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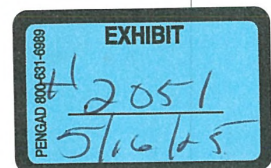
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXACT SCIENCES CORPORATION,
Plaintiff,
V. C.A. No. 23-1319 (MN)
CONSOLIDATED
GENEOSCOPY, INC.,
Defendant.

[REDACTED]

VIDEOTAPED DEPOSITION
DUNCAN WHITNEY PhD
Thursday, January 9, 2025
Boston, Massachusetts

Reporter: Deborah L. Roth, RPR, CSR
Job No.: 7076674



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Exact Sciences Ex. 2054, Page 1 of 116

Exact Sciences Ex. 2051, Page 1 of 116

1 Thursday, January 9, 2025 2 10:07 a.m. 3 4 Videotaped Deposition of 5 DUNCAN WHITNEY, PhD, held at the offices 6 of Quinn Emanuel Urquhart & Sullivan, LLP, 7 111 Huntington Avenue Suite 520, pursuant 8 to Notice before Deborah Roth, a Certified 9 Reporter and Notary Public of the 10 Commonwealth of Massachusetts. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 Page 2	1 APPEARANCES: 2 3 ATTORNEY(S) FOR DEFENDANT AND WITNESS: 4 Brendan Jones, PhD, Esquire 5 FOLEY HOAG LLP 6 Seaport West 7 155 Seaport Boulevard 8 Boston, Massachusetts 02210 9 (617) 832-1000 10 bjones@foleyhoag.com 11 12 13 ALSO PRESENT: 14 Sean Budd, Videographer 15 Alexandra M. Gorman, Esquire 16 17 PRESENT VIA ZOOM: 18 19 Carly Conway, Esquire, 20 Exact Science 21 (Morning session only.) 22 23 24 Page 4
1 APPEARANCES: 2 3 ATTORNEY(S) FOR PLAINTIFF: 4 Sandra Haberny, PhD, Esquire 5 QUINN EMANUEL URQUHART & SULLIVAN, LLP 6 865 S. Figueroa Street 7 10th Floor 8 Los Angeles, California 90017 9 (213) 443-3000 10 sandrahaberny@quinnemanuel.com 11 -and - 12 Jihong Lou, Esquire 13 QUINN EMANUEL URQUHART & SULLIVAN LLP 14 1300 I St NW 15 Suite 900 16 Washington, DC 20005 17 (202) 538-8000 18 jihonglou@quinnemanuel.com 19 20 21 22 23 24 Page 3	1 PROCEEDINGS 2 THE VIDEOGRAPHER: Stand by. 3 Okay. We are on the record. The 4 videographer speaking, Sean Budd, with 5 Veritex Legal Solutions. 6 Today's date is January 9, 2015 7 and the time is 10:07 a.m. We are here in 8 Boston, Massachusetts to take the video 9 deposition of Duncan Whitney PhD in the 10 matter of Exact Science Corporation versus 11 Geneoscopy Inc. 12 Would counsel please introduce 13 themselves for the record. 14 MS. HABERNY: Sandra Haberny of 15 Quinn Emanuel on behalf of the plaintiff, 16 Exact Sciences, also with me is Jihong Lou 17 of Quinn Emanuel on behalf of Exact Sciences 18 and Alex Gorman of Exact Sciences? 19 MR. JONES: Brendan Jones for 20 Foley Hoag on behalf of Geneoscopy and the 21 witness. 22 THE VIDEOGRAPHER: The court 23 reporter today is Deborah Roth. Will you 24 please swear in the witness. Page 5

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Exact Sciences Ex. 2051, Page 2 of 116

1 DUNCAN WHITNEY PhD,
2 having been satisfactorily
3 identified by the production of his/her
4 driver's license, and duly sworn by the
5 Notary Public, was examined and testified as
6 follows:
7 (Exhibit 23 was marked for
8 identification.)
9 EXAMINATION
10 BY MS. HABERNY:
11 Q. Good morning, Dr. Whitney.
12 A. Good morning.
13 Q. You've been handed what's marked as
14 Exhibit 23. Do you have that in front of
15 you?
16 A. Yes.
17 Q. What is Exhibit 23?
18 A. It appears to be a copy of the second
19 declaration that I have written.
20 Q. Is this the second declaration that's
21 been filed in the district court litigation
22 between Exact Sciences and Geneoscopy?
23 A. Yes, I believe it is.
24 Q. And your signature is on Page 77?

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1 A. There is no page number, but it
2 would appear to be Page 77. It comes after
3 Page 76.
4 Q. Okay. And before you signed, did you
5 read the declaration carefully?
6 A. Yes.
7 Q. Did you write the declaration
8 yourself?
9 A. I wrote this in conjunction with
10 counsel.
11 Q. How much time did you spend preparing
12 your second declaration for this case?
13 A. I spent many hours over at least a
14 couple of weeks.
15 Q. What's your estimate of how many?
16 A. I really don't know how many hours,
17 but I know that it was at least a few dozen
18 hours.
19 Q. Two dozen?
20 A. I'll stay with a few dozen.
21 Q. How many dozen? Your best estimate.
22 A. I really don't know.
23 Q. Was it more than 50 hours?
24 A. It was probably not under 50 hours.

Page 7

1 Q. Did you consider the deposition
2 transcripts of the experts for Exact
3 Sciences in this case in preparing your
4 declaration?
5 A. Could you specify who the experts are
6 that you're talking about?
7 Q. Do you know who Exact Sciences'
8 experts are in this case?
9 A. I do know some of them, yes.
10 Q. Who do you know of?
11 A. I know of Dr. Patterson, Dr. Eshoo.
12 Certainly those two.
13 Q. Did you consider the deposition
14 transcript of Dr. Patterson -- strike that.
15 I will start over.
16 Did you consider the transcript of
17 the deposition of Dr. Patterson in preparing
18 your second declaration?
19 A. I did.
20 Q. Did you consider the transcript of the
21 deposition of Dr. Eshoo in preparing your
22 second declaration?
23 A. I did.
24 Q. Did you review Dr. Patterson and

Page 8

1 Dr. Eshoo's deposition transcripts
2 themselves?
3 A. I had a written copy of the
4 transcripts if that's what you mean.
5 Q. And did you review the written copies
6 of the transcripts?
7 A. I did.
8 Q. How much time did you spend reviewing
9 those transcripts?
10 A. Again I can't say for certain, but it
11 was many hours.
12 Q. Did you review the entirety of the
13 transcript of the deposition of
14 Dr. Patterson?
15 A. I mean the way I would answer that is
16 I was given a written copy of the
17 transcripts. I read the entirety of what I
18 was given.
19 Q. So you read the transcript of the
20 entire deposition of Dr. Patterson?
21 A. I can't confirm whether or not that
22 was the entire deposition of Dr. Patterson,
23 but again I reviewed what I was given in
24 terms of the written record.

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3 (Pages 6 - 9)

1 Q. Were you given the full transcript of 2 Dr. Patterson's deposition? 3 A. You're asking me something that I've 4 already answered. I don't know if I was -- 5 if the written transcript that I received 6 was, in fact, a representation of the entire 7 deposition. 8 Q. I'm going to hand you what's marked as 9 Exhibit 24, which is the transcript of the 10 November 22, 2024 deposition of Bruce K. 11 Patterson. 12 (Exhibit 24 was marked for 13 identification.) 14 Q. Do you recognize this? 15 A. (Witness reviews document.) 16 Yes. 17 Q. Did you review this entire deposition 18 transcript in preparation for your second 19 declaration in this case? 20 A. Yes, I believe I did. 21 Q. All of it? 22 A. (Witness reviews document.) 23 Yes, I believe I did. 24 Page 10	1 declaration in its entirety? 2 MR. JONES: Objection to form. 3 Compound. There are multiple declarations 4 submitted in this case by Dr. Patterson. 5 Q. Did you review the declaration that 6 Dr. Patterson submitted in this litigation 7 in its entirety? 8 A. (Witness reviews document.) 9 Q. Sorry, let me strike that. 10 Do you know how many declarations 11 Dr. Patterson submitted in this litigation? 12 A. I believe he has submitted two. 13 Q. Did you review both of those 14 declarations in their entirety in preparing 15 your second declaration in this case? 16 A. You're asking me if I reviewed both of 17 the declarations that he has written? 18 Q. Yes. 19 A. Yes, I have. 20 Q. Okay. Did you review the declaration 21 that Dr. Eshoo submitted in this case in its 22 entirety in preparing for your second 23 declaration? 24 A. (Witness reviews document.) Page 12
1 (Exhibit 25 was marked for 2 identification.) 3 Q. And now marked as Exhibit 25 is the 4 November 14, 2024 deposition transcript of 5 the deposition of Mark W. Eshoo PhD. 6 A. (Witness reviews document.) 7 Q. Do you recognize this? 8 A. Yes. 9 Q. Did you review the deposition 10 transcript of Dr. Eshoo that's herein 11 Exhibit 25 in its entirety in preparation 12 for your second declaration in this case? 13 A. Yes, I believe I did. 14 Q. The entire transcript in its entirety? 15 A. (Witness reviews document.) 16 Yes, I believe I did. 17 Q. Did you review the declaration of 18 Dr. Patterson that was submitted in this 19 case in preparation for your declaration, 20 for your second declaration? 21 MR. JONES: Objection. 22 A. Yes, that was part of the preparation 23 that I did for writing the declaration. 24 Q. And did you review Dr. Patterson's Page 11	1 I am having some difficulty 2 recalling exactly the dates of when this 3 deposition was taken and recorded and when I 4 had written the second declaration, but I 5 know that I had reviewed it and that it was 6 included in part of my considerations for the 7 declaration. 8 Q. So you don't know whether or not you 9 reviewed Dr. Eshoo's declaration before you 10 submitted your second declaration? 11 A. No, I believe I did. What I'm saying 12 is I'm having difficulty remembering the 13 exact dates as to when I had written the 14 second declaration relative to this. 15 THE VIDEOGRAPHER: The time is 16 10:21. Off the record. 17 (A discussion was held off the record.) 18 THE VIDEOGRAPHER: We are back on 19 the record. The time is 10:24. 20 BY MS. HABERNY: 21 Q. Did you review any materials that were 22 submitted in the IPR proceeding in 23 connection with preparing your second 24 declaration? Page 13

4 (Pages 10 - 13)

1 MR. JONES: Objection to form.
2 Q. Sorry, let me clarify that.
3 Did you review any materials that
4 were submitted in any IPR proceeding in
5 connection with preparing your second
6 declaration?
7 A. Yes. To the extent that a lot of the
8 same cited references in the IPR are common
9 to this proceeding, I reviewed some of those.
10 Q. Did you -- strike that.
11 Were there some cited references in
12 the IPR that you did not review in
13 connection with preparing your second
14 declaration?
15 MR. JONES: Objection to form.
16 A. I don't recall. There were many
17 references in both. So I couldn't accurately
18 answer that question.
19 Q. Did you review Exact Sciences' patent
20 owner response and corresponding exhibits
21 that were submitted in the IPR relating to
22 the '781 patent in preparing your second
23 declaration?
24 A. I'm sorry, could you ask that again.

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1 Q. Did you review Exact Sciences' patent
2 owner response and corresponding exhibits
3 that were submitted in the IPR relating to
4 the '781 patent in preparing your second
5 declaration?
6 A. Who is the specific person you're
7 referring to?
8 Q. Do you -- are you aware of any patent
9 owner response that was filed in the IPR
10 proceeding challenging the '781 patent?
11 A. Maybe I'm getting hung up on the
12 nomenclature, but I regard the owner as Exact
13 Sciences, and the inventor, which as I
14 understand is a different word, is not an
15 Exact Sciences employee.
16 Q. Have you seen a document titled
17 "Patent Owner's Response" that was submitted
18 in the IPR proceeding relating to the '781
19 patent?
20 A. I have.
21 Q. Do you know what that document is?
22 A. I believe I know what it is.
23 Q. What do you understand it to be?
24 A. If you could give me a copy of that to

Page 15

1 refresh my memory that would be wonderful.
2 Q. So you don't know sitting here today?
3 A. I didn't say that. If there is going
4 to be a series of followup questions to this,
5 I would like to see what it is that I'm
6 referring to.
7 (Exhibit 27 was marked for
8 identification.)
9 Q. Marked as Exhibit 27 is the patent
10 owner's response in Case No. IPR2024-00459
11 regarding U.S. Patent 11,634,781.
12 MR. JONES: So we are skipping 26?
13 MS. HABERNY: Yes.
14 MR. JONES: Okay.
15 A. (Witness reviews document.)
16 Q. Did you review this patent owner's
17 response that is Exhibit 27 when preparing
18 your second declaration in this case.
19 A. (Witness reviews document.)
20 Yes.
21 Q. Did you consider the patent owner's
22 response in Exhibit 27 in its entirety in
23 preparing your opinions for your second
24 declaration?

Page 16

1 A. This is -- this was written as part of
2 the IPR as I understand it.
3 Q. Correct.
4 A. I considered many, many different
5 sources of information as part of the second
6 declaration. I suspect I included parts of
7 this as well.
8 Q. You don't know whether or not you
9 reviewed the patent owner's response in its
10 entirety in preparing your opinions in your
11 second declaration?
12 A. What I'm saying is that I have
13 reviewed it in its entirety, and then the
14 second part of your question is about whether
15 or not that was in preparation for the second
16 declaration, but once I've reviewed it, it's
17 something that I'm aware of, and so whether
18 that was part of the second declaration or
19 any other declaration, it's something that's
20 in my consciousness.
21 Q. Okay. Did you review all of the
22 exhibits that were submitted with this
23 patent owner's response in the IPR in
24 preparing your opinions for this case?

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5 (Pages 14 - 17)

1 MR. JONES: Objection to form. 2 A. I'm looking at all of the exhibits. 3 (Witness reviews document.) 4 I looked at many of these. I can't 5 say that I looked at all of them as I look at 6 this now. 7 Q. Did you review the declaration of 8 Peter Wood that was an exhibit to the patent 9 owner's response in preparing your opinions 10 for this case? 11 A. Yes, I believe I did. 12 Q. Do you know for sure? 13 A. Yes, I did. 14 Q. Did you review Peter Wood's 15 declaration in its entirety in forming your 16 opinions for this case? 17 A. Yes. 18 Q. Can you please turn in Exhibit 23, 19 which is your second declaration to the 20 Materials Considered, which is Exhibit A 21 behind your signature page? 22 A. Okay. Excuse me. Okay. 23 Q. So you see at the bottom it says 24 "Documents and Publications"? Page 18	1 A. Okay. 2 Q. Okay. So you identify only one 3 document that was produced by Exact Sciences 4 in this litigation as part of your Materials 5 Considered, correct? 6 MR. JONES: Objection to form. 7 A. I see that there's one line item 8 listed there. There is a publication below 9 that. I don't recall exactly what's in that 10 one line item that you are referring to. 11 Q. Did you consider any documents that 12 Exact Sciences produced in this litigation 13 other than this one in your Materials 14 Considered in forming your opinions for this 15 case? 16 MR. JONES: Objection to form. 17 A. Again I don't know what's in that 18 document. So I don't -- I can't answer that 19 question. 20 Q. So if you look right behind this in 21 your declaration, do you see that that is a 22 document that you've identified in that line 23 items that begins with EXAS-GEN Bates stamp? 24 A. I do see that those numbers match, Page 20
1 A. Yes. 2 Q. And you list one Bates-stamped 3 document, one document that was produced in 4 this deposition; is that right? 5 A. I'm sorry, could you repeat that? 6 Q. You list in your Materials Considered 7 only one document that has a Bates stamp 8 that was produced as part of this 9 litigation, correct? 10 MR. JONES: Objection to form. 11 A. I don't know what a Bates stamp is. 12 Q. Do you see that number EXAS-GEN with 13 numbers? 14 A. Yes. 15 Q. Do you understand that that is a 16 number that identifies a document that Exact 17 Sciences produced in discovery in this 18 litigation? 19 A. I don't recognize the number. 20 Q. I will represent that documents 21 stamped with a number beginning EXAS-GEN are 22 documents that Exact Sciences produced 23 during discovery in this litigation; is that 24 fair? I represent that to you. Page 19	1 yes. 2 Q. Okay. So did you review any document 3 produced by Exact Sciences in this 4 litigation other than this one PowerPoint 5 deck that you've attached as Exhibit B to 6 your declaration? 7 MR. JONES: Objection to form. 8 A. Well, "document" seems like a very 9 broad term. So I'm not exactly sure what 10 you're asking. 11 Q. Anything that was either a hard copy 12 on paper or a document in PDF or some other 13 document form on a computer. 14 A. Are we including declarations and 15 those types of documents as well? 16 Q. No. Just documents that have these 17 Bates stamps at the bottom beginning 18 EXAS-GEN. 19 MR. JONES: Objection to form. 20 A. Yeah, to be honest, as I testified a 21 moment ago, I don't -- I didn't recognize 22 that number. I haven't been paying a lot of 23 attention to the EXAS-GEN designations on the 24 documents. So I can't answer that question. Page 21

6 (Pages 18 - 21)

1 Q. So other than declarations, did you
2 review any documents produced by Exact
3 Sciences in this litigation other than the
4 one that's Exhibit B to your declaration?
5 MR. JONES: Objection to form.
6 A. I don't know that I can answer that
7 question in the sense that I obviously did
8 not get this document directly myself from
9 Exact Sciences, and I rely on some documents
10 coming from counsel, and so I don't know of
11 all the documents that I have received and
12 reviewed, which ones are directly from Exact,
13 in order to answer your question.
14 Q. Did you ask counsel to provide you
15 with any other PowerPoint decks that Exact
16 Sciences produced in this case other than
17 the one that's in your declaration as
18 Exhibit B?
19 A. So you're asking specifically about
20 PowerPoints?
21 Q. Correct.
22 A. I don't believe I did.
23 Q. Did you ask counsel whether Exact
24 Sciences had produced any PowerPoints in

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1 this litigation, apart from the one that is
2 Exhibit B to your declaration?
3 MR. JONES: Objection to form.
4 Also, I object that calls for conversations
5 with counsel.
6 MS. HABERNY: I'm just asking him
7 what he considered.
8 MR. JONES: You're not asking him
9 what he considered. You're asking him what
10 he asked counsel.
11 MS. HABERNY: Yeah, did he want to
12 see --
13 MR. JONES: Ask him that question.
14 BY MS. HABERNY:
15 Q. Did you want to see any PowerPoint
16 decks other than -- sorry, let me start
17 over.
18 Did you want to see any PowerPoint
19 decks produced by Exact Sciences in this
20 litigation other than the one that's
21 attached as Exhibit B to your second
22 declaration?
23 A. I will answer that by saying that this
24 particular PowerPoint was very illustrative

Page 23

1 in some ways, but, also introduced a number
2 of questions in my mind related to this and
3 other topics, and I would have wanted to see
4 other PowerPoints, the answer would be yes.
5 Q. The only PowerPoint provided to you in
6 the materials that you considered for your
7 second declaration is this one PowerPoint
8 that is in Exhibit B?
9 A. (Witness reviews document.)
10 Again I don't -- well, I believe
11 with respect to PowerPoint representations, I
12 think that's an accurate statement, that this
13 is the only one that I have seen.
14 Q. Did you review any Excel spreadsheets
15 produced by Exact Sciences in this
16 litigation in forming your opinions?
17 A. I don't know that I can answer that.
18 Again I have seen a lot of documents, some of
19 them may have been in Excel format. I don't
20 know honestly that I can answer that.
21 Q. So sitting here today, you can't say
22 that you reviewed any Excel spreadsheet
23 produced by Exact Sciences in this
24 litigation in forming your opinions?

Page 24

1 A. What I'm saying is that I have
2 reviewed a lot of documents. I know that
3 there were many PDFs. There were Word docs,
4 there was at least one PowerPoint. I have
5 seen lists of things that may have been in
6 Excel format, but I can't confirm that is
7 what I'm saying.
8 Q. Are there any documents that you
9 reviewed in forming your opinions for your
10 second declaration that you did not list in
11 the Materials Considered?
12 A. (Witness reviews document.)
13 I don't know that I can accurately
14 answer that. I certainly -- could you ask
15 the question again, I'm sorry.
16 Q. Are there any documents that you
17 reviewed in forming your opinions for your
18 second declaration that you did not list in
19 the Materials Considered?
20 A. Well, this list certainly does not
21 include any of -- or many of the exhibits and
22 references in those -- are not explicitly
23 listed here. There is one publication here
24 listed from Troy, et al., but otherwise there

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7 (Pages 22 - 25)

1 were certainly many other documents of those 2 kind that are not listed here. 3 (Exhibit 28 was marked for 4 identification.) 5 Q. I have handed you what is marked as 6 Exhibit 28. Do you recognize this, 7 Exhibit 28? 8 A. Yes. 9 Q. What is it? 10 A. It's a list of patents, sorry, as well 11 as a number of other documents. 12 Q. And this document is titled "Materials 13 Considered"; is that correct? 14 A. It is. 15 Q. Is this Materials Considered the 16 compilation of materials that you considered 17 in connection with your first declaration in 18 this litigation? 19 A. (Witness reviews document.) 20 You're asking me about the first 21 declaration? 22 Q. Actually let me withdraw that and give 23 you your first declaration and then maybe 24 you can answer it. Page 26	1 Q. What is this? 2 A. This is my CV. 3 Q. Was this Exhibit A the CV that you 4 attached to your first declaration in this 5 case? 6 A. Let me refresh my memory. Can you 7 tell me where would I find that? 8 Ah, yes, sorry. List of Exhibits 9 indicates CV of Dr. Duncan Whitney as 10 Exhibit A. So I believe this is the same 11 copy. 12 Q. Okay. And then if you go back to 13 Exhibit 28, which is titled "Exhibit B" and 14 it's "Materials Considered." Do you see 15 that? 16 A. Yes. 17 Q. Can you confirm this is the Materials 18 Considered that you attached to your first 19 declaration submitted in this case? 20 A. (Witness reviews document.) 21 Yes, I believe it is. 22 Q. Okay. Do you see anywhere in the 23 Materials Considered for your first 24 declaration in this case, do you see any Page 28
1 (Exhibit 1 introduced.) 2 Q. This was marked as Exhibit 1 last 3 time. Do you recognize Exhibit 1? It's 4 entitled "Declaration of Duncan Whitney," 5 and you see at the very top there is a stamp 6 that says "Document 123"? 7 A. Yes, I see that. 8 Q. Is this your first declaration that 9 you submitted in this litigation? 10 A. Yes, I believe it is. 11 Q. Okay. Now, if you look at Exhibit 26, 12 do you see that's titled "Exhibit A" and has 13 a stamp at the top that's "Document 123-1"? 14 A. Sorry, hold on. So Exhibit -- 15 Q. 26 -- 16 A. -- 26? Hold on. There is no 26. 17 Q. I am handing it to you now. 18 (Exhibit 26 was marked for 19 identification.) 20 Q. So I have just handed you what's 21 marked as Exhibit 26, which is Exhibit A, 22 and it's titled "Duncan H. Whitney PhD." Do 23 you see that? 24 A. Yes. Page 27	1 document that has that Bates stamp EXAS-GEN? 2 MR. JONES: Objection to form. 3 A. I do not. 4 Q. Okay. Are there any materials that 5 you omitted from the Materials Considered 6 for your first declaration, but that you 7 actually reviewed? 8 MR. JONES: Objection to form. 9 A. I'm not sure I can accurately answer 10 that question. I reviewed a lot of 11 materials, not all of it ended up being 12 encompassed within the declaration itself. 13 So it's hard for me to answer that question. 14 Q. Sitting here today, can you identify 15 any document that Exact Sciences produced in 16 this litigation that have that Bates stamp 17 EXAS-GEN that you reviewed with your first 18 declaration? 19 MR. JONES: Objection to form. 20 A. As I sit here today, I cannot recall 21 anything that had that Bates stamp, as you 22 call it. 23 Q. So sitting here today, across the 24 materials you considered for both your first Page 29

8 (Pages 26 - 29)

