

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner

v.

EXACT SCIENCES CORPORATION,
Patent Owner

Case No. IPR2024-01330
U.S. Patent No. 11,970,746

PATENT OWNER'S 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 1002, 1004-1006, 1010-1013, 1016, 1020-1029, 1031-1032, and 1034-1083. 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 1002 – Declaration of Dr. Duncan Whitney**

Grounds for Objection: FRE 401-403, 701-702, 801-803.

Patent Owner objects to the admissibility of certain portions of Exhibit 1002 under FRE 401-403 and 801-803. Patent Owner objects to Exhibit 1002 to the extent that is not cited by the petition, including but not limited to paragraphs 1-8, 14-16, 89-99, 103-106, 112, and 143. Because the petition does not rely on those portions of Exhibit 1002, they are not relevant to the instituted grounds of review. Further, to the extent the uncited portions of Exhibit 1002 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 the petition. Patent Owner further objects to the admissibility of Exhibit 1002 under FRE 801-803 to the extent it includes hearsay. Patent

Owner also objects to the admissibility of Ex. 1002 under FRE 701-702 to the extent Dr. Whitney offers unsupported opinions and/or opinions outside the scope of his expertise.

B. Objections to Exhibit 1004 – Lenhard

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1004 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1004 is an authentic copy. Patent Owner further objects to Exhibit 1004 as hearsay. Patent Owner further objects to Exhibit 1004 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

C. Objections to Exhibit 1005 – Vilkin

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1005 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1005 is an authentic copy. Patent Owner further objects to Exhibit 1005 as hearsay. Patent Owner further objects to Exhibit 1005 as Petitioner has not established that it is a printed publication, including the date by which it became publicly

available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

D. Objections to Exhibit 1006 – Itzkowitz

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1006 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1006 is an authentic copy. Patent Owner further objects to Exhibit 1006 as hearsay. Patent Owner further objects to Exhibit 1006 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

E. Objections to Exhibit 1010 – Melvin

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1010 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1010 is an authentic copy. Patent Owner further objects to Exhibit 1010 as hearsay. Patent Owner further objects to Exhibit 1010 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

F. Objections to Exhibit 1011 – Nishikawa

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1011 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1011 is an authentic copy. Patent Owner further objects to Exhibit 1011 as hearsay. Patent Owner further objects to Exhibit 1011 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

G. Objections to Exhibit 1012 – Kutzner

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1012 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1012 is an authentic copy. Patent Owner further objects to Exhibit 1012 as hearsay. Patent Owner further objects to Exhibit 1012 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

H. Objections to Exhibit 1013 – Levin

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1013 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1013 is an authentic copy. Patent Owner further objects to Exhibit 1013 as hearsay. Patent Owner further objects to Exhibit 1013 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

I. Objections to Exhibit 1016 – Joost Louwagie LinkedIn Page

Grounds for Objection: FRE 106, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1016 under FRE 106, 801-803, and 901-902. Petitioner proffers this exhibit as the LinkedIn Page of Joost Louwagie. The exhibit submitted appears incomplete and thus is objected to as an incomplete writing under FRE 106. Petitioner also has not established that Exhibit 1016 is an authentic copy. Patent Owner further objects to Exhibit 1016 as hearsay. Patent Owner further objects to Exhibit 1016 as Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

J. Objections to Exhibit 1020 – Young 2007

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1020 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1020 is an authentic copy. Patent Owner further objects to Exhibit 1020 as hearsay. Patent Owner further objects to Exhibit 1020 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

K. Objections to Exhibit 1021 – Guittet

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1021 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1021 is an authentic copy. Patent Owner further objects to Exhibit 1021 as hearsay. Patent Owner further objects to Exhibit 1021 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

L. Objections to Exhibit 1022 – Olson

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1022 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1022 is an

authentic copy. Patent Owner further objects to Exhibit 1022 as hearsay. Patent Owner further objects to Exhibit 1022 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

M. Objections to Exhibit 1023 – Hoepffner

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1023 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1023 is an authentic copy. Patent Owner further objects to Exhibit 1023 as hearsay. Patent Owner further objects to Exhibit 1023 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

N. Objections to Exhibit 1024 – Nechvatal

Grounds for Objection: FRE 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1024 under FRE 801-803 and 901-902. Petitioner has not established that Exhibit 1024 is an authentic copy. Patent Owner further objects to Exhibit 1024 as hearsay. Patent Owner further objects to Exhibit 1024 as Petitioner has not established

that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

O. Objections to Exhibit 1025 – Cologuard Launch Press Release

Grounds for Objection: FRE 401-403, 901

Patent Owner objects to the admissibility of Exhibit 1025 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 1025 because Petitioner has not established that Exhibit 1025 is an authentic copy of what it purports to be.

