further opinions). Because, by his own admission, Dr. Del Priore lacks the requisite expertise to provide testimony relating to enzyme kinetics, that testimony is inadmissible under FRE 702. Accordingly, Dr. Del Priore’s testimony relating to enzyme kinetics, including the discussion in paragraph 62 of his declaration and all testimony relying directly or indirectly upon that subject matter (e.g., EX2192, ¶¶109, 175, 179, 210-11, 216, 221), should be excluded. *See also* Fed. R. Evid. 105 (limiting evidence to proper scope).

VII. CONCLUSION

Accordingly, Exhibits 2001-2002, 2004-2005, 2007, 2010-2013, 2015, 2018, 2020-2021, 2024-2026, 2033, 2036-2037, 2077, and 2192 should be excluded or limited to their proper scope.

Respectfully submitted,

Dated: March 4, 2025

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

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Motion to Exclude was served on March 4, 2025, at the following electronic service addresses:

Mark J. Feldstein
Joshua L. Goldberg
Drew D. Christie
Matthew Hays Everhart
William C. Neer
FINNEGAN, HENDERSON,
FARABOW, GARRETT &
DUNNER LLP
mark.feldstein@finnegan.com
joshua.goldberg@finnegan.com
drew.christie@finnegan.com
matthew.everhart@finnegan.com
william.neer@finnegan.com

Eliot D. Williams
Paul A. Ragusa
Carolyn Pirraglia
BAKER BOTTS LLP
eliot.williams@bakerbotts.com
paul.ragusa@bakerbotts.com
carolyn.pirraglia@bakerbotts.com

Respectfully submitted,

Dated: March 4, 2025

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