1 and second declarations in this case, there 2 is only one document that has that Bates 3 stamp EXAS-GEN, correct? 4 MR. JONES: Objection to form. 5 A. As I said, as I am sitting here today, 6 it's the only one that I recall. 7 Q. So sitting here today, you can only 8 recall having reviewed one document produced 9 by Exact Sciences in this litigation in 10 forming your opinions for this case? 11 MR. JONES: Objection to form. 12 A. No, I didn't say that. What I said is 13 that you were asking me if I had reviewed 14 only one document with that Bates stamp, and 15 what I indicated is that, as I sit here 16 today, I only recall reviewing one document 17 with the Bates stamp. 18 Q. Did you ask to see any documents 19 relating to Exact Sciences' RNA biomarker 20 research other than the one PowerPoint that 21 you attached to your second declaration? 22 MR. JONES: Objection. Form. 23 A. Did I ask who? 24 Q. Counsel. Page 30	1 A. That's correct. 2 Q. Was there a certain goal for the level 3 of sensitivity that you were trying to 4 achieve in developing a colorectal cancer 5 screening test while at Exact Sciences? 6 MR. JONES: Objection to form. 7 A. Our goal was to try to maximize the 8 sensitivity of a screening test for 9 colorectal cancer. 10 Q. Was there a level of sensitivity that 11 you would have considered inadequate? 12 MR. JONES: Objection to form. 13 A. I'm not exactly sure how to answer -- 14 sorry, I'm stalling -- I'm not stalling. 15 I am not exactly sure how to answer 16 that question. I am -- certainly we knew 17 that from some of the very first experiments 18 that were run and published in a publication 19 around 2000 that our sensitivity reported in 20 that paper was about 90 percent or so, and we 21 were excited about that result, and I would 22 say that our subsequent goals were to be able 23 to achieve something at least similar to 24 that. Page 32
1 THE WITNESS: Am I allowed to 2 answer that? 3 MR. JONES: Yes, you can answer 4 that "yes" or "no." 5 A. No. 6 Q. Can you turn back to Exhibit 26, 7 please. This is your curriculum vitae. 8 A. Yes. Sorry, I didn't know there was a 9 questions. 10 Q. Maybe there wasn't. 11 Okay. So you worked at Exact 12 Sciences from 2000 to 2005? 13 A. That's correct. 14 Q. And you worked on trying to develop 15 colorectal cancer screening tests while at 16 Exact Sciences? 17 A. Yes, I did. 18 Q. And after you left Exact Sciences, you 19 did not work on developing any tests using 20 stool samples, correct? 21 A. No, that's not correct. 22 Q. After you left Exact Sciences, you did 23 not work on developing any colorectal cancer 24 tests using stool samples, correct? Page 31	1 Q. Was there a certain goal for a level 2 of specificity that you were seeking to 3 achieve with a colorectal cancer screening 4 test while at Exact Sciences? 5 MR. JONES: Objection to form. 6 A. Again we were looking to be able to 7 develop a test which had high sensitivity and 8 high specificity. We did not, as far as I 9 recall, have a specific level of specificity 10 that we were willing to accept at that time. 11 Q. Were you involved in developing a test 12 for both nucleic acid biomarkers and blood 13 proteins from a stool sample while you were 14 at Exact Sciences? 15 A. The work that I did when I was at 16 Exact did not directly involve working with 17 blood-protein-based testing. 18 Q. Did it occur to you while you were at 19 Exact Sciences that a test that assayed both 20 nucleic acid biomarkers and blood proteins 21 would be a desirable test? 22 A. Yes. 23 Q. Did you tell anybody that? 24 MR. JONES: Objection to form. Page 33

9 (Pages 30 - 33)

1 A. I recall that it was certainly 2 something that was talked about beyond just 3 myself. In fact, I -- yeah, no, I'll leave 4 it at that. 5 Q. Who talked about it? 6 A. There were several people in the 7 company. I know that one of the people who 8 was also thinking about this was a guy named 9 Barry Berger. 10 Q. Do you think it would have been easy 11 to develop a test that assayed both nucleic 12 acid biomarkers and blood proteins in stool 13 to test for colorectal cancers while you 14 were at Exact Sciences? 15 MR. JONES: I object to the form. 16 A. How are you defining "easy"? 17 Q. How much work do you think it would 18 have taken to develop a test that assayed 19 both nucleic acid biomarkers and blood 20 proteins from stools to test the colorectal 21 cancer while you were at Exact Sciences? 22 MR. JONES: Objection to form. 23 A. In the time I was there, we certainly 24 were spending a lot of the time working on Page 34	1 A. I certainly -- so I certainly am aware 2 of that now. I'm having some difficulty 3 recalling exactly when or if I was aware of 4 it at that time -- in that time period. 5 Excuse me. 6 Q. Do you think it would have been 7 trivial to develop a test that assays both 8 nucleic acid biomarkers and blood proteins 9 from the same stool sample before the 2005 10 time period? 11 MR. JONES: Objection to form. 12 A. Again I think that calls for some kind 13 of subjective assessment as to the ease of 14 doing this. 15 What I certainly -- excuse me -- 16 recognize now and am having difficulty 17 recalling whether I knew that then is that 18 there was prior art for people doing exactly 19 that. 20 Q. Sitting here as an expert in this 21 case, is it your opinion that it would have 22 been trivial to develop a test that assays 23 both nucleic acid biomarkers and blood 24 protein during the 2000 to 2005 time period? Page 36
1 developing and optimizing the DNA-based tests 2 and specific biomarkers that were being used 3 for that. 4 My starting assumption on the blood 5 protein side was that there were already 6 well-established fecal occult blood tests 7 that would not necessarily need any further 8 development. 9 Q. In the five years that you worked at 10 Exact Sciences, are you aware of anyone who 11 actually performed a test that assayed both 12 nucleic acid biomarkers and blood protein 13 from the same stool sample? 14 MR. JONES: Objection to form. 15 A. Are you asking specifically in the 16 labs at Exact Sciences? 17 Q. Anyone anywhere. 18 A. Oh, sorry, could you read back the 19 question? 20 Q. Are you aware of anyone who actually 21 performed a test that assayed both nucleic 22 acid biomarkers and blood proteins from 23 stool samples during the five years that you 24 worked at Exact Sciences? Page 35	1 MR. JONES: Objection to form. 2 A. I think that's a very -- the same 3 question you just asked me. 4 Q. I'm asking for your opinion on that. 5 A. Could you read me back what I said 6 before? 7 Q. No. I'm asking your opinion and that 8 wasn't responsive, what you said before. 9 MR. JONES: Objection. 10 A. I gave you my -- 11 Q. I will ask again. 12 Do you have an opinion one way or 13 the other whether it would have been trivial 14 to develop a test that assays both nucleic 15 acid biomarkers and blood proteins from the 16 same stool sample during the 2000 to 2005 17 time period? 18 A. Yeah, again I think that triviality, 19 the ease or the difficulty in developing such 20 a test is a subjective call. What I am 21 saying is that in that time frame there were 22 people who had done that. 23 Q. So you don't have an opinion one way 24 or another as to whether it would have been Page 37

10 (Pages 34 - 37)

1 trivial to develop a test that assays both 2 DNA biomarkers and blood proteins from the 3 same stool samples during the 20000 and 1005 4 time period? 5 MR. JONES: Objection to form. 6 A. I was not tasked with running those 7 experiments. I didn't run those kind of 8 experiments. 9 What I do know is that other people 10 have done that, and I can't speak to their 11 opinion as to how trivial or not that was. 12 Q. Can you turn to Paragraph 5 of your 13 second declaration, please. Do you see 14 Paragraph 5? 15 A. I do. 16 Q. Okay. About three-quarters of the way 17 down is a sentence that reads, "There is 18 also no dispute that the prior art, 19 including Lenhard, demonstrated that 20 combining a fecal nucleic acid biomarker 21 test with a fecal blood protein test 22 resulted in increased test sensitivity for 23 the detection of CRC." Do you see that? 24 A. Yes. Page 38	1 Q. Would you consider 42 percent to be a 2 high sensitivity? 3 MR. JONES: Objection to form. 4 A. If this were a test that was going to 5 be used for clinical applications, I would 6 not regard 42 percent as a high value. 7 Q. What was the blood protein assay that 8 was performed in this study reported in the 9 Lenhard paper? 10 A. It was a FOBT test. 11 Q. Was it a guaiac FOBT test? 12 A. (Witness reviews document.) 13 Hold on. Yes. It appears it was a 14 guaiac test. 15 Q. And looking back at Table 4 of the 16 Lenhard paper -- 17 A. Uh-huh. 18 Q. -- what was the sensitivity of the 19 guaiac FOBT test used in that study? 20 A. So for all of the cancers, the 21 sensitivity was 35 percent. 22 Q. Would you consider 35 percent to be a 23 high sensitivity? 24 MR. JONES: Objection to form. Page 40
1 (Exhibit 6 was introduced.) 2 Q. Let me show you the Lenhard paper. 3 This was previously marked as Exhibit 6. 4 A. Okay. 5 Q. Do you recognize this as the 6 Lenhard paper that you were discussing in 7 Paragraph 5 of your second declaration? 8 A. Yes, I do. 9 Q. What was the fecal nucleic acid 10 biomarker that was tested in the Lenhard 11 paper? 12 A. As described in the paper, they were 13 looking at the methylation of a gene referred 14 to as the HIC1. 15 Q. Do you know what the sensitivity of 16 assaying the HIC1 biomarker was for 17 detecting CRC? 18 A. I don't have the exact number in my 19 head, but I'm sure I can find it in here. 20 (Witness reviews document.) 21 Q. Can I point you to Table 4 to answer 22 that question. 23 A. Sure. So for all cancers, it lists 24 the sensitivity as 42 percent. Page 39	1 A. Are you asking about for an FOBT test 2 or for some other context? 3 Q. For a clinical test to detect CRC. 4 A. For a clinical test in general? 5 Q. Yes. Would you consider 35 percent to 6 be a high sensitivity for a test for 7 colorectal cancer? 8 MR. JONES: Objection to form. 9 A. For screening applications, I would 10 not regard this as a high number. 11 Q. If someone were intending to -- strike 12 that. 13 If a person of skill in the art 14 were intending to develop a biomarker 15 screening test for CRC in the 2009 time 16 frame, do you think they would start with 17 markers that have low sensitivity? 18 MR. JONES: Objection to form. 19 A. I'm not exactly sure how to answer 20 that question. I think that combinations of 21 markers was a well-known strategy to provide 22 for an overall sensitivity which is 23 sufficiently high, and that any of the given 24 individual biomarkers may, in fact, be Page 41

11 (Pages 38 - 41)

1 relatively low. 2 Q. If a person of skill in the art in the 3 2009 time frame were intending to develop a 4 screening test for CRC, wouldn't that person 5 start with the highest sensitivity 6 biomarkers they knew of? 7 MR. JONES: Objection to form. 8 A. No. I mean you're asking about 9 sensitivity in absence of specificity. I 10 think one always has to consider the 11 combination of the two, and so I would not 12 agree with that statement. 13 Q. You would agree that a person of skill 14 in the art in 2009 could not predict from 15 the data presented in Lenhard whether 16 combinations of markers other than HIC1 and 17 the guaiac FOBT test would improve 18 sensitivity, correct? 19 MR. JONES: Objection to form. 20 A. You're asking me if any -- I'm sorry, 21 could you repeat the question? 22 Q. Is it your opinion that a person of 23 skill in the art in 2009 could predict from 24 the data presented in Lenhard whether a Page 42	1 that Lenhard looked at. 2 MS. HABERNY: Do you want to take 3 a break? I think we have been going over an 4 hour. 5 MR. JONES: Sure. 6 THE VIDEOGRAPHER: The time is 7 11:14. We are off the record. 8 (A recess was taken.) 9 THE VIDEOGRAPHER: We are back on 10 the record. The time is 11:30. 11 BY MS. HABERNY: 12 Q. Dr. Whitney, would you please take a 13 look at Paragraph 5 in your second 14 declaration. Let me know when you're there. 15 A. Yes. 16 Q. You don't cite any references other 17 than Lenhard, Itzkowitz and Shuber in 18 Paragraph 5 of your second declaration, 19 correct? 20 A. That appears to be the case, yes. 21 MR. JONES: Objection to form. 22 Q. And you see in Paragraph 5 the 23 sentence "Dr. Patterson acknowledges that 24 such tests for detecting blood protein and Page 44
1 combination of the markers other than HIC1 2 and the guaiac FOBT would improve 3 sensitivity? 4 MR. JONES: Objection to form. 5 A. The question doesn't make any sense to 6 me. You're asking me in reference to 7 Lenhard, where they looked at two specific 8 biomarkers, if someone could consider other 9 biomarkers that are not considered in 10 Lenhard, whether or not that would improve 11 sensitivity. That question doesn't make 12 sense to me. 13 Q. So sitting here today, you don't have 14 the opinion that a person of skill in the 15 art could predict from the Lenhard paper 16 whether combinations of markers other than 17 HIC1 and guaiac FOBT would improve 18 sensitivity, correct? 19 MR. JONES: Objection to form. 20 A. If one were to look to see if other 21 biomarkers could improve sensitivity, other 22 than the two that are listed here, I don't 23 believe that they would refer to Lenhard, 24 because these are the only two biomarkers Page 43	1 nucleic acids in fecal samples were known 2 and routine by February 9, 2009, the 3 priority date"? Do you see that? 4 A. I see that sentence, yes. 5 Q. You don't cite any support for that 6 statement, correct? 7 A. No. 8 Q. You don't cite any portion of 9 Dr. Patterson's deposition transcript for 10 that statement, correct? 11 A. There is no citation. 12 Q. In Paragraph 6 of your second 13 declaration you make a statement "As 14 Dr. Patterson acknowledged in his 15 deposition, 'the general thought of 16 everybody in cancer screening' was that 17 'sensitivity is the most important 18 characteristic of screening tests.'" Do you 19 see that? 20 A. Yes, I do. 21 Q. How many times did you cite that 22 testimony from Dr. Patterson's declaration? 23 A. I don't recall. 24 Q. Did you cite it more than once? Page 45

12 (Pages 42 - 45)

1 A. Yes.
2 Q. Did you cite it more than five times?
3 A. I don't know. I don't know how many
4 times I cited it.
5 Q. Do you understand that you cited that
6 testimony eight times in your declaration?
7 A. I just said I don't know how many
8 times I cited that statement.
9 Q. Do you doubt that you cited that
10 statement eight times in your declaration?
11 MR. JONES: Objection to form.
12 A. It's possible that I cited that
13 statement eight times.
14 Q. Did you consider other testimony from
15 Dr. Patterson stating his opinion that a
16 person of skill in the art would consider
17 both sensitivity and specificity as
18 important characteristics of screening
19 tests?
20 MR. JONES: Objection to form.
21 Vague.
22 A. I'm sorry. Could you ask again? I'm
23 trying to listen to the exact words you
24 choose.

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1 Q. Did you consider other testimony from
2 Dr. Patterson stating his opinion that a
3 person of skill in the art would consider
4 both sensitivity and specificity as
5 important characteristics of screening
6 tests?
7 MR. JONES: Objection to form.
8 A. So the question is did I consider his
9 testimony, and the answer to that part of the
10 question is, yes, I did consider his
11 testimony.
12 Q. Is there a reason why you're ignoring
13 the rest of my question?
14 A. No. What I'm saying is that I -- I'm
15 sorry, read the question one more time.
16 Q. I will ask it a different way.
17 A. Yes.
18 Q. Are you aware that Dr. Patterson gave
19 testimony in his deposition stating his
20 opinion that a person of skill in the art
21 would consider both sensitivity and
22 specificity as important characteristics of
23 screening tests?
24 MR. JONES: Objection to form.

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1 A. I don't recall all of the words that
2 he used in his testimony so I'm not sure I
3 can answer that question.
4 Q. Can you turn to the Patterson
5 deposition transcript, which is Exhibit 24.
6 A. Yes.
7 Q. Okay. So I would like you to take a
8 look at that testimony by Dr. Patterson that
9 you cited eight times in your declaration,
10 which is on Page 105 of the transcript.
11 MR. JONES: Objection to form.
12 A. 105 of the transcript?
13 Q. Page 104 to 105 actually.
14 A. Okay.
15 Q. And Page 104, Line 22 to 105, Line 10.
16 A. (Witness reviews document.)
17 Okay.
18 Q. Now, you didn't cite what
19 Dr. Patterson said after that in the
20 transcript, correct, in your declaration?
21 MR. JONES: Objection to form.
22 A. Hold on. I did not cite the remaining
23 script there, if that's what you're asking
24 me.

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1 Q. Okay. If you look at Page 105, Lines
2 19 to 25, it says, "Question: And as you
3 said, it was the general thought of
4 everybody in cancer screening that
5 sensitivity is the most important
6 characteristic of screening tests, right?"
7 And Dr. Patterson answered "But not
8 at the expense of specificity."
9 Do you see that?
10 A. I see that.
11 Q. Why did you omit that statement from
12 your declaration when you were citing the
13 testimony on Page 104 to 105?
14 MR. JONES: Objection to form.
15 A. I think the statement stands as
16 written that sensitivity is the most
17 important characteristic of screening tests,
18 as he had quoted, as he had said.
19 Q. And did he not say "but not at the
20 expense of specificity"?
21 A. He says that later on in this, but
22 these are all -- these are relative terms, so
23 I think this should all be in the context of
24 whatever particular, you know, pieces we are

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13 (Pages 46 - 49)

1 taking about. 2 Q. But you didn't put it into context, 3 correct, because you omitted this portion of 4 his testimony? 5 MR. JONES: Objection to form. 6 A. That line on -- that statement on 7 Line 24 and 25 is not in here. 8 Q. In your declaration, correct? 9 A. Correct. 10 Q. And you omitted that on purpose? 11 MR. JONES: Objection to form. 12 A. No. 13 MR. JONES: Harassing. 14 A. No, I didn't omit it on purpose. 15 Q. Why didn't you include it in your 16 declaration? 17 MR. JONES: Objection to form. 18 A. There is much of this which is not 19 included. What was done was to take the 20 pieces that are intended to be important for 21 the sake of making a point. 22 Q. Did it occur to you that to provide 23 context about Dr. Patterson's opinions that 24 you were addressing you should have quoted Page 50	1 point you're trying to make and what do you 2 include and what do you omit; and there is a 3 clear statement in here that he indicates 4 that sensitivity is the most important 5 aspects of the screening test. 6 Q. And Dr. Patterson also testifies "but 7 not at the expense of specificity," correct? 8 A. I see that he says that, yes, and he 9 has many other opinions in here as well that 10 also were not included in the quote. It's a 11 qualifying statement. 12 Q. That's correct, to qualify his 13 opinion, correct? 14 MR. JONES: Objection to form. 15 A. There are many, many qualifying 16 statements in there. We did not include all 17 of the qualifying statements, but the 18 statement itself stands in his opinion that 19 he regards sensitivity as the most important 20 thing in screening tests. 21 Q. But not at the expense of specificity, 22 correct? 23 MR. JONES: Objection to form. 24 Asked and answered. Page 52
1 his entire opinion on the thought that 2 everybody in cancer screening that is 3 sensitivity is the most important 4 characteristic of screening tests? 5 MR. JONES: Objection to form. 6 A. Repeat the question. 7 Q. You would agree that based on 8 Dr. Patterson's testimony at Page 105 of his 9 transcript, his full opinion is that, in 10 response to the question, "it was the 11 general thought of everybody in cancer 12 screening that sensitivity is the most 13 important characteristic of screening tests, 14 right," his opinion is "but not at the 15 expense of specificity"? 16 MR. JONES: Objection to form. He 17 can't possibly know what the extent of 18 Dr. Patterson's full opinion is. 19 MS. HABERNY: Stop the speaking 20 objections. 21 A. This transcript offers a lot of 22 opinion from him, which is -- extends 23 obviously for many, many pages, and so at 24 some point you have to decide what is the Page 51	1 A. I have answered the question. 2 Q. But not at the expense of specificity, 3 correct? 4 MR. JONES: Objection to form. 5 A. I have answered the question. 6 Q. You have not. 7 A. I have. 8 Q. Does Dr. Patterson opine that it was 9 the general thought of everybody in cancer 10 screening that sensitivity is the most 11 important characteristic of screening tests 12 at the expense of the specificity? 13 MR. JONES: Objection to form. 14 A. What he indicates is that sensitivity 15 is the most important aspect of a screening 16 test. He follows it up with many qualifying 17 statements. It's my opinion and my belief 18 that the statement that he made about 19 sensitivity stands on its own. 20 Q. So that did not answer the question. 21 Do you believe Dr. Patterson opines 22 that it was the general thought of everybody 23 in cancer screening that sensitivity is the 24 most important characteristic of screening Page 53

14 (Pages 50 - 53)

1 tests at the expense of specificity? 2 MR. JONES: Objection to form. 3 Q. That's a yes-or-no question. Do you 4 believe it? 5 MR. JONES: Objection to form. 6 A. I don't know what he believes, if 7 that's what you are asking me. 8 Q. This is a yes-or-no question that I'm 9 going to ask. Do you understand that? 10 A. Yes. 11 Q. Do you believe Dr. Patterson testified 12 to an opinion that it was the general 13 thought of everybody in cancer screening 14 that sensitivity is the most important 15 characteristic of screening tests at the 16 expense of specificity? 17 MR. JONES: Objection to form. 18 A. He does not state that sensitivity is 19 the most important at the expense of 20 specificity. 21 Q. You understand that Dr. Patterson 22 testified to an opinion that it was the 23 general thought of everybody in cancer 24 screening that sensitivity is the most Page 54	1 Q. Do you have any legal training? 2 A. I do not. I think I state that in my 3 declaration. 4 Q. Can you go to Paragraph 9 of your 5 second declaration. 6 A. Yes. 7 Q. You see the very last sentence that 8 says "Dr. Patterson's opinions do not 9 satisfy Exact's burden of demonstrating a 10 nexus between the Cologuard product and any 11 asserted secondary consideration"? Do you 12 see that? 13 A. I see that. 14 Q. What standard did you use to judge 15 whether Exact Sciences met its burden of 16 providing nexus? 17 A. This was written in consult with 18 counsel, and the standard -- you're asking 19 about the standard I used? 20 Q. Yes. 21 A. Again, not as a lawyer, but relying on 22 the expertise of counsel, the standard that I 23 applied is that there must be a direct 24 connection between the asserted claims, and Page 56
1 important characteristic of screening tests, 2 but not at the expense of specificity, 3 correct? 4 MR. JONES: Objection to form. 5 A. He adds that as a secondary statement. 6 Q. And that's part of his opinion, 7 correct? 8 MR. JONES: Objection to form. 9 A. It's what's in the transcript. 10 Q. In fact, you reviewed Dr. Patterson's 11 deposition transcript in its entirety, 12 correct? 13 A. Yes. 14 Q. And you're aware that Dr. Patterson 15 testified about the importance of 16 specificity several times in his deposition, 17 correct? 18 MR. JONES: Objection to form. 19 A. I do believe that he, yeah, he 20 discussed specificity several times. 21 Q. And you're aware that Dr. Patterson -- 22 strike that. 23 Are you an attorney? 24 A. Am I an attorney? No. Page 55	1 in this case, the Cologuard product itself. 2 Q. So in the same paragraph, Paragraph 9 3 of your second declaration, you mention 60 4 Exact Sciences patents that are directed to 5 Cologuard." Do you see that? 6 A. Yes. 7 Q. Did you review those 60 patents? 8 A. I looked at the 60 patents. I cannot 9 honestly testify that I read every one word 10 for word, but I made sure that I had some 11 understanding as to what each of those 12 patents was associated with. 13 Q. Did you do an analysis of whether 14 Cologuard practices the claims of all of 15 those 60 patents? 16 A. No, I did not. 17 Q. Do you have an opinion as to whether 18 Cologuard practices the claims of the 60 19 patents you mention in Paragraph 9 of your 20 second declaration? 21 A. Do I have an opinion? My opinion is 22 that each of the 60 patents was likely 23 written for the sake of protecting some 24 aspect of what Exact Sciences was working on Page 57

15 (Pages 54 - 57)

