

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTS,
Patent Owner.

Case No. PGR2023-00014
Patent 11,278,505

PETITIONER'S OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Forte Biosciences, Inc. (“Petitioner”) submits the following objections to University of Massachusetts’ (“Patent Owner”) Exhibits EX2002-EX2005, EX2009-EX2114, and any reference to or reliance on the foregoing Exhibits by Patent Owner. 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 EX2061, EX2098, and any Reference to/Reliance Thereon

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

Petitioner objects to EX2061 and EX2098 because the probative value of the exhibits are substantially outweighed by unfair prejudice and confusion of the issues. F.R.E. 401-403. The documents purport to be non-peer reviewed letters to the editor, including letters apparently created by individuals affiliated with Patent Owner (e.g., inventor of the challenged patent). Petitioner also objects to the extent the exhibits are or contain hearsay. F.R.E. 801-802. Even if admissible for some purpose, the exhibits must be restricted to its proper scope. F.R.E. 105.

B. Objections to EX2002, EX2028, EX2042, EX2053-EX2057, EX2059-EX2060, EX2065, EX2070, EX2073, EX2074, EX2079, EX2085, EX2110, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 703, 801-802, and 901.

Patent Owner relies on EX2002, EX2028, EX2042, EX2053-EX2057, EX2059-EX2060, EX2065, EX2070, EX2073, EX2074, EX2079, EX2085, and EX2110 as allegedly informative as to what was understood prior to the critical date, but Petitioner objects to each of the exhibits for Patent Owner's failure to authenticate the documents, especially as being publicly available before the critical date. F.R.E. 703, 901. Petitioner also objects to each of the exhibits as hearsay and as containing hearsay. F.R.E. 801-802. Moreover, Patent Owner fails to demonstrate that the post-critical date documents are 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, each exhibit must be restricted to its proper scope. F.R.E. 105.

C. Objections to EX2003-EX2004, EX2045-EX2046, EX2052, EX2096, EX2099, EX2101, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 703, 801-802, and 901.

Patent Owner relies on EX2003-EX2004, EX2045-EX2046, EX2052, EX2096, EX2099, and EX2101 as allegedly informative as to the patentability of the '505 patent, but Petitioner objects to each of the exhibits for Patent Owner's

failure to authenticate the documents, especially as being publicly available before the critical date. F.R.E. 703, 901. Petitioner also objects to each of the exhibits as hearsay and as containing hearsay. F.R.E. 801-802. Moreover, Patent Owner fails to demonstrate that the post-critical date documents are 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, each exhibit must be restricted to its proper scope. F.R.E. 105.

D. Objections to EX2005, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 401-403, 602, 701-703.

Petitioner objects to EX2005 to the extent Dr. Damsky'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. Damsky'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 also objects to EX2005 to the extent that Dr. Damsky relies on facts or data that are not the kinds of facts or data an expert in Dr. Damsky's particular field would rely on in forming an opinion on the subject. Petitioner also objects to EX2005 to the extent the probative value of Dr. Damsky'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 EX2005 that is cited for a different purpose than that for which it is relied on in the Patent Owner's Response.

E. Objections to EX2010-EX2012, EX2026, EX2033-EX2034, EX2036, EX2038-EX2040, EX2058, EX2062-EX2064, EX2066-EX2069, EX2080, EX2082-EX2084, EX2090, EX2095, EX2100, and any Reference to/Reliance Thereon

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

Patent Owner fails to demonstrate that EX2010-EX2012, EX2026, EX2033-EX2034, EX2036, EX2038-EX2040, EX2058, EX2062-EX2064, EX2066-EX2069, EX2080, EX2082-EX2084, EX2090, EX2095, and EX2100 are relevant and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Any assertions contained in the documents are inadmissible hearsay to the extent they are offered for the truth of any matters asserted. F.R.E. 801-802.