P. Objections to Exhibit 1026 – “Cologuard Patent Coverage, 2024”

Grounds for Objection: FRE 401-403, 901

Patent Owner objects to the admissibility of Exhibit 1026 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 1026 because Petitioner has not established that Exhibit 1026 is an authentic copy of what it purports to be.

Q. Objections to Exhibit 1027 – “Cologuard Patent Coverage, 2014”

Grounds for Objection: FRE 401-403, 901

Patent Owner objects to the admissibility of Exhibit 1027 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 1027 because Petitioner has not established that Exhibit 1027 is an authentic copy of what it purports to be.

R. Objections to Exhibit 1028 - '278 Patent

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1028 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.

S. Objections to Exhibit 1029 - '278 Patent Office Action Response

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1029 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.

T. Objections to Exhibit 1031 – IPR2024-00459 Petition

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1031 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.

U. Objections to Exhibit 1032 – IPR2024-00459 POPR

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1034 under FRE 401-403. Patent Owner objects to Exhibit 1032 as it is not cited by the petition. Because the petition does not rely on Exhibit 1032, it is not relevant to the instituted grounds of review.

V. Objections to Exhibit 1034 – Simon

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1034 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1034 as it is not cited by the petition. Because the petition does not rely on Exhibit 1034, it is not relevant to the instituted grounds of review. Further, to the extent

Exhibit 1034 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1034 is an authentic copy. Patent Owner further objects to Exhibit 1034 as hearsay. Patent Owner further objects to Exhibit 1034 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

W. Objections to Exhibit 1035 – Sidransky

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1035 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1035 as it is not cited by the petition. Because the petition does not rely on Exhibit 1035, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1035 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1035 is an authentic copy. Patent Owner further objects to Exhibit 1035 as hearsay. Patent Owner further objects to Exhibit 1035 as Petitioner has not established that it is a printed publication, including the date by which it became publicly

available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

X. Objections to Exhibit 1036 – Muller

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1036 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1036 as it is not cited by the petition. Because the petition does not rely on Exhibit 1036, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1036 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1036 is an authentic copy. Patent Owner further objects to Exhibit 1036 as hearsay. Patent Owner further objects to Exhibit 1036 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

Y. Objections to Exhibit 1037 – Schuebel

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1037 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1037 as it

is not cited by the petition. Because the petition does not rely on Exhibit 1037, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1037 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1037 is an authentic copy. Patent Owner further objects to Exhibit 1037 as hearsay. Patent Owner further objects to Exhibit 1037 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

Z. Objections to Exhibit 1038 – Shen

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1038 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1038 as it is not cited by the petition. Because the petition does not rely on Exhibit 1038, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1038 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1038 is an authentic copy. Patent Owner further objects to Exhibit 1038 as hearsay.

Patent Owner further objects to Exhibit 1038 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

AA. Objections to Exhibit 1039 – Tagore

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1039 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1039 as it is not cited by the petition. Because the petition does not rely on Exhibit 1039, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1039 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1039 is an authentic copy. Patent Owner further objects to Exhibit 1039 as hearsay. Patent Owner further objects to Exhibit 1039 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

BB. Objections to Exhibit 1040 – Rennert

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1040 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1040 as it is not cited by the petition. Because the petition does not rely on Exhibit 1040, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1040 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1040 is an authentic copy. Patent Owner further objects to Exhibit 1040 as hearsay. Patent Owner further objects to Exhibit 1040 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

CC. Objections to Exhibit 1041 – Grow

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1041 under FRE 401-403. Patent Owner objects to Exhibit 1041 as it is not cited by the petition. Because the petition does not rely on Exhibit 1041, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1041 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