1 as part of their effort to develop Cologuard. 2 I cannot say what the -- in all 3 honesty what the connection between these 4 specific 60 patents are and the practice of 5 the Cologuard test. 6 Q. When you say that you think each of 7 the 60 patents were likely written for the 8 sake of protecting some aspects of 9 Cologuard, is that based on any facts? 10 MR. JONES: Objection to form. 11 A. No. You asked for my opinion. My 12 opinion is that there was probably -- it's 13 just a logical opinion that there must have 14 been some value in the 60 patents for them to 15 spend the money to develop these patents. 16 Q. But you don't actually know one way or 17 another whether the 60 patents were written 18 for the sake of protecting some aspects of 19 Cologuard? 20 MR. JONES: Objection to form. 21 A. I think one -- in order to answer that 22 question, one would have to look at each of 23 those individual patents, which you have 24 already asked me about, and you would have to Page 58	1 Paragraph 9? 2 MR. JONES: Objection to form. 3 A. (Witness reviews document.) 4 My opinion here is that 5 Dr. Patterson's argument fails to make the 6 connection between the asserted claims and 7 the diagnostic accuracy and the patient 8 uptake, and so the other 60 unrelated Exact 9 patents are provided as an example of the 10 fact that there may be many other reasons why 11 there was, for example, uptake of the test, 12 beyond just the asserted claims in the 13 disputed patent. 14 Q. And did the fact that some of those 60 15 patents were expired factor into that 16 opinion? 17 A. The opinion is not based on the fact 18 that there are 60 other patents. The opinion 19 is based on the fact that, in my opinion, 20 that his arguments fails to make that 21 connection between the accuracy and patient 22 uptake on the asserted claims of the '781 23 patent. 24 Q. So are the 60 other patents you Page 60
1 do a careful analysis of what exactly is 2 claimed and described in each of those 3 patents and compare that to all of the 4 aspects of the Cologuard product itself. I 5 have not done that analysis. 6 Q. Are you aware of whether any of those 7 60 patents you reference in Paragraph 9 of 8 your second declaration are expired? 9 MR. JONES: Objection to form. 10 A. I know that some of the patents that 11 we reference were expired. I don't recall 12 which ones or how many. 13 Q. Did that factor into your opinion? 14 MR. JONES: Objection to form. 15 A. Which opinion? 16 Q. Any opinion that you have. 17 MR. JONES: Objection to form. 18 A. You'd have to ask me a more specific 19 question in order for me to answer that. 20 Q. Did you consider whether -- I'm sorry. 21 Strike that. 22 Did the fact that some of the 60 23 patents you reference in Paragraph 9 were 24 expired affect the opinion that you offer in Page 59	1 reference in Paragraph 9 relevant to your 2 opinion then? 3 MR. JONES: Objection to form. 4 A. Like I said, the opinion which is what 5 you were asking about, as to whether or not 6 there is a nexus between the asserted claims 7 of the patent '781 and test accuracy and 8 patient uptake, whether his argument, if I 9 agree with the argument, and my opinion is 10 that I do not. It's added as an example that 11 there are other reasons why accuracy and 12 patient uptake of Cologuard could be -- the 13 reason for that could be associated with 14 these other 60 patents. It's not stating for 15 a fact that those 60 patents are, in fact, 16 the reason for patient uptake or accuracy of 17 the test. 18 Q. So you don't have an opinion as to 19 whether or not those 60 patents are the 20 reason for patient uptake or accuracy of the 21 test? 22 MR. JONES: Objection to form. 23 A. I have an opinion on patient uptake of 24 Cologuard, but I don't have -- I'm not Page 61

16 (Pages 58 - 61)

1 asserting that there is a direct connection
2 between the patient uptake and those 60
3 patents, either in my declaration or here.
4 Q. Do you know how many employees Exact
5 Sciences had at the end of 2008?
6 A. No, I don't.
7 Q. Are you aware that Exact Sciences had
8 only four employees at the end of 2008?
9 MR. JONES: Objection to form.
10 A. No. In that time frame, I -- again I
11 did not know how many people were working for
12 Exact Sciences.
13 Q. And you did not consider the number of
14 employees that were working at Exact
15 Sciences around the 2009 time frame in
16 formulating your opinions?
17 A. So you're asking me did -- were my
18 opinions formed by the number of employees at
19 Exact Sciences in that time frame?
20 Q. Was part of the consideration in
21 forming your opinions the number of
22 employees that were working at Exact
23 Sciences around the 2009 time frame?
24 A. I don't know how many people were

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1 employed at Exact in 2009.
2 Q. Are you aware that Exact Sciences was
3 developing products other than Cologuard
4 before 2009?
5 MR. JONES: Objection to form.
6 A. Certainly when I was at Exact
7 Sciences, we were developing products. They
8 were not called "Cologuard," that obviously
9 being before 2009. So I don't know if that
10 answers your question, but those are
11 certainly different from Cologuard.
12 Q. And are you aware as to whether or not
13 the 60 patents you reference in Paragraph 9
14 covered those earlier Exact Sciences
15 products that were different from Cologuard?
16 A. I don't recall as I sit here today.
17 Q. Are you familiar with a reference by
18 first author Nishikawa?
19 A. Yes.
20 (Exhibit 14 was introduced.)
21 Q. I am going to hand you what was marked
22 as Exhibit 14 in your prior deposition.
23 Do you recognize this as a paper
24 that you considered in forming your

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1 opinions? This is a Nishikawa paper
2 published in Clinica Chimica Acts in 2002.
3 A. Yes.
4 Q. And is this -- if you turn to
5 Paragraph 15 of your second declaration, is
6 this the Nishikawa reference that you are
7 referring to in that paragraph?
8 A. (Witness reviews document.)
9 Yes.
10 Q. Nishikawa is dated 2002, correct?
11 A. Yes, it is.
12 Q. And you were working at Exact Sciences
13 in 2002?
14 A. Yes, I was.
15 Q. Did you read the Nishikawa paper while
16 you were working at Exact Sciences?
17 A. I don't recall.
18 Q. Do you believe that Nishikawa
19 discloses advantages associated with
20 combining DNA tests and a fecal blood test
21 in a CRC assay?
22 MR. JONES: Objection to form.
23 A. I believe that he provides a
24 description of a well-known sentiment at the

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1 time by people skilled in the art, as
2 indicated in the last paragraph of the paper,
3 that indicates that the technique is highly
4 specific, noninvasive and cost-effective, and
5 should provide a more sensitive and specific
6 tool for mass screening of colorectal cancer
7 than is currently available, especially if
8 used in combination with fecal occult blood
9 testing and other methods for detecting
10 genetic abnormalities.
11 I think what he's teaching or
12 expressing is that people skilled in the art
13 at the time knew that that would be a
14 suitable way to improve sensitivity and
15 maintain sensitivity.
16 Q. If people skilled in the art in 2002
17 knew that combining fecal occult blood
18 testing and other methods for detecting
19 genetic abnormalities, if that was
20 well-known, what is your explanation for why
21 Exact Sciences wasn't doing it?
22 MR. JONES: Objection to form.
23 A. Exact Sciences at that time was tasked
24 primarily with trying to find ways of

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17 (Pages 62 - 65)

1 developing -- well, discovering, developing 2 stool DNA testing methodologies; and as I 3 testified earlier, in that time frame there 4 was the thought that combining DNA with FOBT 5 could be a way to also improve the 6 performance of the test. 7 Q. So what's your explanation for why 8 Exact Sciences wasn't actually doing that 9 when you worked there? 10 A. What's my explanation? 11 MR. JONES: Objection to form. 12 A. I don't have an explanation. I wasn't 13 the CEO of the company. 14 Q. If combining DNA with FOBT would 15 improve the performance of a test, wouldn't 16 the logical approach have been back in 2000 17 to 2005 to actually do that? 18 MR. JONES: Objection to form. 19 A. I will repeat what I just said a 20 couple moments ago, which is that idea had 21 been discussed. You're asking me why wasn't 22 it implemented. I can't answer that 23 question. 24 Q. A guaiac FOBT test does not require a Page 66	1 Q. And the date of the Kutzner reference 2 is 2005? 3 A. That's correct. 4 Q. And the Kutzner paper reports a study 5 using the guaiac FOBT, correct? 6 A. Let me confirm. 7 (Witness reviews document.) 8 It would appear that's the case. 9 (Phone ringing.) 10 MS. HABERNY: Do you need to take 11 that? 12 THE WITNESS: Do you mind? 13 MS. HABERNY: That's fine. We can 14 go off the record. 15 THE VIDEOGRAPHER: The time is 16 12:08. We are off the record. 17 (A discussion was held off the record.) 18 THE VIDEOGRAPHER: We are back on 19 the record. The time is 12:11. 20 BY MS. HABERNY: 21 Q. Dr. Whitney, you've not identified any 22 actual at-home CRC screening test that 23 combines blood and nucleic acid markers that 24 was performed before 2009, correct? Page 68
1 buffer that stabilizes proteins, correct? 2 MR. JONES: Objection to form. 3 A. I've actually never run a guaiac FOBT 4 test, but my understanding is that the smears 5 are put on cards, and they are dried, and 6 then developed after that. 7 Q. So a guaiac FOBT test does not require 8 a buffer that stabilizes proteins, correct? 9 MR. JONES: Objection to form. 10 A. I believe that's correct, yes. 11 Actually can I readdress that 12 question? 13 Q. No. 14 Are you familiar with a reference 15 by first author Kutzner? 16 A. Yes. 17 (Exhibit 11 was introduced.) 18 Q. I'm going to hand you what's been 19 marked as Exhibit 11 in your prior 20 deposition. This is a paper published in 21 Cancer Letters in 2005 by first author 22 Kutzner. Did you review this paper in 23 preparing your opinions for this case? 24 A. Yes, I did. Page 67	1 MR. JONES: Objection to form. 2 A. Are you asking me about a commercial 3 test? 4 Q. Let me ask it a different way. 5 You did not identify any actual 6 at-home CRC screening test of any kind that 7 combines blood and nucleic acid markers 8 between 2005 and 2009, correct? 9 MR. JONES: Objection to form. 10 A. The studies that were identified are 11 ones that clearly combined the DNA testing 12 and the FOBT test and -- as well as other 13 references that indicate, you know, what's 14 required in terms of being able to stabilize 15 samples for collecting at home and shipping 16 to a lab, and so in combination this provides 17 for, as we have written in the declaration, 18 the basis for indicating that the combined 19 understanding in the art was that this was 20 all doable. 21 Q. You have not identified any single 22 reference that standing alone discloses an 23 actual at-home CRC screening test of any 24 kind that combines blood and nucleic acid Page 69

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1 markers that was done between 2005 and 2009, 2 correct? 3 MR. JONES: Objection to form. 4 A. It's my understanding that the 5 argument against -- the argument in favor of 6 the obviousness does not need to come from a 7 single study or a single reference. The 8 combinations are sufficient. 9 Q. So that was not my question. 10 My question was, you have not 11 identified any single reference that 12 standing alone discloses an actual at-home 13 CRC screening test that combines blood and 14 nucleic acid markers that was done between 15 2005 and 2009, correct? 16 MR. JONES: Objection to form. 17 A. So let me answer it slightly 18 differently. 19 So what I have done is to identify 20 different studies that allow for collecting 21 DNA and FOBT -- sorry -- scratch that. 22 What I have done is to identify 23 different studies that describe how a single 24 fecal sample can be used to test for FOBT and Page 70	1 Q. I'm going to hand you what was marked 2 as Exhibit 10 in your prior deposition. 3 This is a 2008 paper that was published in 4 Gastroenterology by first author Levin. 5 Did you consider this Levin paper 6 in forming your opinions? 7 A. Yes, I did. 8 Q. Can you take a look at Paragraph 15 of 9 your second declaration and please look at 10 the last sentence of Paragraph 15. Do you 11 see it? 12 A. Yes, I do. 13 Q. Okay. That sentence, it's a long one, 14 but I will read it into the record "Indeed, 15 the 2008 joint guideline from the American 16 Cancer Society, the U.S. Multi-Society Task 17 Force on Colorectal Cancer and the American 18 College of Radiology proposed investigating 19 whether 'including a sensitive gFOBT or FIT 20 [another acronym for iFOBT] at the time of 21 testing would improve sensitivity of 22 DNA-based assays without adversely affecting 23 specificity." Do you see that? 24 A. Yes. Page 72
1 DNA, and that those are also methods for 2 being able to stabilize samples for shipping 3 from home, but those studies are not 4 encompassed within one study for all of those 5 different components. 6 Q. So yes or no, have you identified any 7 single reference that standing alone 8 discloses an actual at-home CRC screening 9 test that combines blood and nucleic acid 10 markers that was done between 2005 and 2009? 11 MR. JONES: Objection to form. 12 A. Say that again? 13 Q. The question I was about to ask you is 14 a yes-or-no question. Okay. Do you 15 understand that? 16 A. Yes. 17 Q. Yes or no, have you identified any 18 single reference that standing alone 19 discloses an actual at-home CRC screening 20 test that combines blood and nucleic acid 21 markers that was done between 2005 and 2009? 22 MR. JONES: Objection to form. 23 A. No. 24 (Exhibit 10 was introduced.) Page 71	1 Q. And that 2008 joint guideline is the 2 Levin paper that's Exhibit 10, correct? 3 A. That's correct. 4 Q. Okay. Let's take a look where that 5 appears in Levin. Okay. Can you turn to 6 Page 1578 of Levin, that's the journal page 7 number, not the exhibit page number. 8 So in the right-hand column, the 9 second paragraph, a little more than halfway 10 down, there is a sentence that reads 11 "Another question worthy of consideration is 12 whether or not including a sensitive gFOBT 13 or FIT at the time of testing would improve 14 sensitivity without adversely affecting 15 specificity." Do you see that? 16 A. I do. 17 Q. And that's what you were quoting in 18 Paragraph 15 of your declaration? 19 A. Yes. 20 Q. Okay. When you quoted that you began 21 the quote with the word "including," 22 correct, in your declaration? 23 A. Yes. 24 Q. And you said that this Levin paper Page 73

19 (Pages 70 - 73)

1 proposed investigating whether "including a 2 sensitive gFOBT or FIT," through the end of 3 that sentence, correct? 4 A. Yes. 5 Q. But the Levin paper actually says "The 6 question worthy of consideration is whether 7 or not including a sensitive gFOBT or FIT," 8 et cetera, towards the end of the sentence, 9 right? 10 A. What -- 11 Q. Does it say that? 12 A. It says -- the full sentence is 13 different from what's in the quotes in the 14 declaration, if that's what you're asking. 15 Q. And you say that the question was 16 whether including this test would improve 17 sensitivity, but the Levin paper actually 18 says whether or not? 19 A. What the Levin paper is saying is that 20 in research studies it was known that the 21 addition of FOBT to DNA testing can improve 22 sensitivity, and we provide in the 23 declaration, we provide references for that 24 that are prior to the 2009 priority date. Page 74	1 just gave. 2 Q. You're not answering my question. Why 3 did you -- I will ask you a different 4 question. 5 Why did you selectively omit the 6 "or not" from your declaration? 7 A. Because -- 8 MR. JONES: Objection to form. 9 A. -- my opinion is exactly how I just 10 described it, which is that what he is 11 describing is the need for taking research 12 studies and putting that into the clinical 13 realm, and this is a guidelines paper talking 14 about running those kinds of studies, and he 15 is not suggesting that there isn't evidence 16 that it wouldn't work, because it's already 17 been shown that there is improvement from 18 adding FOBT to DNA testing. 19 What he is asking is a very 20 different question, which is not germane to 21 in my opinion, to what you're asking. 22 Q. I don't see an answer to my question 23 there. 24 Why did you selectively omit the Page 76
1 What Levin is talking about, as a 2 representation of clinical guidelines, is 3 whether or not this would still hold true in 4 clinical studies. 5 Q. Right. And he didn't say -- he wasn't 6 questioning just whether it would hold true 7 in clinical studies, he was questioning 8 whether or not, correct? 9 A. What he is questioning is whether or 10 not. He is also questioning whether -- 11 presumably he is questioning the extent to 12 which sensitivity could be improved. 13 He is basically saying that there 14 are some clear learnings from research 15 studies that have been published, and he is 16 posing the question that this would be a very 17 good thing to try in a clinical study as 18 people skilled in the art would have 19 recognized at that time. 20 Q. Well, his actual question is whether 21 or not this would be a good thing to try, 22 not just whether it would be, correct? 23 A. I think we are dissecting words here. 24 What he -- I would stick by the answer that I Page 75	1 "or not" from your declaration? 2 MR. JONES: Objection to form. 3 Assumes facts not in evidence. 4 THE WITNESS: Sorry? 5 MR. JONES: Nothing. Go ahead. 6 A. I actually think I answered the 7 question. I think I answered the question. 8 Q. Why did you selectively omit the "or 9 not" from your declaration? 10 MR. JONES: Objection to form. 11 Assumes facts not in evidence. 12 A. In my opinion, which is what is quoted 13 here, is that the guidelines committee had 14 indicated that there was a very high 15 likelihood that this was going to provide a 16 positive result, and that's why they're 17 recommending that. 18 Q. Levin also questioned whether the 19 combination would improve sensitivity 20 without adversely affecting specificity, 21 correct? 22 MR. JONES: Objection to form. 23 A. Yes, he does. 24 Q. But you didn't include that in your Page 77

20 (Pages 74 - 77)

1 declaration, did you? 2 MR. JONES: Objection to form. It 3 misrepresents his declaration. 4 A. In my opinion, and I think this is 5 what was known to people in the art, is that 6 when we are going to combine different types 7 of biomarkers, that one would start with 8 biomarkers that are reasonably high 9 specificity, recognizing that addition of 10 different biomarker types could provide for 11 cumulatively improved sensitivity, but 12 specificity doesn't work in the same way. 13 So what he's saying is that by 14 having a test like FOBT, which is already 15 known to be fairly highly specific, that 16 would be a good place to start. 17 Q. You did not reference Levin's 18 questioning of whether the combination would 19 improve sensitivity without adversely 20 affecting specificity in your declaration, 21 correct? 22 MR. JONES: Objection. 23 Misrepresents the quote in the 24 specification. Page 78	1 tests, correct? 2 A. I believe that Levin probably 3 recognized that is important, and I think 4 most people in the field would recognize the 5 same thing. 6 Q. Levin does not teach or suggest 7 processing fecal samples into two portions 8 at home to be stabilized into two different 9 buffers, correct? 10 MR. JONES: Objection to form. 11 A. The Levin paper is a guidelines paper 12 that is referring to other literature. It's 13 not a paper that is trying to suggest how, 14 you know, at that level of detail how samples 15 should be collected or processed. 16 Q. Can you please go to Paragraph 20 of 17 your declaration. Do you see it? 18 A. Yes. 19 Q. You opine that Dr. Patterson attacks 20 the prior art references that you cite 21 individually rather than considering their 22 collective teachings in combination; is that 23 right? 24 A. Yes, that's what is written here, yes. Page 80
1 MS. HABERNY: No speaking. Stop 2 the speaking objections. 3 MR. JONES: Stop misrepresenting 4 his declaration. 5 MS. HABERNY: Stop it. There is 6 no speaking objections. 7 A. The point that's being made here is 8 about improving the sensitivity, that's the 9 part that was quoted. 10 Q. And you did not include Levin's 11 questioning of whether the combination would 12 improve sensitivity without adversely 13 affecting specificity in your declaration, 14 correct? 15 MR. JONES: Objection. 16 Misrepresents the quote in the declaration. 17 A. The declaration says "without 18 improving sensitivity" -- "would improve 19 sensitivity without adversely affecting 20 sensitivity." It says that in the quote in 21 the declaration. 22 Q. You agree that Levin recognized that 23 specificity is also important in whether it 24 would be advantageous to combine these Page 79	1 Q. What do you mean by that? 2 A. I think it is self-explanatory 3 actually. I can read it for you. 4 Q. No. It's not self-explanatory. I 5 would like to know what you mean by it. 6 MR. JONES: Objection to form. 7 A. My understanding is, as required in 8 obviousness analysis, is that the different 9 elements of the claims do not need to be 10 represented in a single reference or study, 11 and that by looking at individual references 12 and ignoring the collective teaching of the 13 combined reference is not what is supposed to 14 be done. 15 Q. You would agree that detecting 16 advanced adenomas is important for 17 prevention of CRC, correct? 18 A. What do you mean by preventing CRC? 19 Q. You would agree that detecting 20 advanced adenomas is important to screening 21 for CRC, correct? 22 MR. JONES: Objection to form. 23 A. I agree there's certainly interest in 24 being able to detect advanced adenomas, but I Page 81

21 (Pages 78 - 81)

1 also recognize that, I believe it's only 2 about 10 percent of advanced adenomas that 3 progress to cancer. So using that as a 4 primary aim would be ill-advised, I would 5 say. 6 Q. Do you have any experience -- strike 7 that. 8 Do you have any experience treating 9 colorectal cancer patients? 10 A. No, I don't. 11 Q. Do you have any experience diagnosing 12 colorectal cancer patients? 13 A. No, I do not. 14 Q. Do you have any experience screening 15 colorectal cancer patients? 16 A. Depends how you define "screening." 17 Q. Have you ever screened a patient for 18 colorectal cancer? 19 A. I have run patient samples that 20 constitute a screening test. 21 Q. Where? 22 A. At Exact Sciences. 23 Q. Do you have any experience in 24 treatment decisions based on the results of Page 82	1 A. Let me read it. 2 (Witness reviews document.) 3 Yes. 4 Q. And you have an opinion that DNA 5 biomarkers and blood protein biomarkers 6 would be expected to pick up different 7 instances of CRC and therefore be 8 complementary? 9 A. My opinion is that there are different 10 mechanisms by which DNA could become altered 11 and used as a biomarker, compared to blood, 12 which is based on a generalized phenomenon of 13 tumors that bleed and even some other 14 lesions, and so based on that, because 15 they're very different mechanisms, my opinion 16 is that there is a better chance that these 17 could be complementary than two types of 18 biomarkers that originate from the same 19 origin. 20 Q. Would you agree that whether DNA 21 biomarkers and blood protein biomarkers 22 would be expected to pick up different 23 instances of CRC would depend on which DNA 24 biomarker is being used? Page 84
1 a colorectal cancer screening test? 2 A. I do not. 3 Q. Have you ever developed a commercial 4 colorectal cancer screening assay yourself? 5 MR. JONES: Objection to form. 6 A. I have been part of a team that has 7 developed a colorectal cancer screening test. 8 Q. A commercial one? 9 A. Yes. 10 Q. Which one? 11 A. PreGen-26. 12 Q. Where did you do that? 13 A. Exact Sciences. 14 Q. And that was sold to patients? 15 A. Correct. I believe so. 16 Q. Can you turn to Paragraph 28, please. 17 MR. JONES: Of his declaration? 18 MS. HABERNY: Yes, sorry. 19 Q. Of your second declaration. 20 A. Okay. 21 Q. Here you refer to a complementary 22 nature of a candidate biomarkers that you 23 say leads to improvements in assay 24 sensitivity when biomarkers are combined? Page 83	1 MR. JONES: Objection to form. 2 A. For stool-based DNA biomarkers, I 3 certainly recognize that different biomarkers 4 have different levels of sensitivity and 5 specificity, candidate biomarkers, I should 6 say. 7 Q. Is it your opinion that in 2009 it was 8 predictable that the combination of DNA and 9 blood protein biomarkers would improve 10 sensitivity in a CRC screening test? 11 A. I believe it was predictable. It was 12 also demonstrated in selected studies that we 13 reference in the declaration. 14 Q. You were not working on CRC screening 15 tests in 2009, correct? 16 A. I'm sorry, was I? 17 Q. Were you? 18 A. No. No. 19 THE VIDEOGRAPHER: The time is 20 12:39. We are off the record. 21 (A lunch recess was taken.) 22 23 24 Page 85

22 (Pages 82 - 85)

