

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PREOMICS GMBH AND BIOGNOSYS AG.,
Petitioners,

v.

THE BRIGHAM AND WOMEN'S HOSPITAL, INC.,
Patent Owner.

Case No. IPR2024-01473
Patent No. 11,435,360

PATENT OWNER'S OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), The Brigham and Women's Hospital, Inc. ("Patent Owner") submits the following objections to the Exhibits enumerated below that were submitted by PreOmics GmbH and Biognosys AG. ("Petitioners") with the Petition, and any reference to or reliance by the Petitioners on the same. Patent Owner'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, Patent Owner's objections below apply the Federal Rules of Evidence ("F.R.E.").

II. OBJECTIONS

A. Objections to EX1003, 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.

Patent Owner objects to EX1003 to the extent Dr. Vargas' testimony is not rationally based on her own personal and percipient knowledge (F.R.E. 602, 701) and to the extent her testimony is not providing an opinion within Dr. Vargas' 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). Patent Owner further objects to EX1003 to the extent Dr. Vargas is not shown to be qualified as a person of

ordinary skill in the art. F.R.E. 702; *see also Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022); *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340 (Fed. Cir. 2024). Patent Owner objects to EX1003 to the extent that Dr. Vargas relies on facts or data that are not the kinds of facts or data an expert in Dr. Vargas' particular field would rely on in forming an opinion on the subject. Patent Owner also objects to EX1003 to the extent Dr. Vargas' 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 EX1003 that is cited for a different purpose than that for which it is relied on in the Petition.

Patent Owner additionally objects to any portions of Dr. Vargas' declaration that are not cited in the Petition 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, Patent Owner objects to any portions of Dr. Vargas' 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 EX1005, and any Reference to/Reliance Thereon

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

Patent Owner objects to EX1005, which is a combination of pages created by Petitioners after the critical date for purposes of litigation. EX1012, ¶¶26-33. The pages appended with purported supplemental information have not properly been authenticated as being publicly available before the critical date. F.R.E. 901. Patent Owner thus also objects to EX1005 on the bases of hearsay (F.R.E. 802), lack of relevance, and being unhelpful to the trier of fact (F.R.E. 401-403). Patent Owner further objects to the exhibit as constituting an incomplete portion of a writing (excerpts of a larger writing). F.R.E. 106. Even if admissible for some purpose, EX1005 must be restricted to its proper scope. F.R.E. 105.

C. Objections to EX1009, and any Reference to/Reliance Thereon

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

Patent Owner objects to EX1009, which is an exhibit that does not purport to have been publicly available prior to the critical date. Petitioner thus objects to the document as hearsay. Furthermore, Petitioners fail to demonstrate that the post-critical date document is within the scope of this proceeding, 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, EX1009 must be restricted to its proper scope. F.R.E. 105.

D. Objections to EX1023, EX1025, and EX1032, and any Reference to/Reliance Thereon

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

Patent Owner objects to each of EX1023, EX1025, and EX1032 for constituting an incomplete portion of a writing (excerpts of a larger writing).

F.R.E. 106. Petitioners also fail to demonstrate that each of EX1023, EX1025, and EX1032 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, each of the exhibits must be restricted to its proper scope. F.R.E. 105.

E. Objections to EX1020, EX1021, and EX1030, and any Reference to/Reliance Thereon

Grounds for Objection: F.R.E. 105, 401-403, 602, 703, 802, 901.

In EX1020 and EX1021, Petitioners submit unauthenticated webpage printouts. EX1030 is an unauthenticated PDF document. None of EX1020, EX1021, and EX1030 purport to have been published before the critical date in an enumerated volume of a periodical publication. Patent Owner thus objects to each of EX1020, EX1021, and EX1030 for Petitioners' failure to authenticate the alleged prior art documents (F.R.E. 901), for lacking foundation (F.R.E. 602/703), and as constituting hearsay. F.R.E. 802. Petitioners fail to demonstrate that the unauthenticated documents are within the scope of this proceeding, 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 of EX1020, EX1021, and EX1030 must be restricted to its proper scope. F.R.E. 105.

III. CONCLUSION

The aforementioned exhibits were filed together with Petitioners' Petition for *Inter Partes* Review. Trial was instituted on April 17, 2025. These objections are made within 10 business days of institution pursuant to 37 C.F.R. § 42.64.

Respectfully submitted,

Date: May 1, 2025

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

CERTIFICATE OF SERVICE

I certify that the foregoing Patent Owner's Objections to Institution Decision was served on this 1st day of May, 2025, on the Petitioner at the following electronic service addresses:

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Date: May 1, 2025

/ Michael T. Rosato /
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