DD. Objections to Exhibit 1042 – Imperiale 2004

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1042 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1042 as it is not cited by the petition. Because the petition does not rely on Exhibit 1042, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1042 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1042 is an authentic copy. Patent Owner further objects to Exhibit 1042 as hearsay. Patent Owner further objects to Exhibit 1042 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

EE. Objections to Exhibit 1043 – Ahlquist 2008

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1043 under FRE 401-403, 801-803 and 901-902. Patent Owner objects to Exhibit 1043 as it is not cited by the petition. Because the petition does not rely on Exhibit 1043, it is not relevant to the instituted grounds of review. Further, to the extent

Exhibit 1043 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1043 is an authentic copy. Patent Owner further objects to Exhibit 1043 as hearsay. Patent Owner further objects to Exhibit 1043 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

FF. Objections to Exhibit 1044 – Young 2004

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1044 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1044 as it is not cited by the petition. Because the petition does not rely on Exhibit 1044, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1044 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1044 is an authentic copy. Patent Owner further objects to Exhibit 1044 as hearsay. Patent Owner further objects to Exhibit 1044 as Petitioner has not established that it is a printed publication, including the date by which it became publicly

available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

GG. Objections to Exhibit 1045 – Karl

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1045 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1045 as it is not cited by the petition. Because the petition does not rely on Exhibit 1045, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1045 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1045 is an authentic copy. Patent Owner further objects to Exhibit 1045 as hearsay. Patent Owner further objects to Exhibit 1045 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

HH. Objections to Exhibit 1046 – White

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1046 under FRE 401-403, 801-803 and 901-902. Patent Owner objects to Exhibit 1046 as it is

not cited by the petition. Because the petition does not rely on Exhibit 1046, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1046 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1046 is an authentic copy. Patent Owner further objects to Exhibit 1046 as hearsay. Patent Owner further objects to Exhibit 1046 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

II. Objections to Exhibit 1047 – Mahon

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1047 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1047 as irrelevant because it is not prior art and thus is irrelevant to a person of ordinary skill's knowledge and understanding at the relevant time. Patent Owner also objects to Exhibit 1047 as it is not cited by the petition. Because the petition does not rely on Exhibit 1047, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1047 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in

view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1047 is an authentic copy. Patent Owner further objects to Exhibit 1047 as hearsay. Patent Owner further objects to Exhibit 1047 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

JJ. Objections to Exhibit 1048 – Beaulieu

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1048 under FRE 401-403. Patent Owner objects to Exhibit 1048 as it is not cited by the petition. Because the petition does not rely on Exhibit 1048, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1048 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

KK. Objections to Exhibit 1049 – Ostrow

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1049 under FRE 401-403, 801-803 and 901-902. Patent Owner objects to Exhibit 1049 as it is not cited by the petition. Because the petition does not rely on Exhibit 1049,

it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1049 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1049 is an authentic copy. Patent Owner further objects to Exhibit 1049 as hearsay. Patent Owner further objects to Exhibit 1049 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

LL. Objections to Exhibit 1050 – Cleator

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1050 under FRE 401-403. Patent Owner objects to Exhibit 1050 as it is not cited by the petition. Because the petition does not rely on Exhibit 1050, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1050 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

MM. Objections to Exhibit 1051 – Kahi

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1051 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1051 as it is not cited by the petition. Because the petition does not rely on Exhibit 1051, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1051 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1051 is an authentic copy. Patent Owner further objects to Exhibit 1051 as hearsay. Patent Owner further objects to Exhibit 1051 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

NN. Objections to Exhibit 1052 – Zou

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1052 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1052 as it is not cited by the petition. Because the petition does not rely on Exhibit 1052, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1052 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the

petition. In addition, Petitioner has not established that Exhibit 1052 is an authentic copy. Patent Owner further objects to Exhibit 1052 as hearsay. Patent Owner further objects to Exhibit 1052 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

OO. Objections to Exhibit 1053 – Eguchi

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1053 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1053 as it is not cited by the petition. Because the petition does not rely on Exhibit 1053, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1053 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1053 is an authentic copy. Patent Owner further objects to Exhibit 1053 as hearsay. Patent Owner further objects to Exhibit 1053 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