1 AFTERNOON SESSION 2 THE VIDEOGRAPHER: Stand by. We 3 are back on the record. The time is 1:17. 4 BY MS. HABERNY: 5 Q. Can you please turn to Paragraphs 31 6 and 32 of your second declaration. 7 A. Yes. 8 Q. And here you're opining on a reference 9 by first author Vilkin? 10 A. Yes. 11 Q. Is that correct? 12 A. Yes. 13 (Exhibit 29 marked for 14 identification.) 15 Q. Okay. I'm marking as Exhibit 29 a 16 paper by first author Vilkin published in 17 2005 in the American Journal of 18 Gastroenterology. 19 Is this the Vilkin paper that 20 you're opining on in your declaration? 21 A. Yes. Yes. 22 Q. Would you turn to Page 2520 of Vilkin. 23 A. Okay. 24 Q. And you see the "Methods" section? Page 86	1 A. In this research study that Vilkin 2 ran, which is not how FOBT or how the FIT 3 test is used clinically, in this study, yes, 4 he collected three consecutive samples. 5 Q. That again had a bunch of 6 nonresponsive stuff in it. 7 The question is, the method 8 reported -- the method in the study reported 9 in Vilkin involved collecting three 10 consecutive daily fecal samples, correct? 11 MR. JONES: Objection to form. 12 A. In my response I believe that the 13 context of this study is important. And by 14 omitting that you change the way my response 15 can be interpreted. 16 Q. Okay. Are you capable of answering 17 only the question that I'm asking you? 18 MR. JONES: Objection. 19 Argumentative. 20 A. What I'm capable of doing is giving 21 you a response to your question in a way that 22 I believe is honest and complete which 23 includes context. 24 Q. Did the method of the study that was Page 88
1 A. Yes. 2 Q. You see a subsection called "Fecal 3 Sampling"? 4 A. Yes. 5 Q. And you see about two-thirds of the 6 way down there is a sentence that says "The 7 examinee is requested to prepare three 8 consecutive daily samples during the week 9 before a colonoscopy examination." 10 A. I see that. 11 Q. Okay. So you agree that the method 12 that the study reported in Vilkin used 13 involved collecting three consecutive daily 14 samples, correct? 15 A. The study as designed by Vilkin 16 collected three samples, but I will also note 17 that that's not necessarily how that would be 18 run clinically. 19 Q. I wasn't asking about clinically. I 20 was asking about the Vilkin study. 21 So you agree that the method the 22 study reported and Vilkin used involved 23 collecting three consecutive daily samples, 24 correct? Page 87	1 performed and then reported in Vilkin 2 involve collecting less than three 3 consecutive daily fecal samples? 4 MR. JONES: Objection. Form. 5 A. That's a different question. Let me 6 review. (Witness reviews document.) 7 To answer that question, I believe 8 -- I do not believe that the subjects were 9 asked to complete less than three samples. 10 Q. Would you please turn to Page 2523 of 11 Vilkin. Do you see Table 3? 12 A. Yes. 13 Q. You would agree that there was a range 14 of sensitivity across the three sample sets 15 that were analyzed in the Vilkin paper, 16 correct? 17 MR. JONES: Objection to form. 18 A. I'm not sure if I would agree to that 19 in the sense that there were six cancer 20 samples here. 21 Let me think about that. 22 There were six cancer subjects, I 23 should say, and I don't know if the 24 differences in those numbers are Page 89

23 (Pages 86 - 89)

1 statistically significantly different. 2 Q. Well, do you think that the difference 3 between 66.7 percent specificity and 100 4 percent sensitivity -- let me start he over. 5 Do you think that the difference 6 between 66.7 percent sensitivity and 100 7 percent sensitivity is not statistically 8 significant? 9 MR. JONES: Objection to form. 10 A. I don't know. I haven't run the stats 11 on that. These are a very small number of 12 cancer samples. 13 Q. So you don't know one way or another 14 whether there is a range of sensitivity 15 across the three sample sets as reported in 16 Vilkin, correct? 17 MR. JONES: Objection to form. 18 A. What I see from the table and what 19 he's reporting is that he had different 20 sensitivities for the three different samples 21 for each of these subjects, but as I already 22 indicated, it's not clear if those 23 differences are statistically significant. 24 Q. Okay. So you don't know one way or Page 90	1 when all three tests were performed and 2 utilized for analysis"? 3 A. I see that sentence. 4 Q. Do you have any reason to doubt that 5 that is accurate? 6 A. I think what Vilkin is saying in this 7 statement here is that -- I'm not sure what 8 he means by "best results," but if I were to 9 presume that he means that the sensitivity 10 that one gets is highest by looking at three 11 different samples, then I would conclude that 12 what he believes is that by running three 13 different tests on the same patient is that 14 one could get perhaps some improved results 15 that way, but it doesn't preclude the idea of 16 using one test. 17 Q. So you think that a person of skill in 18 the art reading the Vilkin statement that 19 "the best results were obtained when all 20 three tests were performed and utilized for 21 analysis" would be motivated to run just one 22 test? 23 MR. JONES: Objection to form. 24 A. What I believe Vilkin teaches very Page 92
1 another whether there is a statistically 2 significant range of sensitivity across the 3 three sample sets as reported in Vilkin? 4 A. I do not. 5 Q. So you don't have any opinion on that? 6 A. Opinion on what? 7 Q. You don't have any opinion on whether 8 there is a statistically significant range 9 of sensitivities across the three sample 10 sets as reported in Vilkin? 11 A. I don't -- I haven't, as I said, I 12 haven't run the statistics on this to know 13 that there is a significant difference in 14 there. So what I'm saying is that, yeah, at 15 this point, as I look at that, I don't know 16 that those are significant differences 17 between the three different samples. 18 Q. Can you turn to Page 2522 of Vilkin. 19 Do you see in the right-hand column the 20 paragraph that starts "Inpatient 21 Complementary Variation"? 22 A. Yes. 23 Q. And you see the last sentence in that 24 section says "The best results were obtained Page 91	1 clearly in this paper is that he's run a 2 research study to try to characterize the 3 performance of this test and that in his 4 particular design he's done it this way where 5 he is taking three samples from each subject, 6 and he is interpreting the results of his 7 study, but he clearly indicates later on in 8 the paper that for clinical application, 9 which is very different from this research 10 study, that one would have to do an 11 independent analysis of the cost/benefit of 12 running one or more samples. 13 He further goes on to point out 14 that in the clinical realm, that there are, 15 in fact, different numbers of tests run per 16 patient in different countries. 17 Q. Are you reading from the Vilkin 18 reference? 19 A. I'm summarizing what is in my 20 declaration. I could read it directly if you 21 would like. 22 Q. Can you show me where the Vilkin paper 23 says that for clinical application one would 24 have to do an independent analysis of the Page 93

24 (Pages 90 - 93)

1 cost/benefit of running one or more samples?
2 A. Let me go to the declaration and see
3 if I can find the section.
4 (Witness reviews document.)
5 In my declaration -- shall I cite
6 where I'm reading from?
7 Q. Sure.
8 A. I don't have to.
9 Q. Please.
10 A. Paragraph 69, "Contrary to Patterson's
11 assertions, Vilkin does not require the
12 collection of three daily clinical samples
13 for use of the disclosed FIT test. Vilkin
14 explains that 'the decision of the number of
15 fecal samples to be obtained and optimal
16 fecal hemoglobin threshold chosen for the
17 screening in average risk population will
18 also involve evaluation of cost/benefit.'"
19 Q. And that portion of Vilkin is
20 referring to annual or biannual testing,
21 correct?
22 MR. JONES: Objection to form.
23 A. I'm not sure where you're referring
24 to.

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1 Q. The preceding paragraph in Vilkin says
2 "At present we will continue with collecting
3 three annual fecal tests," correct?
4 A. That's what -- this paragraph starts
5 by saying that, yes.
6 Q. And that's not referring to any
7 methodology regarding consecutive daily
8 tests, correct?
9 A. In that sentence it does not, but it
10 also doesn't say that there is more than one.
11 Q. What would be the point of doing
12 annual fecal tests?
13 MR. JONES: Objection to form.
14 A. The point of doing fecal occult blood
15 test screening is to pick up colorectal
16 cancer.
17 Q. And you, sitting here as an expert, in
18 your opinion, what would be the purpose of
19 doing annual fecal tests?
20 A. The purpose of -- I'm not sure I
21 understand the question.
22 Q. You see where Vilkin refers to --
23 MS. HABERNY: Hold on a second.
24 There is someone outside the door.

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1 THE VIDEOGRAPHER: The time is
2 1:34. We are off the record.
3 (A discussion was held off the record.)
4 THE VIDEOGRAPHER: Stand by.
5 We're back on the record. The time is 1:34.
6 BY MS. HABERNY:
7 Q. Do you see where Vilkin refers to
8 collecting three annual fecal tests, on
9 Page 2524?
10 A. Yes, I do.
11 Q. As an expert what do you understand to
12 be the purpose of doing annual fecal tests?
13 A. The purpose is to use that test to
14 screen for colorectal cancer.
15 Q. And why would one want to do that
16 annually?
17 MR. JONES: Objection to form.
18 A. My belief is that every screening test
19 should be done with some degree of
20 regularity. Just as colonoscopy is done on
21 some schedule, my understanding is the
22 Cologuard is run on some schedule. So there
23 is repeated testing for different tests.
24 Q. Is a reason to do the screening

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1 annually because the results can change from
2 year to year?
3 A. That's true of any test. I mean
4 colonoscopy is run every five to ten years,
5 and the point is that, you know, cancers can
6 grow over time.
7 Q. And to meaningfully detect that
8 change, a reasonable time span between
9 screening would be annual, correct?
10 MR. JONES: Objection to form.
11 A. No. The schedule in which different
12 types of tests would be run depends on the
13 specific tests.
14 Q. And here for the fecal occult blood
15 tests that are being referenced in Vilkin
16 the authors posit that a reasonable time
17 span between screening would be annual,
18 correct?
19 MR. JONES: Objection to form.
20 A. The Vilkin paper is a research study.
21 My belief is that what he is describing here
22 is what's done clinically in different
23 countries, but this is again, in my belief,
24 he is not trying to dictate clinical practice

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25 (Pages 94 - 97)

1 here. What he's doing is he is pointing out 2 there are different intervals that are used 3 in different countries. 4 Q. Okay. If you go back to the "Methods" 5 section where Vilkin explains that the 6 samples are prepared over three consecutive 7 days. Do you see that? 8 A. Yes. 9 Q. And the point of that is to run the 10 test in triplicate, correct? 11 MR. JONES: Objection to form. 12 A. In this research study, he's 13 collecting three different samples. I'm not 14 sure what you mean by running them in 15 triplicate. 16 Q. Are you a trained laboratory 17 scientist? 18 A. Yes, I am. 19 Q. When you do assays is it common to do 20 them in triplicate? 21 A. Not necessarily. 22 Q. It's not a common practice? 23 A. Not necessarily. 24 Q. What about, for example, if you're Page 98	1 A. In some cases, as I just explained, 2 people may be running experiments in 3 duplicate or in triplicate in order to assess 4 reproducibility. 5 Q. Would -- in your experience as an 6 expert, would a patient who is undergoing 7 fecal occult blood test over three 8 consecutive days be likely to show a 9 difference in cancer status? 10 MR. JONES: Objection to form. 11 A. Repeat the question. 12 Q. Would testing by fecal occult blood 13 test over three days be likely to show a 14 difference in cancer status of a patient? 15 MR. JONES: Objection to form. 16 A. Reproducibility could depend on many 17 different factors. 18 Q. Would testing by fecal occult blood 19 test over three consecutive days be likely 20 to show a difference in cancer status of a 21 patient? 22 MR. JONES: Objection to form. 23 A. Depending on the reproducibility of 24 any given -- okay, depending on the Page 100
1 going to do a biochemical assay, is it 2 common to perform such an assay in 3 triplicate? 4 A. I can tell you when I do research now 5 using RNA sequencing, I don't do that in 6 triplicate. 7 Q. If you are doing an assay that 8 requires a biochemical reaction, is it 9 common to do that in triplicate? 10 MR. JONES: Objection to form. 11 A. The answer to the question is it 12 depends on what the assay is, that's what I 13 was trying to explain. 14 Q. When would a scientist want to do 15 assays in triplicate? 16 MR. JONES: Objection to form. 17 A. Assays -- if assays are simple enough 18 to run, it's not uncommon to run them either 19 in duplicate or triplicate in order to assess 20 the reproducibility. 21 Q. So then a reason that scientists 22 commonly run assays in triplicate is to 23 assess reproducibility? 24 MR. JONES: Objection to form. Page 99	1 reproducibility of the fecal occult blood 2 test as it's run may impact differences in 3 terms of reproducibility. 4 Q. And Vilkin reported that the best 5 results in their test were obtained when all 6 three of the consecutive daily fecal samples 7 were tested and utilized for analysis, 8 correct? 9 MR. JONES: Objection to form. 10 A. What Vilkin indicates is that in their 11 study, with the very small number of cancer 12 samples, and calculating averages, that there 13 was differences between the three different 14 samples, but what is not described in here is 15 how reproducible that test is in their hands, 16 for instance, compared to any other lab where 17 it may have much less variability than what 18 he is showing on the table. 19 Q. You said that you thought Vilkin 20 teaches determining whether one or more 21 consecutive tests would be desirable; is 22 that your opinion? 23 A. I can read it for you. 24 MR. JONES: Objection to form. Page 101

26 (Pages 98 - 101)

1 A. Let me read it to you again. "Vilkin
2 does not require the collection of three
3 daily clinical samples for use of the
4 disclosed FIT test. Vilkin explains that
5 'the decision on the number of fecal samples
6 to be obtained, an optimal fecal hemoglobin
7 threshold chosen for screening in an average
8 risk population will also involve evaluation
9 of cost/benefit.'"
10 Q. Okay. Nowhere in that passage does
11 Vilkin say a person of skill in the art
12 should test just one sample, correct?
13 MR. JONES: Objection to form.
14 A. In that particular passage he says
15 nothing about -- well, no.
16 (Witness reviews document.)
17 In terms of the discussion of
18 number of fecal samples, he's very clear that
19 there is no specification of how many samples
20 should be run.
21 Q. That wasn't my question.
22 Nowhere in that passage does Vilkin
23 say a person of skill in the art should test
24 just one sample, correct?

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1 MR. JONES: Objection to form.
2 A. What he says is the number of samples,
3 which is what you are asking about, should be
4 determined based on a cost/benefit analysis.
5 Q. Does Vilkin or does Vilkin not say a
6 person of skill in the art should test just
7 one sample?
8 MR. JONES: Objection to form.
9 A. Can you read me back my other
10 response?
11 Q. That's not responsive. It's a
12 yes-or-no question.
13 Does he say it or doesn't he?
14 A. No. If you take it out of context, it
15 completely changes the response.
16 Q. I would like an answer to my question.
17 It's simple. He either does or he doesn't.
18 A. It's not a yes-or-no question.
19 Q. It is. Does Vilkin or does Vilkin not
20 say that a person of skill in the art should
21 test just one sample?
22 MR. JONES: Objection to form.
23 A. What you're asking me to say is with
24 respect to the number of fecal samples, he is

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1 very clear in that passage as to what his
2 opinion is on the number of samples that
3 should be tested.
4 Q. Read me the sentence where he says a
5 POSA should test just one sample?
6 MR. JONES: Objection to form.
7 A. This isn't about a POSA.
8 Q. Where does he, anywhere in this paper,
9 say that it is desirable to test just one
10 sample?
11 MR. JONES: Objection to form.
12 A. What's clearly -- I mean I will just
13 repeat the same thing I've said before.
14 Clearly he is talking about the number of
15 fecal samples that should be tested, that
16 should be used to report a result, and he is
17 saying that that decision should be made
18 based on a cost/benefit analysis. It's very
19 clear.
20 Q. Do you know what the word "one,"
21 o-n-e, means?
22 MR. JONES: Objection.
23 Argumentative. Harassing the witness.
24 Q. Do you?

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1 MR. JONES: Objection. Harassing
2 the witness.
3 Q. I'm asking you where -- I want you to
4 read me the sentence -- Vilkin says that it
5 is desirable to use just one fecal sample
6 for fecal occult blood sampling?
7 MR. JONES: Objection to form.
8 A. Your question is not relevant.
9 Q. You have to answer it. It's my
10 question.
11 A. Okay. My answer is "the decision of
12 the number of fecal samples to be obtained
13 and optimal fecal hemoglobin threshold chosen
14 for the screening in average risk population
15 will also involve evaluation of cost/
16 benefit."
17 Q. Okay. I would like to get that
18 cleanly. So please read me the sentence
19 where Vilkin says that it is desirable to
20 use just one fecal sample for fecal occult
21 blood sampling testing?
22 MR. JONES: Objection to form.
23 A. He says that the number of samples is
24 to be determined.

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1 Q. Okay. 2 A. That's what he is saying. 3 Q. Does he anywhere determine that that 4 number should be one? 5 MR. JONES: Objection to form. 6 A. He doesn't specify how many it should 7 be. 8 Q. Okay. 9 A. He does specify, however, that in 10 different countries, it's a single sample run 11 at different time intervals. 12 Q. It's your opinion that a POSA would 13 understand that the Vilkin reference does 14 not require refrigeration of the stool 15 samples? 16 A. I'm sorry, repeat the question. 17 Q. Is it your opinion that a POSA would 18 understand that the Vilkin reference does 19 not require refrigeration of stool samples? 20 A. What Vilkin does in this study is he 21 asks the participants to put samples in the 22 refrigerator when they're collecting three 23 samples, but that is not representative of 24 clinical practice necessarily. Page 106	1 asked for the subjects in this case to handle 2 those. 3 Q. What would be the benefit of 4 refrigerating the three consecutive daily 5 fecal samples? 6 A. The benefit would be that it would 7 minimize any degradation of the hemoglobin 8 that would be in the samples by holding them 9 over, I guess, up to three days in an 10 uncontrolled environment. 11 Q. Can you turn to page 2524 of Vilkin. 12 A. Yes. 13 Q. Do you see the top paragraph, not the 14 first full paragraph, but the top paragraph? 15 MR. JONES: 16 A. Which column? 17 Q. Sorry, the left column. 18 A. Starting "For many years?" 19 Q. No. The one above that. 20 A. Okay. 21 Q. Do you see where Vilkin says "It is 22 important to emphasize to the patient and to 23 the medical service the correct storage and 24 duration of storage"? Page 108
1 Q. Does Vilkin say that is not 2 representative of clinical practice? 3 MR. JONES: Objection to form. 4 A. No, I don't believe he does. 5 Q. Do you have any support for your 6 assertion that refrigerating fecal samples 7 is not representative of clinical practice? 8 A. My understanding is that if one were 9 to run a single fecal sample, there would be 10 no reason to refrigerate that, they would 11 send it in directly as soon as the sample was 12 collected, and then it would be received at 13 the lab for testing. 14 Q. But if one were to run three 15 consecutive daily fecal samples, then there 16 would be a reason to refrigerate the 17 samples? 18 A. Not necessarily. 19 Q. What's your explanation for why Vilkin 20 required his subjects to refrigerate their 21 three consecutive daily fecal samples? 22 A. I believe that it was a research study 23 design aspect that they had decided on, and 24 that's how they collected the samples and Page 107	1 A. Yes. I see where you're referring to. 2 Q. And the storages in the Vilkin study 3 was in the refrigerator, correct? 4 MR. JONES: Objection to form. 5 A. Hold on. Let me read the context 6 here. (Witness reviews document.) 7 Yeah, I mean that sentence follows 8 a preamble that talks about the samples being 9 kept up to three weeks, which I don't believe 10 is representative of how this would be used 11 clinically. 12 Q. That's not answering the question. 13 A. Okay. 14 Q. The storage used in the Vilkin study 15 was in the refrigerator, correct? 16 MR. JONES: Objection to form. 17 A. In his research study, he asked 18 participants to store samples in the 19 refrigerator. 20 Q. Okay. And can you please go to the 21 right-hand column. 22 A. Okay. 23 Q. And it's the second-to-last paragraph 24 before "Acknowledgements." The paragraph Page 109

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1 starts with "The participation rate." 2 A. Okay. 3 Q. Do you see in that paragraph where the 4 Vilkin authors report "The storage of the 5 prepared iFOBT in the refrigerator until 6 development is important for maintaining the 7 test stability"? 8 A. I see that. 9 Q. Okay. Do you disagree with the Vilkin 10 authors? 11 A. (Witness reviews document.) 12 What I interpret from what he's 13 saying here is that -- he doesn't specify at 14 what point the storage he's referring to, 15 whether it's after collection of the sample, 16 before sending it into a lab, versus after it 17 has been received at a lab, before it's been 18 run on an instrument. 19 Q. Does Vilkin anywhere talk about 20 refrigerating samples at a lab before it's 21 -- before they have been run on an 22 instrument? 23 A. I believe he does. 24 Q. And you think that's what this Page 110	1 refrigeration at home? 2 A. Not necessarily. All he may be saying 3 in this case is that even in -- if there's 4 countries with high ambient temperatures, 5 that would apply to homes and labs. 6 So again he doesn't specify, he's 7 adding that even in homes when there's no 8 air-conditioning that can certainly provide 9 for high temperatures in the home, but he is 10 not talking about where the storage is 11 occurring or at what length of time he is 12 talking about. 13 Q. So he's just pontificating about home 14 temperatures when he is really referring to 15 storage in a laboratory? 16 A. No. I don't read it that way at all. 17 I read it as saying that including homes. 18 Q. Okay. The next sentence says "The 19 double zip-lock bags were provided" -- let 20 me start over. 21 The next sentence says "The double 22 zip-lock bags we provided answered some of 23 the screenees' hesitancy about keeping the 24 prepared test transiently in their home Page 112
1 sentence refers to? 2 A. I don't know. I just told you that. 3 Q. Okay. So you don't have any reason to 4 disagree with Vilkin's statement that the 5 storage of the prepared iFOBT in a 6 refrigerator until development is important 7 for making the test stability, correct? 8 MR. JONES: Objection to form. 9 A. I don't know which storage he is 10 talking about, but if someone were to make 11 the comment that -- he is making the comment 12 here, I can't tell you if I agree with it or 13 not, only because I don't know over what 14 period of time he is talking about storing 15 these samples, where is the storage 16 occurring. I don't have an opinion on that 17 just for those reasons. 18 Q. Okay. You see the next sentence that 19 says "This is critical in countries with 20 high ambient temperatures, even when homes 21 are air conditioned"? 22 A. I see that. 23 Q. Does that give you the context to 24 understand that Vilkin is talking about Page 111	1 refrigerator." Do you see that? 2 A. I do. 3 Q. Okay. So now does that give you 4 context to understand that Vilkin believes 5 it is important to refrigerate the samples 6 collected at home in a home refrigerator? 7 A. I think what he is saying is that for 8 the sake of collecting three samples, as was 9 described in this paper, that because there 10 was three samples, they wanted to control 11 uncontrolled temperature, as he is describing 12 here, and that for the sake of this study, 13 they provided those zip-lock bags so the 14 people would be more acceptable to putting 15 those samples in their home refrigerator. 16 What I don't believe he is doing is trying to 17 dictate clinical practice. 18 Q. I didn't ask you about clinical 19 practice, do you understand that? 20 MR. JONES: Objection to form. 21 A. I was offering that to you. 22 Q. Yes, well, it's not part of the 23 question. 24 MR. JONES: Objection to form. Page 113

