UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GENEOSCOPY, INC.,
Petitioner

v.

EXACT SCIENCES CORPORATION,
Patent Owner

_____

Case No. IPR2024-00459
U.S. Patent No. 11,634,781 B2

_____

PATENT OWNER'S SECOND NOTICE OF OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Exact Sciences Corporation ("Patent Owner"), submits the following objections to Petitioner Geneoscopy, Inc.'s ("Petitioner") Exhibits 1080-1088, and 1090-1091. As required by 37 C.F.R. § 42.62, Patent Owner's objections below apply the Federal Rules of Evidence ("FRE").

II. OBJECTIONS

A. Objections to Exhibit 1080 – Second Expert Declaration of Dr. Duncan Whitney

Grounds for Objection: FRE 401-403, 701-702, 801-803, 37 C.F.R. § 42.23

Patent Owner objects to the admissibility of certain portions of Exhibit 1080 under FRE 401-403. Patent Owner objects to Exhibit 1080 to the extent that is not cited in Petitioner's Reply, including but not limited to paragraphs 1-15, 44-47, 76, 82, 86, 91, and 96. Because petitioner's reply does not rely on those portions of Exhibit 1080, they are not relevant to the instituted grounds of review. Further, to the extent the uncited portions of Exhibit 1080 are deemed relevant, their admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that they are not cited in petitioner's reply. Patent Owner also objects to the admissibility of Ex. 1080 under FRE 701-702 to the extent Dr. Whitney offers unsupported opinions and/or

opinions outside the scope of his expertise. Patent Owner also objects to the admissibility of Exhibit 1080 under FRE 801-803 to the extent it includes hearsay.

Patent Owner further objects to Exhibit 1080 under 37 C.F.R. § 42.23(b) to the extent it contains impermissible new evidence cited in Petitioner's Reply in support of new arguments that were not made in the Petition, including, but not limited to, paragraphs 20-43, 51-75, 77-79, 88-90, 92, 94-95, 99-106, and 110-117.

B. Objections to Exhibit 1081 and 1082 – Cologard® Physicians Brochure and Cologuard® Instructions for Use

Grounds for Objection: FRE 106

Patent Owner objects to Exhibits 1081 and 1082 under FRE 106. The documents submitted as Exhibits 1081 and 1082 are both contained within Patent Owner's Exhibit 2032, information available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf, and such information in fairness should be considered as a whole.

C. Objections to Exhibit 1083 – "Cologuard Patent Coverage, 2024"[1]

Grounds for Objection: FRE 401-403, 901, 37 C.F.R. § 42.23

[1] Petitioner's Amended Exhibit List identifies EX1083 with the short name "Cologuard Patent Coverage, 2024." Patent Owner notes that the face of the

Patent Owner objects to the admissibility of Exhibit 1083 under FRE 401-403 as irrelevant to the merits of the proceeding, and because its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner also objects to the admissibility of Exhibit 1083 because Petitioner has not established that Exhibit 1083 is an authentic copy of what it purports to be. Patent Owner further objects to the admissibility of Exhibit 1083 under 37 C.F.R. § 42.23(b) because it is impermissible new evidence in support of new arguments that were not made in the Petition.

D. Objections to Exhibit 1084 – "Cologuard Patent Coverage, 2014"[2]

Grounds for Objection: FRE 401-403, 901, 37 C.F.R. § 42.23

Patent Owner objects to the admissibility of Exhibit 1084 under FRE 401-403 as irrelevant to the merits of the proceeding, and because its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner also objects to the admissibility of Exhibit 1084 because Petitioner has not

document submitted as Exhibit 1083 suggests that it is from 2014. Patent Owner's objections apply to Exhibits 1083 and 1084.

[2] Petitioner's Amended Exhibit List identifies EX1084 with the short name "Cologuard Patent Coverage, 2014." Patent Owner notes that the document submitted as Exhibit 1084 includes no indication that it is from 2014. Patent Owner's objections apply to Exhibits 1083 and 1084.

established that Exhibit 1084 is an authentic copy of what it purports to be. Patent Owner further objects to the admissibility of Exhibit 1084 under 37 C.F.R. § 42.23(b) because it is impermissible new evidence in support of new arguments that were not made in the Petition.

E. Objections to Exhibit 1085 - '278 Patent

Grounds for Objection: FRE 401-403, 37 C.F.R. § 42.23

Patent Owner objects to the admissibility of Exhibit 1085 under FRE 401-403 as irrelevant to the merits of the proceeding, and because its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner further objects to the admissibility of Exhibit 1085 under 37 C.F.R. § 42.23(b) because it is impermissible new evidence in support of new arguments that were not made in the Petition.

F. Objections to Exhibit 1086 - '278 Patent Office Action Response

Grounds for Objection: FRE 401-403, 37 C.F.R. § 42.23

Patent Owner objects to the admissibility of Exhibit 1086 under FRE 401-403 as irrelevant to the merits of the proceeding, and because its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner further objects to the admissibility of Exhibit 1086 under 37 C.F.R. § 42.23(b)

because it is impermissible new evidence in support of new arguments that were not made in the Petition.

G. Objections to Exhibit 1087 – Feiger

Grounds for Objection: FRE 401-403, 37 C.F.R. § 42.23

Patent Owner objects to the admissibility of Exhibit 1087 under FRE 401-403 as irrelevant to the merits of the proceeding, and because its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner further objects to the admissibility of Exhibit 1087 under 37 C.F.R. § 42.23(b) because it is impermissible new evidence in support of new arguments that were not made in the Petition.

H. Objections to Exhibit 1088 – "Exact Sciences Cologuard web page"

Grounds for Objection: FRE 401-403, 37 C.F.R. § 42.23.

Patent Owner objects to the admissibility of Exhibit 1088 under FRE 401-403. Patent Owner objects to the admissibility of Exhibit 1088 because it is not cited in Petitioner's Reply. Because the Reply does not rely on Exhibit 1088, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1088 is deemed relevant, its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time. Patent Owner further objects to the

admissibility of Exhibit 1088 under 37 C.F.R. § 42.23(b) because it is impermissible new evidence cited by Petitioner's expert in support of new arguments that were not made in the Petition.

I. Objections to Exhibit 1090 – Backman Deposition Transcript

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Ex. 1090 under FRE 401-403 to the extent it contains testimony irrelevant to the proceeding.

J. Objections to Exhibit 1091 – Wood LinkedIn Page

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1091 under FRE 401-403. Patent Owner objects to the admissibility of Exhibit 1091 because it is not cited in Petitioner's Reply. Because the Reply does not rely on Exhibit 1091, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1091 is deemed relevant, its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, and wasting time.

Date: February 3, 2025 By: */James Glass/*

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CERTIFICATE OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

The undersigned hereby certifies that the foregoing document was served in its entirety on February 3, 2025 upon the following parties via Electronic Mail:

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Date: February 3, 2025

By: */James Glass/*

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