PP. Objections to Exhibit 1054 – Villa

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1054 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1054 as it is not cited by the petition. Because the petition does not rely on Exhibit 1054, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1054 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1054 is an authentic copy. Patent Owner further objects to Exhibit 1054 as hearsay. Patent Owner further objects to Exhibit 1054 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

QQ. Objections to Exhibit 1055 – Boynton

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1055 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1055 as it is not cited by the petition. Because the petition does not rely on Exhibit 1055, it is not relevant to the instituted grounds of review. Further, to the extent

Exhibit 1055 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1055 is an authentic copy. Patent Owner further objects to Exhibit 1055 as hearsay. Patent Owner further objects to Exhibit 1055 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

RR. Objections to Exhibit 1056 – Jessup

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1056 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1056 as it is not cited by the petition. Because the petition does not rely on Exhibit 1056, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1056 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1056 is an authentic copy. Patent Owner further objects to Exhibit 1056 as hearsay. Patent Owner further objects to Exhibit 1056 as Petitioner has not established that it is a printed publication, including the date by which it became publicly

available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

SS. Objections to Exhibit 1057 – Chen

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1057 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1057 as it is not cited by the petition. Because the petition does not rely on Exhibit 1057, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1057 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1057 is an authentic copy. Patent Owner further objects to Exhibit 1057 as hearsay. Patent Owner further objects to Exhibit 1057 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

TT. Objections to Exhibit 1058 – Itzkowitz 2008

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1058 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1058 as it

is not cited by the petition. Because the petition does not rely on Exhibit 1058, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1058 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1058 is an authentic copy. Patent Owner further objects to Exhibit 1058 as hearsay. Patent Owner further objects to Exhibit 1058 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

UU. Objections to Exhibit 1059 – Li

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1059 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1059 as it is not cited by the petition. Because the petition does not rely on Exhibit 1059, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1059 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1059 is an authentic copy. Patent Owner further objects to Exhibit 1059 as hearsay.

Patent Owner further objects to Exhibit 1059 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

VV. Objections to Exhibit 1060 – Kanaoka 2004

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1060 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1060 as it is not cited by the petition. Because the petition does not rely on Exhibit 1060, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1060 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1060 is an authentic copy. Patent Owner further objects to Exhibit 1060 as hearsay. Patent Owner further objects to Exhibit 1060 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

WW. Objections to Exhibit 1061 – Matsumura 1992

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1061 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1061 as it is not cited by the petition. Because the petition does not rely on Exhibit 1061, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1061 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1061 is an authentic copy. Patent Owner further objects to Exhibit 1061 as hearsay. Patent Owner further objects to Exhibit 1061 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

XX. Objections to Exhibit 1062 – Matsumura 1994

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1062 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1062 as it is not cited by the petition. Because the petition does not rely on Exhibit 1062, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1062 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the

petition. In addition, Petitioner has not established that Exhibit 1062 is an authentic copy. Patent Owner further objects to Exhibit 1062 as hearsay. Patent Owner further objects to Exhibit 1062 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

YY. Objections to Exhibit 1063 – Leung

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1063 under FRE 401-403, 801-803 and 901-902. Patent Owner objects to Exhibit 1063 as it is not cited by the petition. Because the petition does not rely on Exhibit 1063, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1063 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1063 is an authentic copy. Patent Owner further objects to Exhibit 1063 as hearsay. Patent Owner further objects to Exhibit 1063 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

ZZ. Objections to Exhibit 1064 – Ahmed

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1064 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1064 as it is not cited by the petition. Because the petition does not rely on Exhibit 1064, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1064 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1064 is an authentic copy. Patent Owner further objects to Exhibit 1064 as hearsay. Patent Owner further objects to Exhibit 1064 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

AAA. Objections to Exhibit 1065 – Ahlquist 2000

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1065 under FRE 401-403, 801-803 and 901-902. Patent Owner objects to Exhibit 1065 as it is not cited by the petition. Because the petition does not rely on Exhibit 1065, it is not relevant to the instituted grounds of review. Further, to the extent

Exhibit 1065 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1065 is an authentic copy. Patent Owner further objects to Exhibit 1065 as hearsay. Patent Owner further objects to Exhibit 1065 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

BBB. Objections to Exhibit 1066 – Ahlquist 2000(b)