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1 A. Okay. 2 Q. Is it your opinion that Vilkin is 3 discussing keeping the prepared test 4 transiently in subject's home refrigerator 5 because he is really referring to storage in 6 a laboratory? 7 MR. JONES: Objection to form. 8 A. What I believe he is talking about 9 specifically at this point is the zip-lock 10 bags for storing the samples in the home for 11 people who are collecting three samples, 12 which would be different if you were only 13 collecting one sample. It does not -- still 14 does not preclude the idea that storage could 15 also be beyond just the home. 16 Q. So in your opinion Vilkin is using the 17 words "home" and "laboratory" 18 interchangeably? 19 MR. JONES: Objection to form. 20 A. No, I didn't say that. 21 Q. In this paragraph Vilkin is referring 22 to storage of fecal samples in a home 23 refrigerator, correct? 24 A. In the last sentence he is referring Page 114	1 A. What he is saying is that for his 2 study, where they did collect three samples 3 from each individual, that their 4 recommendation was that they would keep those 5 samples in a home refrigerator. 6 Q. And nowhere in the Vilkin reference 7 does Vilkin say that refrigeration is 8 optional, correct? 9 MR. JONES: Objection to form. 10 A. The Vilkin paper describes a 11 particular protocol that they had come up 12 with for the sake of this study, and there 13 wasn't an option of whether or not or they 14 would or would not be refrigerated. The 15 request of all participants was that they 16 collect three samples. It then required 17 storage in a refrigerator. 18 Q. You agree that the iFOBT test reported 19 in Vilkin requires user interaction with the 20 fecal sample? 21 A. The requirement for -- give me a 22 minute. 23 (Witness reviews document.) 24 The requirement for interacting Page 116
1 to storing samples in a home refrigerator -- 2 sorry -- the second-to-last paragraph. 3 Q. And nowhere in this paragraph in 4 Vilkin on Page 2524 does he refer to storage 5 in a laboratory refrigerator, correct? 6 A. He does not, but it does not preclude 7 that as the -- as a possible explanation for 8 what he's talking about when he describes 9 storage generally, because, as they describe 10 earlier in the paper, I believe, samples were 11 also stored in a laboratory in a refrigerator 12 when they were received. 13 The sentence that we are referring 14 to in terms of the storage of the prepared 15 iFOBT in a refrigerator until development is 16 important for maintaining the testability 17 obviously implies that it is more than just 18 the home. These are not developed at home. 19 Q. Even if additional refrigeration is 20 required for the stool samples, the Vilkin 21 authors report that refrigeration is 22 important for maintaining testability and 23 that refrigeration would include in a home 24 refrigerator, correct? Page 115	1 with the fecal sample, I believe is that, 2 yeah, they have to put the -- what's it 3 called -- the -- I'm not sure what you call 4 that device, but it's attached to what looks 5 like the cap of the tube that would have to 6 be stuck into the stool sample and then 7 inserted into a tube. 8 Q. Are you familiar with the Itzkowitz 9 reference that you discuss in your 10 declaration? 11 A. Yes. 12 Q. And you agree that the Itzkowitz paper 13 described direct defecation into a sample 14 collection device that is then sealed? 15 A. Could we refer to the -- well, either 16 a specific section in the declaration or the 17 actual reference? 18 (Exhibit 7 was introduced.) 19 Q. Yeah, I'll hand you what has been 20 previously marked as Exhibit 7. Exhibit 7 21 is a 2007 paper published in Clinical 22 Gastroenterology and Hepatology by, first 23 author, Steven H. Itzkowitz. 24 Is this the Itzkowitz reference Page 117

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1 that you opine on in your declaration? 2 A. Yes. 3 Q. You agree that Itzkowitz described 4 direct defecation into a device that is then 5 sealed? 6 A. Let me just find that part in the 7 methods. 8 (Witness reviews document.) 9 Yes. 10 Q. Do you agree that Itzkowitz does not 11 require user interaction with the stool? 12 MR. JONES: Objection to form. 13 A. There is no -- yeah, there is no 14 manipulation of the stool samples themselves, 15 but they were required to add a stabilization 16 buffer to the stool specimen. 17 Q. Going back to the Lenhard reference, 18 which is Exhibit 6. Do you have that? 19 A. Yes. 20 Q. You understand that the aim of the 21 study reported in the Lenhard paper was to 22 compare testing of HIC1 methylation to gFOBT 23 results? 24 MR. JONES: Objection to form. Page 118	1 question worthy of consideration is whether 2 or not including a sensitive gFOBT or FIT at 3 the time of testing would improve 4 sensitivity without adversely affecting 5 specificity." Do you see that? 6 A. I see that. 7 Q. You would agree that this is not a 8 prediction that the combination will, in 9 fact, improve sensitivity without adversely 10 affecting the specificity, correct? 11 A. I'm sorry, repeat that. 12 Q. You would agree that this is not a 13 prediction that the combination will, in 14 fact, improve sensitivity without adversely 15 affecting the specificity, correct? 16 A. I think we've talked about this, but 17 what he's saying is that, again since this is 18 a paper describing guidelines and 19 recommendations, the suggestion comes from 20 what was known in the art, that the 21 combination of FOBT with DNA testing could 22 provide for improved sensitivity, and so he's 23 saying that that is something that should be 24 evaluated clinically. Page 120
1 A. My understanding of the -- of the 2 paper, the study design was to compare DNA 3 biomarkers in FOBT, but also to look at the 4 combination of the two. 5 Q. Is looking at the combination of the 6 two listed in the "Background and Aims" 7 section of the Lenhard paper? 8 A. Let me check. 9 (Witness reviews document.) 10 They don't explicitly call it out 11 in the abstract, but clearly that must have 12 been one of their aims because they have a 13 table that specifically talks about the 14 combination of these things. 15 Q. Can we go back to the Levin paper, 16 Exhibit 10. 17 A. Okay. 18 Q. If you can go to Page 1578. 19 A. Okay. 20 Q. And if you go to the sentence that we 21 were discussing earlier, it's in the 22 right-hand column. 23 A. Uh-huh. 24 Q. The second paragraph. "Another Page 119	1 Q. Levin is simply questioning whether or 2 not the combination would improve 3 sensitivity without adversely affecting 4 specificity, he's not making a prediction 5 that it will, correct? 6 A. He's not stating how much sensitivity 7 might improve, but what you have to realize 8 is this is a guideline committee that has 9 reviewed a lot of the literature, has a very 10 good understanding of the art, and he's 11 suggesting this because there is a very 12 strong probability that the combination of 13 these two types of tests, specifically the 14 FOBT and the DNA stool DNA, would provide for 15 improved sensitivity. 16 Q. Where does Levin say that there is a 17 strong probability that the combination of 18 FOBT and DNA stool test would provide for 19 improved sensitivity? 20 A. He doesn't use the words "strong 21 probability." What I'm describing is as a 22 guideline committee, making recommendations 23 to other researchers and perhaps clinicians 24 who are going to be looking at these Page 121

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1 combinations, that the suggestion would not 2 be made unless there was a good probability 3 that this would work. 4 Q. You understand Levin is questioning 5 whether or not it would work to be a 6 suggestion that it will work; is that what 7 you're saying? 8 A. What I'm saying is that this is not a 9 description of the -- well, hold on. 10 (Witness reviews document.) 11 Can you repeat the question? 12 Q. Do you understand Levin's questioning 13 whether or not it would work to be a 14 suggestion that it actually will work, is 15 that what you're saying? 16 A. No. I think it's a manner of speech 17 personally, and I would note that he goes on 18 in the very next sentence to say -- to 19 describe results of the Kutzner paper, where, 20 in fact, it was seen that the FOBT and DNA 21 markers that were used in that study did 22 result in an improved sensitivity. 23 Q. You would agree that Levin does not 24 actually say there is a good probability Page 122	1 MR. JONES: Objection to form. 2 A. I don't think I said -- did I say 3 "Levin says"? 4 Q. Do you believe that Levin says there 5 is a strong probability that the combination 6 of FOBT and DNA stool testing would provide 7 for improved sensitivity? 8 A. Levin does not use the specific words 9 "strong probability," if that's all we are 10 arguing about, but what he does indicate, as 11 I was trying to explain, is that he's using a 12 very conservative manner of speech when he 13 says whether or not the combination of these 14 two types of tests would result in improved 15 sensitivity, and he follows it up in the very 16 next sentence by pointing to an independent 17 study where they did exactly that and did see 18 an improved sensitivity. 19 Q. Could we go back to the Lenhard paper. 20 It's Exhibit 6. If you look at the 21 conclusion in the abstract on the first 22 page, do you see where the authors 23 postulate, they say, "We postulate that a 24 panel of merely a few genetic and epigenetic Page 124
1 that the combination will work, correct? 2 A. We are picking on words, and we are 3 talking about manner of speech. He's writing 4 in a very conservative manner to say that 5 this would be a good thing to look at. He's 6 not guaranteeing that it's going to be 7 successful in terms of further clinical 8 study, but he is pointing out that there is 9 other prior art that suggests that it 10 absolutely would work because they describe 11 that in an independent paper. 12 Q. Earlier you stated that Levin says 13 there is a strong probability that the 14 combination of FOBT and DNA stool test would 15 provide for improved probability, correct? 16 MR. JONES: Objection to form. 17 Q. Sensitivity. 18 MR. JONES: Objection to form. 19 A. Can you read that back again? 20 Q. Earlier you stated that Levin says 21 there is a strong probability that the 22 combination of FOBT and DNA stool tests 23 would provide for improved sensitivity, 24 correct? Page 123	1 markers will be required for the highly 2 sensitive and specific detection of CRC and 3 adenoma in fecal samples of affected 4 patients"? 5 A. I see that. 6 Q. The authors here are not concluding 7 that those genetic and epigenetic markers 8 should be combined with a blood protein 9 test, correct? 10 A. In this sentence that you are 11 referring to they don't mention the FOBT test 12 as a possible marker to combine, but I will 13 point out that they are also saying that they 14 are postulating, meaning they don't know if 15 even combinations of genetic and epigenetic 16 markers would give them the sufficient 17 sensitive they might need. There is no way 18 they can conclude that based on this study. 19 Q. Nowhere in the "Conclusion" section of 20 the abstract of Lenhard do the authors even 21 discuss combining a DNA test with a blood 22 protein test for CRC screening in stool, 23 correct? 24 A. I think what we were talking about Page 125

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1 previously is that although the FOBT is not 2 mentioned in the abstract section, clearly it 3 must have been a part of the design of the 4 study, because they have a table in here 5 which looks at the sensitivity and 6 specificity of the combined tests. 7 Q. Are you capable of confining your 8 answer to my question about what the 9 conclusion states in the abstract of 10 Lenhard? 11 MR. JONES: Objection to form. 12 Argumentative and harassing. 13 A. I just did answer it. 14 Q. Are you capable of confining your 15 answer to what the conclusion says in the 16 abstract of the Lenhard paper? 17 MR. JONES: Objection. Harassing. 18 A. My response is to provide the 19 appropriate context to your question, because 20 I believe without the appropriate context it 21 provides a different meaning. 22 Q. So I'm asking you only about what the 23 Lenhard authors report in the conclusion in 24 the abstract, what they report there. You Page 126	1 the teaching of the study as a whole are very 2 clear. 3 Q. I'm allowed to ask you about what is 4 in one part of a paper, okay. If your 5 counsel want to ask you about other things, 6 he can. 7 My question is just about this 8 conclusion section in the abstract, and 9 nowhere in the conclusion section of the 10 abstract of Lenhard do the authors discuss 11 combining a DNA test with a blood protein 12 test for CRC screening of stool samples, 13 correct? 14 A. (Witness reviews document.) 15 One minute. 16 Q. I will note for the record that the 17 witness is reviewing other parts the paper, 18 not the part I asked him about. 19 A. So I'm just going to answer the 20 question the exact same way. In fact, if you 21 can read that back. 22 Q. I withdraw the question, and I will 23 ask you something else. 24 A. Okay. Page 128
1 can have all the time in the world when your 2 counsel redirects you if he wants to talk 3 about other things, but in a deposition 4 proceeding there are rules that you must 5 answer the questions that I ask. And if 6 your counsel wants to ask you different 7 questions after, he can do so; do you 8 understand that? 9 MR. JONES: Objection to form. 10 He's answering the question that you asked. 11 Q. Do you understand what I said? 12 A. I understand what you said. 13 MR. JONES: Objection to form. 14 Harassing. 15 Q. So my question is confined to what is 16 said in the conclusion in the abstract, and 17 nowhere in the conclusion section of the 18 abstract of Lenhard do the authors discuss 19 combining a DNA test with a blood protein 20 test for the CRC screening in stool samples, 21 correct? 22 A. This is a very curious line of 23 questioning when we are talking about what is 24 in one part of a paper, when the lesson and Page 127	1 Q. Would you please read for me the 2 conclusion section of the abstract of the 3 Lenhard paper. 4 A. The conclusion as written here 5 indicates in Lenhard's words "The epigenetic 6 marker HIC1 promoting methylation carries 7 high potential for the remote detection of -- 8 THE COURT REPORTER: Could you 9 read that a little clearer. 10 THE WITNESS: Sorry. 11 A. "The epigenetic marker HIC1 promoting 12 methylation carries high potential for the 13 remote detection of CRCs. We postulate that 14 a panel of merely a few genetic and 15 epigenetic markers will be required for the 16 highly sensitive and specific detection of 17 CRCs and adenomas in fecal samples from 18 affected patients." 19 Q. Okay. The word "protein" does not 20 occur in that passage you just read, 21 correct? 22 A. The word "protein" does not appear in 23 there. 24 Q. The term "FOBT" does not occur in that Page 129

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1 passage you just read, correct? 2 A. FOBT is not in that particular 3 passage. 4 Q. The term "hemoglobin" is not present 5 in the conclusions of the abstract of 6 Lenhard that you just read, correct? 7 A. The word "hemoglobin" is not in there. 8 Q. The term "fecal occult blood test" 9 does not appear in the conclusion section of 10 the Lenhard abstract that you just read, 11 correct? 12 A. Regardless of what it says in the 13 conclusion -- 14 Q. Is it there or not? 15 MR. JONES: Objection to form. 16 A. There is very clear teaching from this 17 study about the combination of DNA tests and 18 the FOBT. 19 Q. You can tell that to your counsel if 20 he wants to ask you about it. I asked you a 21 very straightforward question. If you are 22 able to focus on what I'm asking, it would 23 be simple to answer. 24 MR. JONES: Objection to form. Page 130	1 Q. Was the number of sentences in the 2 conclusion responsive to my question? 3 MR. JONES: Objection to form. 4 A. I believe I'm able to answer a 5 question in the way that I feel provides 6 appropriate context and understanding. I 7 don't think that I have to -- I'm still 8 speaking -- I don't think that I have to have 9 the way I respond to your questions dictated 10 by you. 11 MR. JONES: Objection to form. I 12 don't think this is an appropriate back and 13 forth for a deposition. 14 MS. HABERNY: Well, we will see if 15 the court thinks he's being responsive. 16 MR. JONES: Yeah, I would like to 17 go to the court because he said there are 18 two sentences in the concluding statement. 19 Can we take a break? 20 MS. HABERNY: Almost. 21 Q. Can you go to Page 148 of Lenhard. Do 22 you see the concluding paragraph -- 23 MR. JONES: Objection to form. 24 MS. HABERNY: I wasn't finished. Page 132
1 Q. The term "fecal occult blood test" 2 does not appear in the conclusion section of 3 the Lenhard abstract that you just read, 4 correct? 5 A. "Fecal occult blood test" is not in 6 the conclusion. 7 Q. And there is no reference to a blood 8 protein test in the conclusions of the 9 Lenhard abstract, correct? 10 A. In that particular section of two 11 sentences, which is not a sufficient summary 12 of the whole study, it does not have that in 13 there. 14 Q. Okay. There is no reference to a 15 blood protein test in the conclusions of the 16 Lenhard abstract, correct? 17 A. Again in the two sentences that are 18 described under the "Conclusions" part of the 19 abstract to describe this whole study, it 20 does not have that. 21 Q. Did I ask you how many sentences were 22 in that conclusion? 23 MR. JONES: Objection to form. 24 Harassing. Page 131	1 MR. JONES: Sorry. 2 Q. Do you see the concluding paragraph on 3 the right-hand column of the Lenhard paper 4 on Page 148 that starts with "In summary"? 5 A. Yes. 6 Q. Nowhere in that paragraph do the 7 Lenhard authors refer to blood protein, 8 correct? 9 A. (Witness reviews document.) 10 No. What the paragraph describes 11 is that, there is an initial sentence that 12 says "In summary this study shows HIC1 as a 13 sensitive and specific marker well-suited for 14 stool-based CRC screening," and then it goes 15 on to speculate about a number of other DNA 16 markers that might be useful to combine with 17 the HIC1 -- 18 Q. Okay. I will ask -- 19 A. -- but it's not a summary of what this 20 study is. 21 Q. The last paragraph of the Lenhard 22 paper starts with the two words "In 23 summary," correct? 24 A. Yep. Page 133

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1 Q. Okay. And nowhere in that paragraph 2 do the authors refer to a blood protein, 3 correct? 4 A. They do not refer to a blood protein 5 here. 6 Q. Okay. Thank you? 7 MS. HABERNY: We can take our 8 break. 9 THE VIDEOGRAPHER: The time is 10 2:31. We're off the record. 11 (A recess was taken.) 12 THE VIDEOGRAPHER: Stand by. We 13 are back on the record. The time is 2:43. 14 BY MS. HABERNY: 15 Q. Do you believe that a person of skill 16 in the art relevant to the patents at issue 17 here would have had to have experience with 18 human feces or could it be any feces from an 19 animal? 20 MR. JONES: Objection to form. 21 A. I'm not sure what you're asking about. 22 Q. Do you believe that a person of skill 23 in the art relevant to the patents at issue 24 here would have had to have experience Page 134	1 experience processing or analyzing feces, 2 correct? 3 MR. JONES: Objection to form. 4 A. If someone had experience processing 5 bat feces, they would certainly have 6 experience processing bat feces. I don't 7 know that that's generally applicable to all 8 species. 9 Q. Well, a person who had experience 10 analyzing bat feces would have experience 11 analyzing a form of feces, correct? 12 A. I mean I think it's just saying the 13 same thing twice. If someone has experience 14 processing bat feces, yes, then I would 15 acknowledge that they are knowledgeable on 16 how to process bat feces. 17 Q. Okay. Did you offer -- I'm sorry, 18 let's do that again. Let me start over. 19 A person who had experience 20 analyzing bat feces would have experience 21 analyzing a form of feces, correct? 22 MR. JONES: Objection to form. 23 A. So a person processing bat feces has 24 the experience of that particular type, but Page 136
1 processing feces? 2 A. To do what? 3 Q. To perform the methods that are 4 claimed in the patents, to be a person of 5 skill in the art relevant to those methods? 6 MR. JONES: Objection to form. 7 A. I'm balking at answering only because 8 the patent covers a lot of different topics, 9 and there's also obviously an issue with some 10 of the scope of the patents and what's 11 actually being claimed there. So if you 12 could more specific about what you mean by 13 conducting the patents, that would be 14 helpful, if we could refer to a specific 15 example. 16 Q. Actually I will ask you something 17 different. 18 Do you believe that bat feces is 19 feces? 20 MR. JONES: Objection to form. 21 A. I mean -- if it's called "feces," I 22 would assume it's feces, yes. 23 Q. So a person who had experience 24 processing or analyzing bat feces would have Page 135	1 that does not mean they generally have 2 experience processing any type of feces. 3 Q. But you don't deny that bat feces is a 4 type of feces, correct? 5 A. I'm assuming that it is. I never have 6 worked with bat feces. 7 Q. So you don't know one way or another 8 whether bat feces is feces? 9 MR. JONES: Objection to form. 10 A. I assume by the fact that it has the 11 word "feces" in it that it's probably feces. 12 Q. Okay. Do you offer opinions regarding 13 marketing efforts of Exact Sciences? 14 A. Do I have opinions? 15 Q. Are you offering opinions about 16 marketing efforts of Exact Sciences in this 17 case? 18 A. Offering opinions? I discuss Exact 19 marketing efforts within the declaration. 20 Q. But you're not offering opinions about 21 them? 22 MR. JONES: Objection to form. 23 A. What is written in the declaration is 24 based on materials that were reviewed and Page 137

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1 taking information out of those. 2 MS. HABERNY: I'm sorry, my 3 realtime stopped working. 4 THE VIDEOGRAPHER: The time is 5 2:48. We are off the report. 6 (A discussion was held off the record.) 7 THE VIDEOGRAPHER: Stand by. We 8 are back on the record. The time is 2:51. 9 BY MS. HABERNY: 10 Q. Are you an expert on marketing 11 efforts? 12 A. No. 13 Q. Did you consider any Cologuard 14 advertising materials in forming your 15 opinions in this case? 16 A. I'm trying to recall. 17 I don't know if -- I don't recall 18 if I referred specific -- to any specific 19 marketing materials from Exact but, yeah. 20 Q. So sitting here today, you can't 21 identify any Exact Sciences marketing 22 materials that you considered relating to 23 your opinion? 24 A. I don't recall specifically which Page 138	1 there either. 2 Q. So sitting here today, you can't 3 identify any Exact Sciences marketing or 4 advertising materials that you considered in 5 connection with your opinions? 6 A. Certainly nothing that is listed. I 7 did go on the website and may have seen some 8 materials there. 9 Q. What materials? 10 A. I don't recall specifically. 11 Q. So sitting here today, you can't 12 identify any particular Exact Sciences 13 marketing or advertising materials that you 14 considered in connection with your opinions? 15 A. I couldn't point to any in particular. 16 Q. You agree that Cologuard requires a 17 prescription? 18 A. I believe that to be true. 19 Q. Do you agree that the medical 20 community would not prescribe Cologuard if 21 there was not data to support its use? 22 MR. JONES: Objection to form. 23 A. As we established earlier, I'm not a 24 doctor. So I'm not prescribing these. So I Page 140
1 marketing materials I did refer to, if I 2 referred to them. 3 Q. Do you want to check your Materials 4 Considered and see? 5 A. Sure. 6 MR. JONES: It's Exhibit 26 and 28 7 are your Materials Considered. 8 Q. I think 26, it's 28, and it's part of 9 your second declaration? 10 A. (Witness reviews document.) 11 Yeah, I don't believe I see any 12 marketing materials on here or advertising. 13 Is that what you said? 14 Q. Advertising or marketing materials, 15 either one? 16 A. (Witness reviews document.) 17 No, I don't believe I see anything 18 on here. 19 Q. You also had Materials Considered in 20 your second declaration. It was at the end 21 after -- 22 A. The very end? 23 MR. JONES: Exhibit A. 24 A. Yeah, I don't believe I see anything Page 139	1 would have assumptions about that is all. 2 Q. Do you have any opinion one way or the 3 other as to whether the medical community 4 would prescribe Cologuard if there was not 5 data to support its use? 6 MR. JONES: Objection to form. 7 A. Sorry, the question was opinions? 8 Q. I will repeat it. Do you have any 9 opinion one way or the other as to whether 10 the medical community would prescribe 11 Cologuard if there was not data to support 12 its use? 13 A. I do have opinions about that, yes. 14 Q. On what do you base your opinions? 15 A. I base my opinions based on my 16 understanding as to someone who has worked in 17 this field as to what is required to offer a 18 screening test. 19 Q. And what is your opinion as to whether 20 the medical community would prescribe 21 Cologuard if there was not data to support 22 its use? 23 MR. JONES: Objection to form. 24 A. My opinion is that Cologuard would Page 141