F. Objections to EX2013-EX2025, EX2027-EX2032, EX2037-EX2041, EX2043-EX2044, EX2047-EX2051, EX2071-EX2078 EX2085-EX2089, EX2091-EX2094, EX2102-EX2114, and any Reference to/Reliance Thereon

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

By submitting 112 new exhibits containing 3,443 pages, Patent Owner burdens the Board's efficiency and slows the path to justice by clogging the record with excessive numbers of documents lacking substantial probative value. For example, Patent Owner cites each of EX2013-EX2025, EX2027-EX2032,

EX2049-EX2051, EX2085, EX2087-EX2088, and EX2102-EX2114 to argue in a conclusory fashion that other inhibitors of IL-15 or IL-15R were known. POR, 9-12. But the Board has already explained why such evidence cannot save the challenged claims. Institution Decision at 19-20 (“Patent Owner argues that this disclosure of a ‘large variety and number of species that “might be used to achieve” vitiligo treatment is significantly more than what has been found sufficient’ in other cases to support written description of a claimed method.... Patent Owner’s argument is unpersuasive for at least two reasons....”). Patent Owner’s submission of excessive numbers of documents lacking substantial probative value imposes an undue burden on the Board and on Petitioner. F.R.E. 403.

Patent Owner similarly cites each of EX2037-EX2040, EX2043-EX2044, EX2071-EX2076, and EX2091-EX2094, respectively, in a conclusory manner to support vague premises. POR, 21 (arguing the specification incorporated references), POR, 8 (arguing a “common research paradigm” is shown), POR, 76 (arguing C3H/HeJ mice spontaneously develop autoimmune disease). Each of EX2041, EX2047, EX2048, EX2049, EX2077, EX2078, EX2086, and EX2089 is not even cited in the Patent Owner Response. Patent Owner’s submission of excessive number of documents to support conclusory and vague assertions violates Board rules and imposes an undue burden on the Board and on Petitioner.

F.R.E. 403; 37 CFR § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”).

Petitioner objects to these documents for being irrelevant and unnecessarily cumulative, as well for being a waste of time and for confusing the issue. Patent Owner fails to demonstrate each of the documents are relevant and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Any assertions contained in the documents are inadmissible hearsay to the extent they are offered for the truth of any matters asserted. F.R.E. 801-802. Even if admissible for some purpose, each exhibit must be restricted to its proper scope. F.R.E. 105.

G. Objections to EX2035, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 703, 801-802, and 901.

Petitioner objects to EX2035 for lack of foundation and for Patent Owner’s failure to authenticate EX2035, especially as to being publicly available before the critical date. F.R.E. 703, 901. Moreover, Patent Owner fails to demonstrate that the unauthenticated document 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 EX2035 to the extent it is or contains hearsay. F.R.E. 801-802. Even if admissible for some purpose, the exhibit must be restricted to its proper scope. F.R.E. 105.

H. Objections to EX2009 and EX2097, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 106, 401-403, 602, 703, and 801-802.

Petitioner objects to EX2009 and EX2097 because Patent Owner fails to demonstrate these documents are relevant and that unfair prejudice and confusion of the issues do not substantially outweigh any probative value. F.R.E. 401-403. Patent Owner submits a partial and incomplete record of its correspondence regarding its failed discovery request. The Board concluded that Patent Owner had not demonstrated an entitlement to the requested discovery but nonetheless authorized Patent Owner to propound a particular interrogatory. PGR2023-00014, Paper 17. Patent Owner failed to propound the Interrogatory before the Board's deadline and thereby waived any entitlement to discovery. As such, Petitioner objected to any use of its interrogatory response for any purpose. Patent Owner's submission of a partial record regarding its failed discovery request is unduly burdensome and unduly prejudicial, which substantially outweighs any probative value. F.R.E. 401-403.

III. CONCLUSION

The aforementioned exhibits were filed together with the patent owner's response. These objections are made within 5 business days of service with the reply pursuant to 37 C.F.R. § 42.64. For exhibits discussed at Dr. Abbas' or Dr. Plott's depositions, objections were also lodged at the time of the deposition.

Respectfully submitted,

Dated: October 11, 2023

/Michael T. Rosato/
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Patent Owner's Objections to Evidence was served on October 11, 2023, at the following electronic service addresses:

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Respectfully submitted,

Dated: October 11, 2023

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