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1066 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1066 as it is not cited by the petition. Because the petition does not rely on Exhibit 1066, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1066 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1066 is an authentic copy. Patent Owner further objects to Exhibit 1066 as hearsay. Patent Owner further objects to Exhibit 1066 as Petitioner has not established that it is a printed publication, including the date by which it became publicly

available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

CCC. Objections to Exhibit 1067 – Taylor

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1067 under FRE 401-403. Patent Owner objects to Exhibit 1067 as irrelevant because it is not prior art and thus is irrelevant to a person of ordinary skill's knowledge and understanding at the relevant time. Patent Owner also objects to Exhibit 1067 as it is not cited by the petition. Because the petition does not rely on Exhibit 1067, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1067 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

DDD. Objections to Exhibit 1068 – Lapidus '650

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1068 under FRE 401-403. Patent Owner objects to Exhibit 1068 as it is not cited by the petition. Because the petition does not rely on Exhibit 1068, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1068 is

deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

EEE. Objections to Exhibit 1069 – Lapidus '178

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1069 under FRE 401-403. Patent Owner objects to Exhibit 1069 as it is not cited by the petition. Because the petition does not rely on Exhibit 1069, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1069 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

FFF. Objections to Exhibit 1070 – Hirata

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1070 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1070 as it is not cited by the petition. Because the petition does not rely on Exhibit 1070, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1070 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1070 is an authentic copy. Patent Owner further objects to Exhibit 1070 as hearsay.

Patent Owner further objects to Exhibit 1070 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

GGG. Objections to Exhibit 1071 – Ahlquist 1988

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1071 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1071 as it is not cited by the petition. Because the petition does not rely on Exhibit 1071, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1071 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1071 is an authentic copy. Patent Owner further objects to Exhibit 1071 as hearsay. Patent Owner further objects to Exhibit 1071 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

HHH. Objections to Exhibit 1072 – Lenhard Printout

Grounds for Objection: FRE 106, 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1072 under FRE 106, 401-403, 801-803, and 901-902. Petitioner proffers this exhibit as a printout of *Clinical Gastroenterology and Hepatology* website. The exhibit submitted appears incomplete and thus is objected to as an incomplete writing under FRE 106. Patent Owner also objects to Exhibit 1072 as it is not cited by the petition. Because the petition does not rely on Exhibit 1072, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1072 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1072 is an authentic copy. Patent Owner further objects to Exhibit 1072 as hearsay. Patent Owner further objects to Exhibit 1072 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

III. Objections to Exhibit 1073 – Van Engeland

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1073 under FRE 401-403. Patent Owner objects to Exhibit 1073 as it is not cited by the petition. Because the petition does not rely on Exhibit 1073, it is not relevant

to the instituted grounds of review. Further, to the extent Exhibit 1073 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

JJJ. Objections to Exhibit 1074 – Itzkowitz Printout

Grounds for Objection: FRE 106, 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1074 under FRE 106, 401-403, 801-803, and 901-902. Petitioner proffers this exhibit as a printout of *Clinical Gastroenterology and Hepatology* website. The exhibit submitted appears incomplete and thus is objected to as an incomplete writing under FRE 106. Patent Owner also objects to Exhibit 1074 as it is not cited by the petition. Because the petition does not rely on Exhibit 1074, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1074 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1074 is an authentic copy. Patent Owner further objects to Exhibit 1074 as hearsay. Patent Owner further objects to Exhibit 1074 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

KKK. Objections to Exhibit 1075 – Itzkowitz Press Release

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1075 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1075 as it is not cited by the petition. Because the petition does not rely on Exhibit 1075, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1075 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner proffers this exhibit as a press release issued on December 13, 2006. Petitioner has not established that Exhibit 1075 is an authentic copy. Patent Owner further objects to Exhibit 1075 as hearsay. Patent Owner further objects to Exhibit 1075 as Petitioner has not established that it is a printed publication, including the date by which it became publicly available. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

LLL. Objections to Exhibit 1076 – Cologuard Patient Guide

Grounds for Objection: FRE 106, 401-403.