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1 only be prescribed if it was by a licensed 2 doctor. 3 Q. And I'm asking about data to support 4 its use. 5 A. Oh, sorry. 6 Q. Do you believe -- well, strike that. 7 What is your opinion as to the 8 whether the medical community would 9 prescribe Cologuard if there was not data to 10 support its use? 11 A. I believe that the data to support its 12 use is a part of what is involved in the FDA 13 approval, as a necessary part of offering 14 this test. 15 Q. So earlier you said you had an opinion 16 as to whether the medical community would 17 prescribe Cologuard if there was not data to 18 support its use. Do you still have an 19 opinion on that? 20 A. Sorry, say that again. 21 Q. Earlier you stated that you have an 22 opinion about whether the medical community 23 would prescribe Cologuard if there was not 24 data to support its use. Do you remember Page 142	1 scope of your opinions. 2 Do you not have an opinion then 3 about whether Cologuard practices the 4 asserted claims in this litigation? 5 MR. JONES: Objection to form. 6 A. Again I'm not exactly sure how 7 Cologuard is run. So if I don't have 8 complete information, it's hard for me to be 9 able to say that I have an opinion about 10 whether or not the test follows the claims in 11 the patent. 12 Q. So then you do not have an opinion 13 about whether Cologuard practices the 14 asserted claims in this litigation? 15 A. To me an opinion about whether it does 16 or it doesn't is based on fact. What I'm 17 saying is I don't have all of the facts. 18 Q. It's not a complicated or trick 19 question. I want to know if you have an 20 opinion on it or not. If you're saying you 21 don't have the facts, then I'm just trying 22 to clarify that that means you don't have an 23 opinion about it, right? Let me ask again. 24 You do not have an opinion about Page 144
1 saying that? 2 A. Yes. 3 Q. And what is your opinion about that, 4 not about the FDA, but about whether the 5 medical community would prescribe Cologuard 6 if there was not data to support its use? 7 MR. JONES: Objection to form. 8 A. I see. I see what you're getting at. 9 I believe that the -- let me think 10 about the way I want to answer this. 11 I believe there must be evidence 12 that provides some convincing aspect of 13 utility of a test in order for people to 14 prescribe it. 15 Q. Do you have any opinions about whether 16 Cologuard practices the asserted claims in 17 this litigation? 18 A. I'm not acutely aware of every step of 19 what is done to run Cologuard, but to the 20 extent that the asserted claims have aspects 21 of those -- well, strike that. 22 I don't know precisely how 23 Cologuard is run. 24 Q. So I'm just trying to ascertain the Page 143	1 whether Cologuard practices the asserted 2 claims in this litigation, correct? 3 A. Based on what I understand about how 4 the test is run and the nature of the claims 5 as written, I do not have an opinion as to 6 whether it strictly follows those claims or 7 not. 8 THE VIDEOGRAPHER: The time is 9 3:03. We're off the record. 10 (A recess was taken.) 11 THE VIDEOGRAPHER: Stand by. We 12 are back on the record. The time is 3:10. 13 BY MS. HABERNY: 14 Q. Do you know what DNase is? 15 A. Yes. 16 Q. What is DNase? 17 A. It refers to a type of enzyme which 18 cleaves DNA molecules. 19 Q. Does DNase degrade DNA? 20 A. You could describe it that way. It 21 basically -- it cuts the DNA is what it does. 22 Q. Are you familiar with what an RNase 23 is? 24 A. Yes. Page 145

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1 Q. What is an RNase? 2 A. An RNase will cut the strands of an 3 RNA molecule. 4 Q. Do you believe that DNases are 5 ubiquitous? 6 MR. JONES: Objection to form. 7 A. Ubiquitous where? 8 Q. Let's start in cells. Are DNases 9 ubiquitous in cells? 10 A. There are certainly DNases in cells. 11 Q. Are they ubiquitous? 12 A. You would have to help me with the 13 definition of what you mean by "ubiquitous." 14 Q. Did you use the term "ubiquitous" in 15 your declaration to describe RNases? 16 A. I believe I did. 17 Q. What did you mean by "ubiquitous"? 18 A. What I meant by "ubiquitous" in that 19 context is that there's a large quantity of 20 them, which exist intracellularly as well as 21 extracellularly, and that they can originate 22 in both human cells as well as bacterial 23 cells, as well as food product, I suppose. 24 Q. Using that definition, do you believe Page 146	1 A. My opinion is that it's not so much a 2 question as to whether or not the RNases, or, 3 sorry, the deactivation mechanisms could or 4 could not be applied to stool samples, but 5 that it's -- the further context is that if 6 one wanted to be able to isolate an RNA 7 molecule which was associated with human 8 cells, and furthermore was associated with 9 the small proportion of the human cells which 10 are associated with cancer if it exists, 11 presents a very different context from using 12 those same inhibitors in any sample. 13 Q. So I'm asking just a targeted 14 question, which is whether it's your opinion 15 that the methods known as of 2009 to 16 deactivate RNases could be applied to stool 17 samples? 18 A. What I'm trying to get you to 19 appreciate is that the deactivation is very 20 much dependent on what the goal is but also 21 what the challenge is, and so what I'm trying 22 to answer is that the effectiveness of a 23 deactivation mechanism will depend on those 24 things. Page 148
1 DNases are also ubiquitous? 2 A. I believe that there are certainly 3 high concentrations of DNases in stool 4 samples. 5 Q. RNases are not unique to fecal 6 samples, correct? 7 A. Correct. 8 Q. There are RNases in other types of 9 biological samples? 10 A. Yes. 11 Q. Do you believe that prior to 2009 12 persons of skill in the art understood that 13 RNases were present in stool samples? 14 A. I do believe people knew that, yes. 15 Q. Do you believe that methods existed as 16 of 2009 to inhibit RNase activity? 17 MR. JONES: Objection to form. 18 A. In what type of sample? 19 Q. In any sample. Let's start there. 20 A. I think that there were methods known 21 on how to deactivate RNases. 22 Q. And is it your opinion that those 23 methods to deactivate RNases could not be 24 applied to stool samples? Page 147	1 If you're asking simply could you 2 mix A with B, then, sure, the answer is, yes, 3 you could do it, but if you're looking to see 4 if that deactivation is going to be 5 effective, you have to appreciate the 6 context. 7 Q. So you're kind of dancing around the 8 question. 9 I would like to know whether it's 10 your opinion that the methods known as of 11 2009 to deactivate RNases could be applied 12 to stool samples? Could they or not? 13 MR. JONES: Objection to form. 14 A. So are you asking me if the RNases 15 would be effective -- I'm sorry -- that the 16 deactivators would be effective at 17 deactivating the RNases? 18 Q. Right. Is it your opinion that the 19 methods known as of 2009 to deactivate 20 RNases could be applied to deactivate RNases 21 in stool samples? 22 MR. JONES: Objection to form. 23 A. So I think in that context I think 24 that my opinion is that there have been some Page 149

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1 methods which have been looked at, but it 2 depends on, you know, which deactivator we're 3 talking about in order to understand the 4 effectiveness. 5 Q. So the answer to my question is "yes"? 6 MR. JONES: Objection to form. 7 A. There have been descriptions prior to 8 2009 of people recovering RNA from stool 9 samples. 10 Q. Is it your opinion that the QIAamp DNA 11 Stool Mini Kit would not co-extract both DNA 12 and RNA from a stool sample? 13 A. Well, as the name implied, it's 14 primarily intended to recover DNA from stool 15 samples. I would not exclude the possibility 16 that some RNA might also be extracted along 17 with the DNA. 18 Q. So it's your opinion that the QIAamp 19 DNA Stool Mini Kit would co-extract DNA and 20 RNA, correct? 21 MR. JONES: Objection to form. 22 A. It is my opinion that if one were 23 looking explicitly to extract RNA from a 24 stool sample, you wouldn't necessary start Page 150	1 of nucleic acids? 2 A. What I understand "extract" to mean is 3 reliably recover a targeted amount of nucleic 4 acid from a sample. 5 Q. Okay. Is it your opinion that the 6 QIAamp DNA Stool Mini Kit would not extract 7 both DNA and RNA from a stool sample? 8 A. If I was to use that definition that I 9 just gave which is that it would be a 10 reliable quantity of targeted nucleic acid, 11 then I would -- my opinion is that the QIAamp 12 Kit would not extract reliable quantities of 13 RNA. 14 Q. Have you done experiments to test 15 that? 16 A. I can't point to one -- I'm guessing I 17 have actually, but I can't point to the 18 results of those studies. 19 Q. Sitting here today, can you identify 20 any study that has been done by anyone 21 anywhere to quantify the amount of RNA that 22 can be extracted using the QIAamp Stool Mini 23 Kit? 24 A. You're asking if I recall or if one Page 152
1 with a QIAamp DNA Mini Stool Kit. 2 Q. I did not ask you about explicitly 3 extracting RNA. My question is different. 4 Please listen to it. 5 It is your opinion that the QIAamp 6 DNA Stool Mini Kit would co-extract DNA and 7 RNA, correct? 8 MR. JONES: Objection to form. 9 A. It's my opinion that the QIAamp DNA 10 Stool Kit would contain contaminating 11 quantities of RNA. 12 Q. So it is your opinion that the QIAamp 13 DNA Stool Mini Kit would extract both DNA 14 and RNA from a stool sample, correct? 15 MR. JONES: Objection to form. 16 A. No, I didn't say that. 17 Q. Is it your opinion that the QIAamp DNA 18 Stool Mini Kit would not extract both DNA 19 and RNA from a stool sample? 20 MR. JONES: Objection to form. 21 A. We are putting a lot of emphasis on 22 "extract" without having defined that. 23 Q. Let's define it. What do you 24 understand "extract" to mean in the context Page 151	1 comes to mind? 2 Q. Sitting here today can you identify 3 any study that has been done by anyone 4 anywhere to quantify the amount of RNA that 5 can be extracting using a QIAamp DNA Stool 6 Mini Kit. 7 A. I cannot point to a study, but if that 8 were an area of research that I was 9 interested in, that's something I could do. 10 Q. But you did not do that in connection 11 with forming your opinions in this case, 12 correct? 13 A. I did not conduct a comprehensive 14 search of that. 15 Q. Did you conduct any search whatsoever 16 for any study that has been done by anyone 17 anywhere to quantify the amount of RNA that 18 can be extracted using the QIAamp DNA Stool 19 Mini Kit? 20 A. As far as a study that has targeted 21 that, I can't point to a study that comes to 22 mind that -- where people have looked at 23 that, but I know -- it's my opinion, at 24 least, that recovery of RNA, that that's not Page 153

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1 the kind of kit that people would use for 2 recovering RNA from a stool sample. 3 Q. And that's not based on any sort of 4 experimental data, correct? 5 A. Not in terms of an experiment that I 6 can point to. 7 Q. Do you know whether or not prior to 8 2009 anyone anywhere used the QIAamp DNA 9 Stool Mini Kit to extract RNA from a stool 10 sample? 11 MR. JONES: Objection to form. 12 A. I know of papers where people -- as I 13 mentioned earlier, I know of papers where 14 people are recovering RNA from stool samples. 15 I don't recall which kits they were or which 16 kits technologies they were using in general. 17 Q. And when you testified earlier that 18 you don't believe reliable amounts of RNA 19 could be extracted from stools using the 20 QIAamp DNA Stool Mini Kit, that was not 21 based on any data or experimentation or 22 study, correct? 23 MR. JONES: Objection to form. 24 A. It's not based on any experimentation Page 154	1 don't know of anyone who has used the -- that 2 particular kit to extract RNA from stool. 3 I think what he is speculating is 4 that it might work. You know, I think this 5 is from somebody who has never worked with 6 stool samples and doesn't appreciate the 7 difficulty. 8 Q. Can you turn to Paragraph 122 of your 9 second declaration, please. 10 A. Yeah. 11 Q. Do you see where it says, "First, as 12 Dr. Eshoo acknowledged in his deposition, 13 the QIAamp DNA Stool Mini Kit is a kit for 14 extracting DNA from fecal samples in a 15 laboratory. Such a laboratory kit would not 16 be suitable for use by a patient at home to 17 stabilize their at-home collected fecal 18 sample as done in the asserted claims"? 19 What is your basis for that? 20 A. Just that there is no evidence that 21 I'm aware of to indicate that that kit would 22 stabilize samples. It's used for laboratory 23 work where samples are in contact with the 24 solution for a relatively short period of Page 156
1 that I can recall or that I did myself. 2 My recollection of the papers that I have 3 seen where people are recovering DNA from 4 stool samples that -- I don't believe any of 5 those were using that kit, but again I can't 6 say for certain. 7 Q. Do you have any basis for opining that 8 Dr. Eshoo testified that the QIAamp DNA 9 Stool Mini Kit would not be suitable for a 10 patient at home? 11 A. I think I may have opined about that 12 in here. Do you mind if I look? 13 Q. Feel free. 14 A. (Witness reviews document.) 15 Okay. Sorry, could you repeat the 16 question? 17 Q. Do you have any basis for opining that 18 Dr. Eshoo testified that the QIAamp DNA 19 Stool Mini Kit would not be suitable for a 20 patient at home? 21 A. Well, I would simply note that I don't 22 think his opinion is based on any 23 experimentation either, so I'm not sure where 24 he gets his opinion, and as I indicated, I Page 155	1 time, and so in my opinion there is nothing 2 there to suggest that it could be used for 3 long-term stabilization for shipping samples 4 from home. 5 Q. Are you asserting that Dr. Eshoo 6 testified that the QIAamp DNA Stool Mini Kit 7 can only be used in a laboratory? 8 A. What I'm describing here is that he 9 acknowledges that it's used for extracting 10 DNA from stool samples in a laboratory. 11 Q. You would agree that Dr. Eshoo never 12 testified that the QIAamp DNA Stool Mini Kit 13 can only be used in a laboratory, correct? 14 MR. JONES: Objection to form. 15 A. I -- what I acknowledge here, or, 16 sorry, what I'm writing here is that he 17 acknowledged that it is designed for use in a 18 laboratory. There is nothing here that says 19 anything about what else it might be useful 20 for. 21 Q. Do you contend that Dr. Eshoo 22 testified that the QIAamp DNA Stool Mini Kit 23 can only be used in a laboratory? 24 A. No. I don't believe that's what he's Page 157

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1 saying. What he is saying is that the kit is 2 designed for extracting DNA from fecal 3 samples in a laboratory, and that he is 4 acknowledging that that is the case. 5 Q. Then you would agree that Dr. Eshoo 6 did not testify that the QIAamp DNA Stool 7 Mini Kit can only be used in a laboratory, 8 correct? 9 MR. JONES: Objection to form. 10 A. There is nothing stated to that 11 question in here. 12 Q. So the answer is "yes"? 13 MR. JONES: Objection to form. 14 A. There is nothing said one way or the 15 other. So there is no opinion which is being 16 stated here as to whether it could be used 17 outside of a laboratory or not from his 18 perspective. 19 (Exhibit 17 was introduced.) 20 Q. I am handing you what has been 21 previously been mark Exhibit 17. This is US 22 Patent No. 11,970,746. Do you recognize 23 this as one of the patents that has been 24 asserted in this case? Page 158	1 that the homogenate created from the stool 2 in example 1 contained RNA? 3 MR. JONES: Objection to form. 4 A. I mean my interpretation -- well, hold 5 on. Let me review again exactly what... 6 (Witness reviews document.) 7 The stool homogenization buffer is 8 not described in detail here. So I don't 9 recall if that was described in detail 10 somewhere else in the patent, or what the 11 composition of that is. So I don't have any 12 way of making an assessment as to how well it 13 may have been preserving any RNA that might 14 have been there. 15 Q. So you have no basis for opining that 16 the homogenate created in example 1 of the 17 '746 patent did not contain RNA, correct? 18 MR. JONES: Objection to form. 19 A. There's no way from this example -- I 20 haven't read the whole thing right at this 21 moment, but I have read it before -- but this 22 example goes on to talk about all of the 23 steps that are taken to process that sample 24 and then to analyze DNA, which is recovered Page 160
1 A. Yes, I do. 2 Q. Did you review the '746 patent in 3 preparing your opinions for this case? 4 A. I did. 5 Q. Did you review it in its entirety? 6 A. I did. 7 Q. Did you review example 1 of the '746 8 patent in forming your opinions? 9 A. Yes, I did. 10 Q. It starts on column 28, line 35. 11 A. (Witness reviews document.) 12 Q. Do you see the sentence starting on 13 column 28, line 55, which says "Stool 14 homogenization buffer was added to a ratio 15 one to seven, and the samples were 16 homogenized and aliquoted in portions of 32 17 ml"? 18 A. Yes, I see that. 19 Q. Is it your opinion that that 20 homogenate contained RNA? 21 MR. JONES: Objection to form. 22 A. It is my opinion it has RNA in it. 23 Q. Well, let me ask a different question. 24 Do you have any reason to dispute Page 159	1 from that, but there is no written 2 description whatsoever as to any RNA that 3 might be recoverable from that. So it's 4 really hard to form an opinion on that. 5 Q. So you have no opinion one way or 6 another as to whether the homogenate created 7 in example 1 of the '746 patent did not 8 contain RNA? 9 MR. JONES: Objection to form. 10 A. In this -- the way this passage is 11 written and the fact that there is no 12 assessment whatsoever of any RNA that might 13 be there, it's very dif -- it's impossible to 14 know what that buffer is doing with respect 15 to RNA preservation. 16 Q. Do you or do you not have an opinion 17 as to whether the homogenate created in 18 example 1 of the '746 patent contained RNA? 19 MR. JONES: Objection to form. 20 Asked and answered. 21 A. It's hard to have an opinion on 22 something when there is zero evidence to 23 judge from. 24 Q. So the answer is, "no," you don't have Page 161

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1 an opinion? 2 MR. JONES: Objection to form. 3 A. That's not what you asked me. You 4 asked me if I had an opinion as to whether or 5 not there is RNA in that sample, and my 6 response to that, very clearly is, because 7 there is no indication of any RNA that has 8 been tested, it's impossible to form an 9 opinion. 10 Q. Okay. So can you move on to column 11 29. Actually it's the bridging sentence 12 between column 28 and column 29. It starts 13 at column 28, line 66, and it says, "22 14 milliliters of the supernatant obtained 15 following the second centrifugation step was 16 incubated 5 microliters RNase A for 60 17 minutes at 37 degrees celsius." Do you see 18 that? 19 A. I do. 20 Q. You previously testified that RNase is 21 used to degrade RNA, correct? 22 A. Yes. Well, it's used to cut RNA, 23 yeah. 24 Q. Okay. Do you have any explanation for Page 162	1 proteinase K is to also clean the sample to 2 remove any contaminating proteins. 3 Q. Do you have any corroboration for your 4 suspicions that the inventor of the '746 5 patent was just following the instructions 6 of the QIAamp kit when adding the RNase to 7 the sample in example 1? 8 MR. JONES: Objection to form. 9 A. I'm not saying for certain that that 10 is what they did. What I was suggesting is 11 that -- it's a guess actually on my part that 12 that might be part of the procedure of the 13 kit, but I also know that it's pretty 14 standard procedure for people working with 15 DNA samples who are then going on to do PCR 16 analysis that you treat those with an RNase 17 treatment to clean them up. 18 Q. Do you have any corroboration for your 19 speculation that the inventor of the '746 20 patent used RNase in example 1 in order to 21 remove small amounts of contaminating RNA? 22 MR. JONES: Objection to form. 23 A. What I'm -- you had asked me about why 24 would they possibly -- what are the possible Page 164
1 why RNase A would be used to process the 2 samples in the example 1 of the '746 patent 3 if they did not contain RNA? 4 MR. JONES: Objection to form. 5 A. Yeah, I have a couple of explanations. 6 One is that they're using the QIAamp kit, 7 which I believe has as a standard procedure 8 in the kit to treat DNA samples with RNase, 9 and I suspect that if they were just 10 following the instructions of the kit, that 11 that's one reason why they would have done 12 that. 13 Secondly, I believe that, as you 14 know, if you're recovering DNA samples, it's 15 not uncommon to have even small amounts of 16 contaminating RNA in your sample, which could 17 potentially interfere with downstream PCR 18 reactions, and so to avoid any contamination, 19 you would want to clean up your sample, and 20 that's one way of cleaning up the DNA is by 21 treating it with a RNase. 22 It's also, I believe, why similar 23 type of mindset is further down when they 24 talk about treating the sample with Page 163	1 reasons for why they would do that step; and 2 as part of that, I responded with two parts, 3 which was that it may be part -- I said "may" 4 or something to that effect -- it may be part 5 of the instructions for the kit, but even if 6 not, that's a pretty standard procedure for 7 molecular biology labs to treat the DNA 8 samples with RNase to remove contaminating 9 materials, and so that constitutes a second 10 portion of my answer, which is that that 11 would have been second that they might have 12 been done to address contaminating RNA in the 13 sample. 14 It's also not clear that, in fact, 15 there was any RNA in the sample, and so 16 oftentimes those steps may or may not even be 17 necessary. 18 Q. Do you have any factual basis to 19 dispute that the reason RNase was used in 20 example 1 of the '746 patent was because 21 there was RNA in the sample? 22 MR. JONES: Objection to form. 23 A. Again I think that it's entirely 24 possible that there may have been some Page 165

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1 contaminating qualities of RNA in the sample.
2 So I'm not saying that there wasn't any.
3 Q. Are you aware that the '746 patent
4 cites to a laboratory manual called Sambrook
5 and Russell?
6 A. I think I had seen that before, but
7 let me check.
8 (Witness reviews document.)
9 Do you want to help me out or do
10 you just want me to look through this whole
11 list?
12 Q. No, I'm looking for it, too.
13 Okay. I found it. It's column 21,
14 lines 24 to 25, or actually lines 24 to 26.
15 A. Wait. I'm sorry. Page --
16 Q. Column 21.
17 A. Oh, column 21. Sorry.
18 Okay. Yep.
19 Q. Did you review the Sambrook reference
20 that's cited in column 21 of the '746
21 patent?
22 A. I glanced through parts of it. I have
23 not read that entirely. It's a huge manual.
24 Q. Do you agree that fecal samples

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1 contain intact human cells?
2 A. Do I agree that fecal samples -- I
3 think it -- are you saying when the fecal
4 samples exit the body?
5 Q. We can start there.
6 A. Yes. I believe there's cells in
7 there.
8 Q. And do you believe that if a patient
9 defecates directly into a vessel that feces
10 will contain whole cells?
11 MR. JONES: Objection to form.
12 Q. Whole human cells?
13 MR. JONES: Objection to form.
14 A. I believe that if, as I've already
15 established, there are cells in the fecal
16 sample, and if it drops directly into a
17 bucket, at that moment, then, yes, I believe
18 the cells are still there.
19 Q. The human cells present in a fecal
20 sample are eukaryotic cells, right?
21 MR. JONES: Objection to form.
22 A. Well, I should have clarified that's
23 what I'm referring to as well.
24 Q. Okay.

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1 (Exhibit 30 was marked for
2 identification.)
3 Q. So I'm handing you Exhibit 30. This
4 is an excerpt from Volume 1 of Molecular
5 Cloning Laboratory Manual, Third Edition, by
6 Sambrook and Russell.
7 Do you recognize this as the
8 Sambrook that is cited in column 21 of the
9 '746 patent?
10 MR. JONES: Objection, only to the
11 extent that this isn't the entirety of
12 Sambrook.
13 MS. HABERNY: It's an excerpt.
14 A. Yes. I recognize it as Volume 1.
15 Q. And that's the Sambrook that's cited
16 in column 21 of the '746 patent?
17 A. Yes.
18 Q. So you would agree that the inventor
19 of the '746 patent had possession of the
20 ideas of this reference that he cited in the
21 patent, correct?
22 MR. JONES: Objection to form.
23 A. I would presume, since he has got it
24 referenced in the patent, that he had at

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1 least referred to this. I can't speak to,
2 you know, how well he read it or understood
3 what was in it.
4 Q. You have no reason to dispute that the
5 inventor of the '746 patent had possession
6 of the ideas and protocols in this reference
7 that he cited in the patent, right?
8 MR. JONES: Objection to form.
9 A. Again I can't account for how he
10 handled this material, but I don't have
11 anything in my possession to suggest that he
12 didn't.
13 Q. Okay. Can you turn to Page -- well, I
14 guess we could start at Page 7.9 in the
15 Sambrook reference in Exhibit 30. Do you
16 see Protocol 2?
17 A. Yes.
18 Q. Okay. And do you see that is titled
19 "A single step method for the simultaneous
20 preparation for DNA, RNA and protein from
21 cells in tissues"?
22 A. Yes.
23 Q. You would agree that this is protocol
24 for isolating nucleic acids including RNA

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1 from eukaryotic cells? 2 MR. JONES: Objection to form. 3 A. Let me... 4 (Witness reviews document.) 5 I'm looking for the word 6 "eukaryotic," which I don't see on that page. 7 Q. Oh, sorry, that's -- if you look at 8 Page 7.10, that's the chapter -- the title 9 of the chapter. 10 A. Okay. 11 Q. So you would agree that Protocol 2, 12 starting at Page 7.9 of Sambrook, 13 Exhibit 30, is a protocol for isolating 14 nucleic acids, including RNA, from 15 eukaryotic cells? 16 MR. JONES: Objection to form. 17 A. I would agree -- based on the title 18 certainly, you know, it is a method for 19 simultaneously prepping DNA, RNA protein from 20 cells and tissues, that this is a method that 21 has been described, but I think this -- what 22 it is describing is pure cells and tissues as 23 opposed to stool samples. 24 Q. Do you have any factual basis for Page 170	1 MR. JONES: Objection to form. 2 A. Based on the way it is referred to in 3 the patent, and again because there is no 4 written description here as to whether or 5 not, you know, RNA can be recovered and 6 tested, that I don't have an opinion. 7 Q. So my question is whether or not, yes 8 or no, you have an opinion one way or 9 another as to whether protocol starting at 10 Page 7.9 in Sambrook Exhibit 30 could be 11 used on a fecal sample to isolate RNA? 12 MR. JONES: Please feel free to 13 review the protocol. 14 MS. HABERNY: That's coaching. 15 A. (Witness reviews document.) 16 What the protocol describes -- 17 again is recovering DNA and RNA from cells, 18 cultured cells and tissue samples. It does 19 not say anything about cells that are 20 suspended in stool samples. 21 The fact that this is referenced in 22 the patent as a methodology for working with 23 stool samples would mean that in order to 24 judge whether or not it can be used to Page 172
1 opining that Protocol 2 starting at Page 7.9 2 in Sambrook Exhibit 30 could not be used on 3 a fecal sample to isolate RNA from cells? 4 MR. JONES: Objection to form. 5 A. I don't have any basis to opine that 6 this would be effective at recovering RNA and 7 DNA from human cells in stool. 8 Q. And you also do not have any factual 9 basis for opining that Protocol 2 starting 10 at Page 7.9 in Sambrook Exhibit 30 could not 11 be used on a fecal sample to isolate RNA, 12 correct? 13 A. I base my opinions on things which -- 14 as much as I can -- on positive evidence for 15 proof that things would work or not, and, you 16 know, I don't know what the results of a 17 study would be to use this methodology to try 18 to recover DNA and RNA from stool samples 19 that have cells, human cells. 20 Q. So you don't have an opinion one way 21 or another as to whether Protocol 2, 22 starting at Page 7.9 in Sambrook Exhibit 30, 23 could be used on a fecal sample to isolate 24 RNA, correct? Page 171	1 effectively recover RNA from stool samples, 2 there would have to be some kind of 3 assessment of RNA from the stool samples that 4 are used here, and there is no written 5 description of that. 6 Q. So you have no factual basis for 7 forming an opinion one way or another as to 8 whether the protocol, Protocol 2 starting at 9 Page 7.9 in Sambrook, could be used on a 10 fecal sample to isolate RNA, correct? 11 A. I have no basis for understanding 12 whether it could work, nor if it wouldn't 13 work. 14 Q. Okay. So can you please turn to 15 Paragraph 127 of your second declaration. 16 Are you there? 17 A. Yes. 18 Q. You say here that the common 19 specification explicitly identifies certain 20 off-the-shelf products as ones to be used 21 for DNA analysis only; is that correct? 22 A. In 127? 23 Q. Yes. 24 MR. JONES: Objection to form. Page 173

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1 A. What's written is "Dr. Eshoo then 2 notes that the '746 patent identifies 3 off-the-shelf products" -- I won't read those 4 -- "that a POSA would know extract both RNA 5 and DNA. However, here once again, the 6 common specification explicitly identifies 7 these products as ones to be used for DNA 8 analysis only," which is similar to what I 9 was describing earlier when we were talking 10 about Sambrook, which is that there is no 11 description, there is no written description 12 of any RNA which is isolated from the stool 13 samples. 14 Q. One of the off-the-shelf products that 15 you refer to in Paragraph 127 of your expert 16 report is NucliSens easyMAG, correct? 17 A. That's correct. 18 Q. Do you deny that NucliSens easyMAG can 19 extract both RNA and DNA -- 20 MR. JONES: Objection to form. 21 Q. -- from clinical samples? 22 MR. JONES: Objection to form. 23 A. Are you asking specifically about 24 stool samples? Page 174	1 manufacturer. 2 Q. Why did you not review any materials 3 related to NucliSens easyMAG? 4 MR. JONES: Objection to form. 5 A. I know that I have used that in the 6 past. The -- you know, what I'm writing 7 about here doesn't require that I review what 8 the product characteristics are, the product 9 description. 10 What I am trying to describe in 11 this section is that there was no written 12 description of using this kit and then being 13 able to recover RNA from stool samples in the 14 patent. 15 (Exhibit 31 was marked for 16 identification.) 17 Q. I am handing you what has been marked 18 as Exhibit 31. This is the NucliSens 19 easyMAG new innovation from bioMerieux for 20 nucleic acid extraction press release dated 21 June 7th, 2005. Have you seen this before? 22 A. I may have back in that time frame. 23 Q. Okay. So in the third paragraph down 24 there is a quote from Dr. Christopher Page 176
1 Q. Okay. Do you deny that NucliSens 2 easyMAG can extract both RNA and DNA from 3 stool samples? 4 A. I don't -- off the top of my head, I 5 don't know of studies -- I couldn't point to 6 any studies that have provided convincing 7 evidence that they get recovery of DNA and 8 RNA from stool samples. 9 Q. Did you review any of the NucliSens 10 easyMAG materials? 11 A. You mean marketing materials? 12 Q. Any materials whatsoever relating to 13 that product. 14 MR. JONES: Objection to form. 15 A. What time frame? 16 Q. Have you ever -- strike that. 17 In preparing for your deposition 18 today or for your declaration, either the 19 first or second, did you review any 20 materials whatsoever relating to NucliSENS 21 easyMAG? 22 MR. JONES: Objection to form. 23 A. I have -- no, I don't believe I have 24 looked directly at any materials from the Page 175	1 Menieux R&D and Medical Affairs Senior Vice 2 President that says "With the launching of 3 NucliSens easyMAG we significantly reinforce 4 our position in molecular biology by 5 addressing our customers' needs with a fully 6 automated platform for RNA and DNA 7 extraction." Do you see that? 8 A. Yes. I see that. 9 Q. And if you go down two more 10 paragraphs, it reads "Extraction of nucleic 11 acids (RNA and DNA) in the clinical sample 12 is an important step prior to molecular 13 amplification and detection of the target 14 nucleic acid present using a molecular 15 diagnostics testing platform which performs 16 the latter two steps simultaneously, such as 17 bioMerieux NucliSens EasyQ." Do you see 18 that? 19 A. Yes. 20 Q. And then in the next paragraph, the 21 second sentence says, "Like the NucliSens 22 miniMAG system, the NucliSens miniMAG 23 platform is capable of extracting both RNA 24 and DNA from a broad variety of sample types Page 177

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1 such as plasma, serum, whole blood, stool, 2 sputum and cerebrospinal fluid." Do you see 3 that? 4 A. Yes. 5 Q. Do you have any basis for denying the 6 NucliSENS easyMAG product cited in the '746 7 patent is capable of extracting both RNA and 8 DNA from stool? 9 MR. JONES: Objection to form. 10 A. Yes. I mean this is a -- it's a 11 descriptive statement, but there is no data 12 here. So I don't know this to be true. 13 Q. Do you have any factual basis for 14 denying that what is written in this press 15 release from bioMerieux about NucliSENS 16 easyMAG is true? 17 MR. JONES: Objection to form. 18 A. What I know is that I've read similar 19 types of descriptions back when I was working 20 at Exact Sciences about kits that would be 21 useful for recovering DNA from stool samples 22 and oftentimes products not providing results 23 that are consistent with the claims. 24 Q. And you did not have that experience Page 178	1 A. I don't have an opinion as to whether 2 or not this would be useful for recovering 3 RNA from stool samples. 4 Q. Do you dispute that it was known as of 5 2009 that in certain embodiments expression 6 -- I'm sorry, let me start over. 7 Do you dispute that it was known by 8 persons of skill in the art as of 2009 that 9 expression at the RNA level can be 10 determined by reverse transcription 11 polymerase chain reaction otherwise known as 12 RT PCR? 13 MR. JONES: Objection to form. 14 A. In the 2009 time frame, I believe that 15 it was well-known that RT PCR was one way of 16 being able to measure gene expression. 17 Q. And as of 2009, a person of skill in 18 the art would not have to do RT PCR in a 19 special or unique way to amplify RNA that 20 was extracted from a stool sample, correct? 21 MR. JONES: Objection to form. 22 A. I'm trying to think about how to 23 answer that. 24 I mean again there is no evidence Page 180
1 with NucliSens miniMAG, correct? 2 MR. JONES: Objection to form. 3 A. At that time period, working with 4 stool samples, we were not aiming to recover 5 RNA along with the DNA. 6 Q. Do you have any factual basis specific 7 to NucliSENS easyMAG for denying that what 8 is written in the NucliSENS easyMAG June 9 7th, 2007 press release is true? 10 MR. JONES: Objection to form. 11 A. I have no reason to deny that, but I 12 have no reason to believe it either. 13 Q. So you have no factual basis specific 14 to the NucliSENS easyMAG product for denying 15 that what is written in this June 7th, 2007 16 press release is true? 17 MR. JONES: Objection to form. 18 A. I think that's the same question you 19 just asked me. 20 I have no reason to deny that this 21 is true, but I have no reason to believe that 22 this is true. 23 Q. So you have no opinion on it one way 24 or the other? Page 179	1 that that was done, at least as written in 2 the description of the patents in this case, 3 there is no basis to form an opinion. 4 In terms of prior art, where people 5 were recovering RNA from stool samples, I 6 don't recall exactly how the gene expression 7 was being measured. I would have to go back 8 and look at that. 9 Q. So sitting here now, you don't have an 10 opinion one way or the other as to whether 11 as of 2009 a person of skill in the art 12 would have had to do RT PCR in a special or 13 unique way to amplify RNA that was extracted 14 from a stool sample, correct? 15 MR. JONES: Objection to form. 16 A. I think that the RT PCR step itself -- 17 my opinion is that the RT PCR step itself 18 could probably be done in a way that it's 19 relatively standard procedure, but that in 20 order to determine if the result of those 21 reactions was something that was useful as a 22 biomarker would still have to be 23 demonstrated. And what I mean by that is 24 that the quality of the RNA, the quantity of Page 181

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1 the RNA, and the correlation of that RNA with 2 tumor biology would have to be demonstrated 3 to show that it could be a useful molecule, 4 or, yeah, useful target for diagnostics. 5 Q. Sitting here now you have no factual 6 basis for disputing that as of 2009 a person 7 of skill in the art could use standard RT 8 PCR to amplify RNA that was extracted from a 9 stool sample, correct? 10 MR. JONES: Objection to form. 11 A. You're taking -- you're trying to get 12 me to take my answer out of context, and the 13 point of my context is that one could run a 14 reaction. That's not the question. 15 The question is could you run the 16 reaction for the sake of getting a useful 17 result, and what I'm trying to explain is 18 that the useful result is as important, if 19 not more so, than just running the reaction. 20 Q. Please provide the complete factual 21 basis for any opinion you have that as of 22 2009 a person of skill in the art could not 23 use standard RT PCR to amplify RNA that was 24 extracted from a stool sample? Page 182	1 art at that time may not be able to do that, 2 that's the answer that I gave you already. 3 Q. What corroboration do you have for 4 that opinion? 5 MR. JONES: Objection to form. 6 A. I know from working with -- my own 7 experience working with RNA recovered from a 8 variety of different kinds of samples, that 9 if particular steps aren't taken to preserve 10 the sample, it can dramatically impact the 11 downstream analysis of that. 12 Q. And you know of no factual 13 corroboration for any opinion that as of 14 2009, in fact, persons of skill in the art 15 were unable to isolate RNA from stool 16 samples such that it could be amplified by 17 RT PCR? 18 MR. JONES: Objection. 19 A. I can't speak for all of the 20 experiments that people tried that may not 21 have reported on, and so I think one would 22 have to at least consider all of that work as 23 someone who is skilled in the art in their 24 success, but what I'm trying to explain is Page 184
1 MR. JONES: Objection to form. 2 A. What I'm suggesting is if that one 3 were to do -- well, okay. So here's -- one 4 would have to know that the RNA that is 5 recovered from a stool sample has sufficient 6 integrity, as it's often referred to, or 7 essentially the quality of the RNA molecules, 8 such that one could actually reverse 9 transcribe it as well as then be able to 10 design primers that would be effective when, 11 in fact, the RNA molecules may be degraded or 12 short, and, therefore, it couldn't be done. 13 Q. Please provide the complete factual 14 basis for your opinion that, in fact, as of 15 2009 persons of skill in the art could not 16 use standard RT PCR to amplify RNA that was 17 extracted from a stool sample? A factual 18 basis. 19 MR. JONES: Objection to form. 20 A. So what I was just describing to you 21 -- if you're asking me to point to an 22 experiment, I don't have that in front of me. 23 If you're asking me for my opinion 24 as to why a person of ordinary skill in the Page 183	1 that there's -- that one would have to 2 preserve samples sufficiently, be able to 3 extract samples sufficiently prior to then 4 being able to do an RT step and analyze the 5 cDNA downstream from that. 6 Q. What is the factual basis or 7 corroboration for any opinion that, in fact, 8 a person of skill in the art in 2009 could 9 not preserve samples sufficiently to be able 10 to extract RNA prior to doing an RT PCR on 11 samples from stool? 12 MR. JONES: Objection to form. 13 Q. I'm just looking for a factual basis, 14 because this seems very abstract when you're 15 saying it. 16 MR. JONES: Objection to form. 17 A. I'm not sure what you're actually 18 looking for in terms of factual basis. 19 What I'm describing to you is that 20 it's common knowledge that if, you know, 21 steps are not taken to preserve RNA 22 molecules, that they degrade very quickly, 23 more fragile than DNA molecules, and that 24 these effects can have a dramatic effect on Page 185

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1 the downstream analysis, and so even the RT 2 PCR step doesn't come until after, you know, 3 in the case of stool samples, you know, you 4 have done a good job of preserving the stool 5 sample, but also figuring out a way to 6 robustly extract the RNA, and it's not 7 opinion. This is what is known in the art. 8 So I'm not sure which facts you're looking 9 for. 10 MR. JONES: We have been going for 11 an hour and 15. Can we wrap up soon. 12 MS. HABERNY: A couple minutes. 13 Q. So you're saying that all these things 14 you just mentioned would need to be known in 15 order to be perform RT PCR on RNA from a 16 stool sample. What's your factual basis for 17 saying that they weren't known in 2009? 18 MR. JONES: Objection to form. 19 A. In 2009, like I said, I -- one would 20 have to look at the evidence that's out 21 there. I know that there are papers that 22 were prior art that talk about analyzing RNA 23 from stool samples. I would have to refresh 24 my memory as to what the steps were to Page 186	1 couldn't be done, right? 2 MR. JONES: Objection to form. 3 A. I don't understand what you're asking. 4 Q. Well, I have heard you give a lot of 5 abstract ideas, but I have not heard you yet 6 identify a source of corroboration in any 7 way for any of it. 8 MR. JONES: Objection to form. 9 A. I disagree. 10 MR. JONES: Mischaracterizes. 11 Q. So what is your sources of 12 corroboration, corroborating evidence, for 13 any opinion you might have that a person of 14 skill in the art would be unable to isolate 15 RNA from a fecal sample and perform RT PCR 16 to amplify it? 17 MR. JONES: Objection to form. 18 A. I regard that as a hypothetical 19 consideration, and that in order to disprove 20 it's hypothetical, prove that it could be 21 done, there would have to be positive 22 evidence to support that. There is none in 23 the written description of this patent. 24 Q. Are you aware of any corroborating Page 188
1 process the samples and if they had done the 2 RT PCR step that we are talking about in 3 order to answer the question. So from that 4 perspective, I can't. 5 From the perspective of looking to 6 see whether or not you could do a RT PCR step 7 based on what is written in the description 8 in the common specification of this patent, 9 there is also no way to judge, because there 10 is no written description of any of the RNA 11 that may or may not be in these samples. So 12 it's unknown whether or not one could do RNA 13 or RT PCR based on the written description 14 either. 15 Q. So you don't know one way or another 16 whether one could do RT PCR based on the 17 written description of the '746 patent? 18 MR. JONES: Objection to form. 19 A. No. Based on the written description 20 of the patent, there is nothing to suggest 21 that it could be done. 22 Q. You can't identify any factual basis 23 for the reasons that you mentioned 24 previously that you think it possibly Page 187	1 evidence to show that persons of skill in 2 the art in 2009 failed in attempts to 3 isolate RNA from a fecal sample and perform 4 RT PCR to amplify it? 5 A. So you're asking me did somebody write 6 a paper saying I failed to run RT PCR on RNA 7 from stool samples? I do not know of such a 8 paper. 9 Q. Are you aware of papers reporting that 10 persons of skill in the art in 2009, in 11 fact, were able to isolate RNA from a fecal 12 sample and perform RT PCR to amplify it? 13 A. As I said a couple of times now, I am 14 aware of people in the prior art who have 15 isolated RNA from stool samples and analyzed 16 that in conjunction with colorectal cancer. 17 I do not recall exactly what the steps were 18 they used to process those samples. 19 Q. So you don't know one way or another 20 whether persons of skill in the art in 2009 21 had been able to isolate RNA from a fecal 22 sample and perform RT PCR to amplify it, 23 correct? 24 MR. JONES: Objection. Form. Page 189

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1 A. I will answer it the same way. I know
2 that there's people who recovered RNA from
3 stool samples. I don't know if they have
4 used RT PCR as part of the processing of
5 samples.
6 If they did, then they would have
7 successfully done exactly what you're asking,
8 but if they used some other process, then
9 they may have failed at using RT PCR.
10 So I don't know what the exact
11 steps were. So I can't answer your question.
12 MS. HABERNY: Okay. You want to
13 take a break?
14 MR. JONES: Yep.
15 THE VIDEOGRAPHER: The time is
16 4:28. We are off the record.
17 (A recess was taken.)
18 THE VIDEOGRAPHER: Stand by.
19 Okay. We are back on the record. The time
20 is 4:42.
21 BY MS. HABERNY:
22 Q. When testing a stool sample for blood,
23 would you agree that it may be easier to
24 test for the presence of blood proteins that

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1 appear in higher amounts rather than less
2 common ones?
3 MR. JONES: Objection to form.
4 A. I think one would have to specify
5 which blood proteins we're talking about.
6 Q. When testing a stool sample for blood,
7 would you agree that it would be desirable
8 to test for the presence of blood proteins
9 that appear in high concentrations?
10 MR. JONES: Objection to form.
11 A. So I take that to mean that you're
12 asking if all you wanted to do was to test
13 for the presence of blood, and you're doing
14 that by looking at blood proteins, would it
15 be better to test with higher or lower
16 concentrations?
17 I think that as long as you're
18 within the dynamic range of any given assay,
19 it doesn't necessarily matter if it's high or
20 low concentration.
21 Q. When testing a stool sample for blood,
22 would you agree that it would be easier to
23 test for the presence of blood proteins that
24 are common in blood --

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1 MR. JONES: Objection to form.
2 Q. -- than ones that aren't?
3 MR. JONES: Objection to form.
4 A. Is that different from the question
5 you just asked?
6 Q. Yes. So when testing a stool sample
7 for blood, would you agree that it would be
8 easier to test for the presence of blood
9 proteins that are common in blood as opposed
10 to blood proteins that are not common in
11 blood?
12 MR. JONES: Objection to form.
13 A. Again I think it depends on the assay
14 that one is using to detect the proteins, and
15 as long as the proteins are specific to
16 blood, then -- and were within the dynamic
17 range of an assay, it doesn't necessarily
18 matter if they're high or low concentration.
19 Q. Hemoglobin is one of the more common
20 blood proteins, correct?
21 A. I believe that's true.
22 Q. And if you test a sample for the
23 presence of hemoglobin, you've tested the
24 sample for an amount of a blood protein,

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1 correct?
2 MR. JONES: Objection to form.
3 A. If you've tested a sample for
4 hemoglobin, then you have tested for
5 hemoglobin, that doesn't necessarily mean
6 that you have tested for any blood protein.
7 Q. I asked a different question. I'm not
8 asking you about the word "any."
9 If you test a sample for the
10 presence of hemoglobin, then you've tested
11 the sample for an amount of a blood protein?
12 MR. JONES: Objection to form.
13 A. So if you have tested a sample -- are
14 we talking about a stool sample?
15 Q. Sure, stool sample.
16 A. If we tested a stool sample for amount
17 of hemoglobin, and hemoglobin is contained in
18 blood, then you would be testing for a
19 protein in blood.
20 Q. Are you aware of any tests that test
21 for the presence of blood proteins other
22 than hemoglobin in feces?
23 MR. JONES: Objection to form.
24 A. Are you asking about clinical tests or

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1 research studies, or what are we -- how would 2 you characterize your question? 3 Q. Are you aware of any test of any form 4 that tests for the presence in feces of 5 blood proteins other than hemoglobin? 6 MR. JONES: Objection to form. 7 A. So again I'm not -- I'm just trying to 8 clarify. Are you asking about clinical 9 tests? When you say "tests," how do you 10 characterize what a test is? 11 Q. Are you aware of any assay of any 12 form, clinical or not, that tests for the 13 presence of blood proteins other than 14 hemoglobin in feces? 15 A. I'm aware that people have done 16 research studies to look for other proteins 17 besides hemoglobin in feces. I can't recall 18 exactly which studies those are at this 19 point. 20 Q. Did you cite any of them in your 21 expert declarations? 22 A. Let me review. 23 (Witness reviews document.) 24 I mean you're asking me to confirm, Page 194	1 A. I don't know. You're referring to the 2 first and second declaration? 3 Q. Yes. Anywhere in this case, I would 4 like to know if you've identified any assay, 5 research or clinical that tested for a blood 6 protein other than hemoglobin in feces? 7 A. (Witness reviews document.) 8 I found at least one other 9 citation. 10 Q. Okay. What paragraph is that in? 11 A. So it's end of Paragraph 42. 12 Q. Of which declaration? 13 A. The first. 14 Q. Which reference? 15 A. Well, the title -- the Hirata -- the 16 title is indicated "Usefulness of fecal 17 lactoferrin and hemoglobin in diagnosis of 18 colorectal diseases." 19 Q. So would you agree that in testing for 20 blood protein from stool, tests for the 21 presence of hemoglobin were the more common 22 tests in 2009? 23 A. I would say there's far more studies 24 looking at FOBT-type tests, which target Page 196
1 I think, if I have cited anything relative to 2 those -- the other studies that I recall, but 3 I don't know which ones they are, and quite 4 honestly it would take me some time to go 5 through -- to answer your question, it would 6 take some time to go through and scan for 7 every citation that I made, if that's what we 8 are talking about. 9 Q. So sitting here today, you can't 10 identify any research studies to look for 11 proteins besides hemoglobin in feces that 12 you've cited? 13 MR. JONES: Objection to form. 14 A. No, that's not what I am saying. What 15 I'm saying is that in order to confirm 16 whether or not I did, I would have to go 17 through -- you're asking about this PI 18 declaration in addition to the IPRs? 19 Q. I'm asking just about in the district 20 court litigation. 21 A. Yeah, I could spend some time going 22 through this to answer your question, if 23 that's what we would like to do. 24 Q. How long would it take you? Page 195	1 hemoglobin, than other proteins. 2 Q. So testing for the presence of 3 hemoglobin as the blood protein from stool 4 would be a representative test among the 5 available options at that time? 6 MR. JONES: Objection to form. 7 A. It is one of thousands of proteins 8 which are in the blood. 9 Q. So testing for the presence of 10 hemoglobin as a blood protein from stool 11 would be a representative test among the 12 available options at the time in 2009? 13 MR. JONES: Objection to form. 14 A. Representative for what? 15 Q. Representative of test for blood 16 protein in stool. 17 MR. JONES: Objection to form. 18 A. No. What I'm asking you for 19 clarification is, if one were to measure a 20 blood protein and you're asking me if it's 21 representative, I want to know what it's 22 representative of. 23 Q. Would you agree that FIT, F-I-T, is 24 another way of saying iFOBT, that those Page 197

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1 terms mean the same thing?
2 A. I would agree, yes.
3 Q. And a FIT test is an immunochemical
4 test, correct?
5 A. A FIT test, yeah, I would characterize
6 that as immunochemical, in the sense it uses
7 antibodies to detect the hemoglobin.
8 Q. In 2009, commercial services were
9 available to produce antibodies against
10 numerous antigens, correct?
11 MR. JONES: Objection to form.
12 A. I don't pretend to represent the
13 antibody manufacturing industries, but I
14 would agree that -- well, in that time frame?
15 Actually, no, I don't presume to make any
16 kind of statement as to how common it was to
17 generate antibodies against any protein.
18 Q. So you're not offering an opinion one
19 way or another as to whether commercial
20 services were available in 2009 to generate
21 antibodies against proteins?
22 MR. JONES: Objection to form.
23 A. No, that's not what I said. I --
24 well, so let me clarify.