Patent Owner objects to the admissibility of Exhibit 1076 under FRE 401-403. Patent Owner objects to Exhibit 1076 as it is not cited by the petition. Because the petition does not rely on Exhibit 1076, it is not relevant

to the instituted grounds of review. Further, to the extent Exhibit 1076 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

MMM. Objections to Exhibit 1077 – Imperiale 2014

Grounds for Objection: FRE 401-403, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1077 under FRE 401-403, 801-803, and 901-902. Patent Owner objects to Exhibit 1077 as irrelevant because it is not prior art and thus is irrelevant to a person of ordinary skill's knowledge and understanding at the relevant time. Patent Owner also objects to Exhibit 1047 as it is not cited by the petition. Because the petition does not rely on Exhibit 1077, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1077 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. In addition, Petitioner has not established that Exhibit 1077 is an authentic copy. Patent Owner further objects to Exhibit 1077 as hearsay. Petitioner has not produced evidence sufficient to support a finding that the item is what Petitioner claims it is.

NNN. Objections to Exhibit 1078 – Exact Sciences 2023 Form 10-K

Grounds for Objection: FRE 401-403.

Patent Owner objects to the admissibility of Exhibit 1078 under FRE 401-403. Patent Owner objects to Exhibit 1078 as it is not cited by the petition. Because the petition does not rely on Exhibit 1078, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1078 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition.

**OOO. Objections to Exhibit 1079 – Exact Sciences
Cologuard Web Page**

Grounds for Objection: FRE 401-403

Patent Owner objects to the admissibility of Exhibit 1079 under FRE 401-403. Patent Owner objects to the admissibility of Exhibit 1079 because it is not cited in Petitioner’s Reply. Because the Reply does not rely on Exhibit 1079, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1079 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.

PPP. Objections to Exhibit 1080 – Cologuard Physician Brochure

Grounds for Objection: FRE 106

Patent Owner objects to Exhibits 1080 under FRE 106. The document at Exhibit 1076 is part of information available at

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf, and such information in fairness should be considered as a whole.

QQQ. Objections to Exhibit 1081 – Cologuard Instructions for Use

Grounds for Objection: FRE 106

Patent Owner objects to Exhibits 1081 under FRE 106. The document at Exhibit 1081 is part of information available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf, and such information in fairness should be considered as a whole.

RRR. Objections to Exhibit 1082 - Whitney Declaration in IPR2024-00459

Grounds for Objection: FRE 401-403, 701-702, 801-803.

Patent Owner objects to the admissibility of certain portions of Exhibit 1002 under FRE 401-403 and 801-803. Patent Owner objects to Exhibit 1082 as it is not cited in the Petition. Because the petition does not cite to Exhibit 1082, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1082 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition as well as to the extent that it is duplicative of Exhibit 1002. Patent Owner further objects to the admissibility of Exhibit 1082 under FRE 801-803 to the extent it includes hearsay. Patent Owner also objects to

the admissibility of Ex. 1082 under FRE 701-702 to the extent Dr. Whitney offers unsupported opinions and/or opinions outside the scope of his expertise.

SSS. Objections to Exhibit 1083 – Jones Declaration

Grounds for Objection: FRE 401-403, 602, 801-803, 901-902.

Patent Owner objects to the admissibility of Exhibit 1083 under FRE 401-403, 602, 801-803, and 901-902. Patent Owner objects to Exhibit 1083 as it is not cited by the petition. Because the petition does not rely on Exhibit 1083, it is not relevant to the instituted grounds of review. Further, to the extent Exhibit 1060 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the petition. Moreover, Petitioner proffers Exhibit 1083 as a declaration of Brendan T. Jones. Patent Owner objects to Exhibit 1083 under FRE 602 for Petitioner's failure to introduce sufficient evidence to establish that the declarant, Brendan T. Jones, had personal knowledge of the subject matter stated in Exhibit 1083. In addition, Patent Owner objects to Exhibit 1083 as hearsay. Patent Owner further objects to Exhibit 1083 as Petitioner has not established that the items described in Exhibit 1083 are printed publications, including the dates by which they became publicly available. Petitioner has not produced evidence sufficient to support a finding that the items identified in Exhibit 1083 are what Petitioner claims they are.

Date: March 3, 2025

By: /James Glass/
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Counsel for Patent Owner
Exact Sciences Corporation

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 March 3, 2025 upon the following parties via Electronic Mail:

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Date: March 3, 2025

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