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1 I do know that there were
2 commercial sources available to generate
3 antibodies against protein antigens.
4 Q. And are you offering an opinion one
5 way or another as to whether the commercial
6 services available to generate antibodies
7 against protein antigens in 2009 were
8 common?
9 MR. JONES: Objection to form.
10 A. How do you define "common"?
11 Q. Were widely used by persons of skill
12 in the art.
13 A. I would say that services were
14 certainly available in the 2009 time frame.
15 As to how widely they were used to people
16 trained in the art, I can't say.
17 Q. Are you familiar with a method called
18 NASBA?
19 A. NASBA? I believe I have seen the
20 acronym before, but I don't recall exactly
21 what it stands for or how the assay is run.
22 Q. Are you aware that NASBA is a
23 technique for amplifying RNA?
24 MR. JONES: Objection to form.

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1 A. Sorry, repeat the question.
2 Q. Are you aware that NASBA is a
3 technique for amplifying RNA?
4 MR. JONES: Objection to form.
5 A. I have not used that assay, so -- and,
6 as I said a moment ago, I'm not familiar just
7 based on the acronym as to what is involved
8 in that. So I may have read papers about
9 that technique in the past, but I don't
10 recall at this point the details.
11 Q. Are you familiar with a method called
12 transcription mediated application?
13 MR. JONES: Objection to form.
14 A. I'm aware of the acronym, and I am --
15 yes, so I'm familiar at least with the
16 acronym.
17 Q. Do you know how it works?
18 A. At this moment I could not give a
19 detailed accounting as to how to run the
20 assay.
21 Q. Are you aware that transcription
22 mediated amplification is a technique for
23 amplifying RNA?
24 MR. JONES: Objection to form.

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1 A. I have not -- that's another
2 methodology which I personally have not run.
3 So I can't speak to that from my own personal
4 experience.
5 (Exhibit 32 was marked for
6 identification.)
7 Q. I'm handing you what has been marked
8 as Exhibit 32. This is a 2007 paper
9 published in Cancer Epidemiology Biomarkers
10 Prev -- I'm not sure what that stands for --
11 by first author Hongzhi Zou, H-o-n-g-z-h-i
12 Z-o-u. Did you review this paper in viewing
13 your opinions for this case?
14 A. Yes, I believe I did.
15 Q. Are you aware that this paper analyzes
16 the effect of methylation on gene
17 expression?
18 MR. JONES: Objection to form.
19 A. (Witness reviews document.)
20 Well, in reading the abstract, what
21 I see, is that they describe, the effective
22 methylation on gene expression being
23 evaluated in colon cancer cell lines.
24 Q. And what do you understand "gene

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1 expression" to mean? 2 A. I understand gene expression to be the 3 translation from DNA to RNA and measurement 4 of the relative quantities of RNA. 5 Q. If you can look please at Page 2689 of 6 the Zou paper, Exhibit 32. Do you see that 7 there is a section entitled "Realtime 8 Reverse Transcription - PCR"? 9 A. Yes. 10 Q. And do you see that the authors 11 performed realtime reverse transcription PCR 12 to measure mRNA expression levels? 13 A. Let me review first before answering. 14 (Witness reviews document.) 15 Yes. Sorry, could you repeat the 16 question? 17 Q. Do you see that the authors performed 18 realtime reverse transcription PCR to 19 measure mRNA expression levels in the Zou 20 study of Exhibit 32? 21 A. (Witness reviews document.) 22 I see the section you're talking 23 about. I haven't read, re-read the paper 24 carefully enough to remember where the RNA Page 202	1 reasonably good degree of specificity. 2 Q. Specificity? 3 A. Meaning that they were -- the 4 methylation was specific to cancer. 5 Q. So the authors of the Zou paper, 6 Exhibit 32, were correlating methylation 7 status for genes in colon cancer to mRNA 8 expression levels, correct? 9 MR. JONES: Objection to form. 10 A. I think what they were doing here to 11 -- it's been a little while since I've 12 re-read this paper, but I believe what they 13 were doing was to measure the methylation 14 level of these genes in stool samples 15 collected from cancer patients, and then 16 separately looking at RNA expression levels 17 in cell line RNA. 18 Q. And this was a study that was 19 published in 2007? 20 A. Correct. 21 Q. And if you look at Page 2693 of Zou 22 Exhibit 32, there's a section titled 23 "Reexpression of Methylated Genes in Colon 24 Cancer Cell Lines By Demethylation." Do you Page 204
1 originates from, if that's -- oh, sorry it's 2 right here. So it's from the cancer cell 3 lines, yeah. 4 Q. So you agree that the authors in the 5 Zou -- strike that. 6 You agree that in the Zou study of 7 Exhibit 32 the group performed realtime 8 reverse transcription PCR to measure mRNA 9 expression levels? 10 A. From the description, what they talk 11 about is running standard curves in order to 12 do a quantitation, and that they were using 13 RT PCR procedures to be able to measure then 14 the quantity -- to be able to calculate -- 15 measure and calculate the concentrations of 16 RNA from these colon cancer cell lines. 17 Q. And you understand that the genes that 18 were targeted for this RNA expression 19 measurement were genes that were methylated 20 in colon cancer? 21 A. My -- yeah, my understanding from 22 reading the -- re-reading the abstract was 23 that these are associated with colon cancer, 24 and, in fact, have -- may have had some Page 203	1 see that? 2 A. I see the section, yes. 3 Q. Okay. And the second sentence in that 4 section says "Suppression of mRNA expression 5 in these genes was generally observed in the 6 methylated cell lines without 7 5-aza-deoxycytidine treatment." Do you see 8 that? 9 A. Yes. 10 Q. So here the authors, in fact, showed 11 that there is a correlation between DNA 12 methylation status and colorectal cancer and 13 mRNA levels, correct? 14 MR. JONES: Objection to form. 15 A. From this section, so if we avoid the 16 question of using the methylation level of 17 the same genes from stool samples, which was 18 DNA, and just focus on the experiment here 19 looking at cell lines, what they're talking 20 about is that using a demethylation agent 21 reverses the methylation changes to then have 22 an impact on the expression of the genes. So 23 there is some correlation in the cell lines. 24 Q. Do you have any reason to dispute that Page 205

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[REDACTED]

1 that same correlation would be found in a
2 stool sample?
3 MR. JONES: Objection to form.
4 A. The evidence for that being similar in
5 a stool sample would have to be shown.
6 So again as we have gone through
7 this in other lines of questioning, if there
8 is no evidence, it's hard to have an opinion
9 or to be able to believe or refute in a
10 different context.
11 Q. Have you ever used cancer cell lines
12 to mimic the cancer condition that occurs in
13 a patient's colorectal cancer?
14 A. I don't understand your question.
15 Q. Have you ever used cancer cell lines
16 to do experiments --
17 A. Yes.
18 Q. -- related to colorectal cancer?
19 A. Yes.
20 Q. Why did you use those cancer cell
21 lines?
22 A. To study the behavior of certain cells
23 in a controlled environment.
24 Q. And did you ever relate the results of

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1 your cancer cell line experiments to stool
2 sample experiments?
3 A. Which experiments are you talking
4 about? I don't understand what you're
5 asking.
6 Q. Have you ever relied on cancer cell
7 line experiments to design further
8 experiments on a stool sample?
9 A. I actually don't recall. I'm trying
10 to remember all of the cell line experiments
11 that were done and what we did with that data
12 and it's very hard for me to answer that
13 question. I don't recall.
14 Q. Is it common for scientists to use
15 cell lines to mimic conditions that occur in
16 a full organism?
17 MR. JONES: Objection to form.
18 A. That's a very vague question. I'm
19 really not sure what you are asking, but I --
20 people use cell lines for many, many
21 different reasons.
22 One has to recognize that that's a
23 very different set of conditions to an
24 organism, and whatever one learns from the

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1 cell line experiments, there is always going
2 to be caveats to how that can be translated
3 to clinical examples.
4 Q. Is transfer RNA a biomarker, used as a
5 biomarker to test for CRC?
6 A. I'm not aware of transfer RNA as a
7 biomarker, as I sit here today. It's
8 possible that somebody has used that in a
9 study.
10 Q. Is MicroRNA used as a biomarker to
11 test for CRC?
12 A. What time frame and what sample?
13 Q. Are you aware of MicroRNA ever having
14 been used as a biomarker to test for
15 colorectal cancer?
16 A. Yes.
17 Q. In what context?
18 A. I know that shortly after MicroRNAs
19 were discovered, they were being explored in
20 virtually every cancer, and again I'm not
21 pointing to any particular reference, but I
22 know that people skilled in the art were
23 certainly aware of MicroRNA being used as a
24 biomarker for colon cancer.

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
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11 [REDACTED]
12 [REDACTED]
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17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[illegible]

Page 210

[illegible]

Page 211

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 Q. Is it your opinion that a combination
6 of two or more ideas that are individually
7 in the prior art can never be patentable?
8 MR. JONES: Objection to form.
9 A. Jeez, no, I wouldn't say that.
10 Q. Can you please open your second
11 declaration.
12 A. Sure.
13 Q. Can you turn to the table of contents,
14 please?
15 A. Yes.
16 Q. Can you explain why the word "second"
17 is in bigger font than everything else in
18 the header?
19 A. Nope, I can't explain it.
20 Q. Would you agree that it is not
21 scientifically sound to compare
22 sensitivities reported from studies by
23 different groups testing different sample
24 types from different patient populations?

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1 MR. JONES: Objection to form.
2 A. I mean it depends on what the aim of
3 that comparison is. One can always make
4 comparisons, but you would have to be more
5 specific as to what the aim is.
6 Q. Would you agree that it's not
7 scientifically sound to compare
8 sensitivities reported from different groups
9 in a manner that is not a head-to-head
10 analysis?
11 MR. JONES: Objection to form.
12 A. You haven't clarified what the aim is.
13 So you can't answer the question unless you
14 know what the aim is.
15 Q. What would be the aim of comparing
16 sensitivities reported from different
17 groups?
18 MR. JONES: Objection to form.
19 A. I mean it depends what kind of
20 comparison we're doing. If you're looking at
21 one group, which is looking at one biomarker,
22 and you're looking at another group to see a
23 different biomarker, and each is using
24 different sets of samples, one aim would be

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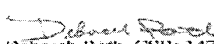
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1 to say who had a higher sensitivity. 2 Q. Would it be scientifically sound to do 3 what you just described in a manner that is 4 not a head-to-head analysis? 5 MR. JONES: Objection to form. 6 A. The analysis of -- a comparative 7 sensitivity analysis as an example would be 8 best done using the same sets of samples and 9 the same analytical procedures. 10 Q. Do you believe that Dr. Patterson's 11 opinions are disingenuous? 12 MR. JONES: Objection to form. 13 A. Could you point me to any particular 14 opinion that you're asking about? 15 Q. Do you have an opinion that 16 Dr. Patterson's interpretation of any of the 17 prior art references at issue in this case 18 is disingenuous? 19 MR. JONES: Objection to form. 20 A. I guess I would want to -- before I 21 answer that question, I would like to know 22 which part of the declaration you're 23 referring to? You're obviously looking at 24 something. Page 214	1 transcripts, was trying to suggest that this 2 is only something which would -- that in 3 order to use this in a broad diagnostic 4 screening program, that this would -- because 5 this wasn't in a broad diagnostic screening 6 program, that this -- you know, that he 7 disregards the teaching. 8 Q. Why did you choose the word 9 "disingenuous"? 10 A. I don't recall, to be perfectly 11 honest. 12 Q. Did you choose that word? 13 A. Yes. 14 Q. Is that a word you chose? 15 A. Yes. Yes. 16 Q. Do you think Dr. Patterson is a liar? 17 MR. JONES: Objection to form. 18 A. No. I mean we're picking on the 19 meaning of words here at this point I guess. 20 I think that it -- from my 21 perspective it is very hard to understand why 22 one would ignore the clear teachings of this 23 paper and instead say this may not be useful 24 for broad diagnostic testing. Page 216
1 Q. Take a look at Paragraph 90 of your 2 second declaration? 3 A. Paragraph 90. Okay. 4 Q. You say here "Dr. Patterson's 5 interpretation of Kutzner is likewise 6 confounding and disingenuous." Do you see 7 that? 8 A. Yes, I see that. 9 Q. Is it your opinion that 10 Dr. Patterson's opinions are disingenuous? 11 A. Let me read what I was referring to 12 there. 13 MR. JONES: Objection. 14 A. (Witness reviews document.) 15 Yeah, so what I was referring to is 16 the results of the Kutzner paper is 17 describing the clear benefit in sensitivity 18 of combining two different types of assays, 19 specifically the MD, which is the DNA 20 portion, and the FOBT, which is the blood 21 protein portion, and that it's, in my 22 opinion, irrefutable based on this study that 23 the combination provides for improvement, and 24 that Dr. Patterson, according to the Page 215	1 Q. Do you believe that increased 2 diagnostic accuracy is an inherent result of 3 a stool test that combines nucleic acid 4 biomarkers and protein biomarkers to screen 5 for CRC? 6 MR. JONES: Objection to form. 7 A. I'm sorry, could you repeat that? 8 Q. Do you believe that increased 9 diagnostic accuracy is an inherent result of 10 a stool test that combines nucleic acid 11 biomarkers and protein biomarkers to screen 12 for CRC? 13 MR. JONES: Objection to form. 14 A. No. I think that the whole point of 15 doing laboratory testing studies is to 16 determine the answer to that question. 17 Q. So a person of skill in the art as of 18 2009 wouldn't have expected a stool test 19 that combines nucleic acid biomarkers and 20 protein biomarkers to have increased 21 diagnostic accuracy, correct? 22 MR. JONES: Objection to form. 23 A. What -- I'm sorry, repeat the 24 question. Page 217

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1 Q. A person of skill in the art as of 2 2009 would not have expected a stool test 3 that combines nucleic acid biomarkers and 4 protein biomarkers to have increased 5 diagnostic accuracy, corrects? 6 A. One would have to be -- in order to 7 form an opinion on that, the -- you know, the 8 person of ordinary skill in the art, myself, 9 would have to understand what is a specific 10 biomarker that we are talking about if one 11 were looking for some kind of increase in 12 performance. 13 Q. So a person of skill in the art as of 14 2009 would only have expected a stool test 15 that combines nucleic acid biomarkers and 16 protein biomarkers to have increased 17 diagnostic accuracy if that person knew what 18 specific biomarkers were going to be used in 19 the test? 20 MR. JONES: Objection to form. 21 A. I think that the general idea of using 22 the DNA biomarker at that time was that there 23 was no description that I'm aware of where 24 the DNA-based test had a hundred percent Page 218	1 Q. Ways that increased diagnostic 2 accuracy could be accomplished? 3 A. Yes. 4 Q. A person of skill in the art in 2009 5 would have expected a stool-based CRC 6 screening test combining DNA and protein 7 biomarkers to increase patient uptake. 8 correct? 9 MR. JONES: Objection to form. 10 A. I think that the patient uptake of a 11 test depends on many things. You're asking 12 me specifically is it a result of combining 13 DNA and FOBT, actually I think you said blood 14 proteins, and I would not suggest -- I would 15 not agree with that generalized statement 16 that you made. 17 Q. Would you agree that the addition of a 18 blood protein test to a fecal nucleic acid 19 test increases its diagnostic accuracy? 20 MR. JONES: Objection to form. 21 A. I believe that the way you're 22 describing it is very general, and if -- I 23 believe that a person of ordinary skill in 24 the art in that time frame, or even today for Page 220
1 sensitivity. 2 Further, it was known that the FOBT 3 tests were generally pretty specific and 4 operate through a completely different 5 mechanism than the DNA-based tests. 6 And so as a general rule at the 7 time people believed that the combination of 8 the two would provide for an improvement, 9 without a big loss in the specificity. 10 Q. So then a person of skill in the art 11 as of 2009 would have understood that 12 increased diagnostic accuracy is a property 13 of a CRC stool-based screening test 14 combining nucleic acid and protein 15 biomarkers? 16 MR. JONES: Objection to form. 17 A. I think what -- a person understanding 18 the art would recognize that based on results 19 of studies that, in fact, combined DNA and 20 FOBT and demonstrated an increase in 21 performance with the combination over either 22 one of those individually would have 23 understood that there were certainly ways 24 that that could be accomplished. Page 219	1 that matter, would make their conclusions 2 based on results of studies. 3 So I wouldn't necessarily make a 4 generalized statement as you are. I would 5 say that they would look for specific studies 6 like Lenhard, like Kutzner and others to come 7 to the conclusion that in some cases one 8 could combine DNA and FOBT to improve 9 accuracy and that that was known in that time 10 frame. 11 MS. HABERNY: Do you want to take 12 a little break? 13 THE VIDEOGRAPHER: The time is 14 5:48. We're off the record. 15 (A recess was taken.) 16 THE VIDEOGRAPHER: All right. 17 Stand by. We are back on the record. The 18 time is 6:00 p.m. 19 MS. HABERNY: I have no additional 20 questions. 21 MR. JONES: I have no questions. 22 MS. HABERNY: Okay. Thank you 23 very much, Dr. Whitney. 24 THE WITNESS: Thank you. Page 221

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1 THE VIDEOGRAPHER: The time is 2 6:01. We are off the record. 3 (The deposition adjourned at 6:02 p.m.) 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	1 ERRATA SHEET FOR THE TRANSCRIPT OF: 2 Case Name: EXACT SCIENCES v. GENEOSCOPE 3 Dep. Date: 1/9/25 4 Deponent: DUNCAN WHITNEY PhD 5 6 CORRECTIONS: 7 Pg. Ln. Now Reads Should Read Reason 8 9 10 11 DUNCAN WHITNEY PhD 12 Signed under the pains and penalties of 13 perjury this _____ day of 14 _____, 20____. 15 16 Subscribed and sworn to before me this 17 day of _____, 20____. 18 19 Notary Public 20 My Commission Expires: _____ 21 22 23 24
Page 222	Page 224
1 CERTIFICATE 2 COMMONWEALTH OF MASSACHUSETTS) 3 COUNTY OF SUFFOLK) 4 I, Deborah Roth, a Registered 5 Professional Reporter and Notary Public duly 6 commissioned and qualified in and for the 7 Commonwealth of Massachusetts, do hereby 8 certify: That DUNCAN WHITNEY PhD, the 9 witness whose deposition is hereinbefore set 10 forth, was duly identified and sworn by me, 11 and that the foregoing transcript is a true 12 record of the testimony given by such 13 witness. 14 I further certify that I am not 15 related to any of the parties in this matter 16 by blood or marriage, and that I am in no 17 way interested in the outcome of this 18 matter. 19 IN WITNESS WHEREOF, I have hereunto 20 set my hand and affixed my notarial seal 21 this 17th day of January 2025. 22 23  24 Deborah Roth, CSR: 14700-S, RPR: 34250 My Commission Expires: December 31, 2021	1 INDEX 2 WITNESS: DUNCAN WHITNEY PhD 3 EXAMINATION PAGE 4 BY MS. HABERNY 6 5 6 EXHIBITS PAGE 7 Exhibit 23 Second Declaration of Duncan 8 Whitney PhD 6 9 Exhibit 24 11/22/24 Deposition of Bruce K. 10 Patterson MD 10 11 Exhibit 25 11/14/24 Deposition of Mark W. 12 Eshoo PhD 11 13 Exhibit 26 Curriculum Vitae of Duncan H. 14 Whitney PhD 27 15 Exhibit 27 Patent Owner's Response in 16 IPR2024-00459 16 17 Exhibit 28 Materials Considered 26 18 Exhibit 29 "Performance Characterized and 19 Evaluation of An Automated- 20 Developed and Quantitate, 21 Immunochemical Fecal Occult 22 Blood Screening Test," 23 Vilkin, et al. 86 24
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1 EXHIBITS PAGE 2 Exhibit 30 Excerpt of Molecular Cloning 3 A Laboratory Manuel, Third 4 Edition, Sambrook and Russell 168 5 Exhibit 31 6/7/05 NucliSens easyMAG 6 Press Release 176 7 Exhibit 32 "Highly Methylated Genes in 8 Colorectal Neoplasia: 9 Implications for Screening," 10 Zou, et al. 201 11 EXHIBITS PREVIOUSLY MARKED PAGE 12 Exhibit 1 Declaration of Duncan Whitney 27 13 Exhibit 6 Konstanze Lenhard, et al. 14 2005 Article 39 15 Exhibit 7 Steven H. Itzkowitz, et al. 16 2007 Article 117 17 Exhibit 10 Bernard Levin, et al. 18 2008 Article 71 19 Exhibit 11 Nadine Kutzner, et al. 20 2005 Article 67 21 Exhibit 14 Takashi Nishikawa, et al. 22 2002 Article 63 23 Exhibit 17 US Patent 11.970.746 B1 158 24 Page 226	1 _X_ Federal R&S Requested (FRCP 30(e)(1)(B)) - Locked .PDF 2 Transcript - The witness should review the transcript and 3 make any necessary corrections on the errata pages included 4 below, notating the page and line number of the corrections. 5 The witness should then sign and date the errata and penalty 6 of perjury pages and return the completed pages to all 7 appearing counsel within the period of time determined at 8 the deposition or provided by the Federal Rules. 9 _ Federal R&S Not Requested - Reading & Signature was not 10 requested before the completion of the deposition. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 Page 228
1 Brendan Jones, PhD, Esquire 2 bjones@foleyhoag.com 3 January 17, 2025 4 RE: Exact Sciences Corporation v. Geneoscopy, Inc. 5 1/9/2025, Dr. Duncan Whitney Ph.D., (#7076674). 6 The above-referenced transcript has been 7 completed by Veritext Legal Solutions and 8 review of the transcript is being handled as follows: 9 _ Per CA State Code (CCP 2025.520 (a)-(e)) - Contact Veritext 10 to schedule a time to review the original transcript at 11 a Veritext office. 12 _ Per CA State Code (CCP 2025.520 (a)-(e)) - Locked .PDF 13 Transcript - The witness should review the transcript and 14 make any necessary corrections on the errata pages included 15 below, notating the page and line number of the corrections. 16 The witness should then sign and date the errata and penalty 17 of perjury pages and return the completed pages to all 18 appearing counsel within the period of time determined at 19 the deposition or provided by the Code of Civil Procedure. 20 Contact Veritext when the sealed original is required. 21 _ Waiving the CA Code of Civil Procedure per Stipulation of 22 Counsel - Original transcript to be released for signature 23 as determined at the deposition. 24 _ Signature Waived - Reading & Signature was waived at the 25 time of the deposition. Page 227	1 Exact Sciences Corporation v. Geneoscopy, Inc. 2 Duncan Whitney Ph.D. (#7076674) 3 E R R A T A S H E E T 4 PAGE__ LINE__ CHANGE__ 5 _____ 6 REASON_____ 7 PAGE__ LINE__ CHANGE__ 8 _____ 9 REASON_____ 10 PAGE__ LINE__ CHANGE__ 11 _____ 12 REASON_____ 13 PAGE__ LINE__ CHANGE__ 14 _____ 15 REASON_____ 16 PAGE__ LINE__ CHANGE__ 17 _____ 18 REASON_____ 19 PAGE__ LINE__ CHANGE__ 20 _____ 21 REASON_____ 22 _____ 23 _____ 24 (Duncan Whitney Ph.D.) Date 25 _____ Page 229

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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