

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 CASE NO. IPR2024-00459
4 U.S. PATENT 11,634,781
5
6

7 GENEOSCOPY, INC.,

8 Petitioner

9 vs.

10 EXACT SCIENCES CORPORATION,

11 Patent Owner

12 *****

13 DEPOSITION OF:
14
15

16 DUNCAN H. WHITNEY, PH.D.

17 QUINN EMANUEL URQUHART & SULLIVAN LLP

18 111 Huntington Avenue

19 Boston, Massachusetts

20 October 10, 2024 10:10 a.m.

21 Darlene M. Coppola, RPR, RMR, CRR
22
23
24

Page 1

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10 Also Present:

11 Alexandra M. Gorman, In-house counsel,

12 Exact Sciences

13
14 Present via Zoom on behalf of Exact Sciences:

15 Jennifer Duke

16 Carly Conway

17 Sarojini Adusumilli

18 Tammy Tran

19 Ashley Hamlett

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EXAMINATION

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DUNCAN H. WHITNEY, PH.D.	
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Cross By Mr. Jones	169

EXHIBITS

None marked

1 P R O C E E D I N G

2
3 (Commencing at 10:10 a.m.)
4

5 DUNCAN H. WHITNEY, PH.D.,
6 a witness called for examination by
7 counsel for the Defendant, having been
8 satisfactorily identified by the production of
9 his driver's license and being first duly
10 sworn by the Notary Public, was examined and
11 testified as follows:
12

13 THE STENOGRAPHER: Thank you.
14 You may proceed.
15

16 DIRECT EXAMINATION

17 BY MS. FERNANDS:

18 Q. Good morning, Dr. Whitney.

19 A. Good morning.

20 Q. For the record, I just want to say
21 that I'm Anastasia Fernands. I'm counsel for
22 Exact Sciences. With me is my colleague from
23 Quinn Emanuel, Sandy Haberny, and also here is
24 in-house counsel from Exact Sciences,

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1 Alexandra Gorman.

2 And we have -- as we were saying off
3 the record, we have a few people from in-house
4 at Exact Sciences who are listening via Zoom.
5 And those are Jennifer Duke, Carly Conway,
6 Sarojini Adusumilli -- apologies, Sarojini --
7 Tammy Tran, and Ashley Hamlett.

8 A. Okay.

9 Q. Could you state your full name for the
10 record?

11 A. Yes. Duncan Harrower (phonetic)
12 Whitney.

13 Q. What is your current address?

14 A. I split my time, but on my CV, it's 25
15 Channel Center Street in Boston.

16 Q. Have you ever testified at a
17 deposition before?

18 A. I have.

19 Q. How many times?

20 A. One other time.

21 Q. Were you serving as an expert in that
22 other time?

23 A. No.

24 Q. So obviously we're on a stenographic

1 record. If you can wait until I finish asking
2 the questions before you answer -- and I'll
3 likewise attempt to do the same and wait until
4 you finish answering before I ask the next
5 question -- it just makes for a much cleaner
6 record.

7 A. (Witness nodding.)

8 Q. Now, you have submitted an expert
9 declaration on behalf of Geneoscopy in
10 connection with the IPR that's numbered IPR
11 459-2024, correct?

12 A. Yes.

13 Q. And you have in front of you a bound
14 document.

15 Did you bring a copy of your expert
16 declaration with you?

17 A. I did.

18 Q. Okay. And is that copy a clean copy,
19 or does it have any markup in it?

20 A. It has no markup.

21 Q. And is that your declaration but none
22 of the exhibits?

23 A. That's correct.

24 Q. When were you engaged by Geneoscopy to

1 prepare the declaration?

2 A. I don't recall exactly, but it was
3 sometime last fall, 2023.

4 Q. Do you recall roughly when in the
5 fall? Was it before or after Thanksgiving?

6 A. I believe it was in November. As to
7 whether it was before or after Thanksgiving, I
8 don't know.

9 Q. Who first contacted you in connection
10 with this matter for Geneoscopy?

11 A. With respect to the IPR? Is that what
12 you're asking about?

13 Q. Yes, with respect to the IPR.

14 A. I first spoke with Brendan.

15 Q. Would you prefer we marked the one you
16 brought with you or another copy as the
17 deposition exhibit here?

18 MR. JONES: You can mark another
19 copy as long as he uses that.

20 MS. FERNANDS: Okay.

21 MR. JONES: As long as it's the
22 same exhibit. I don't think we actually
23 submit anything. I think we just -- I don't
24 think you have to actually mark anything in

1 IPR cases.

2 MS. FERNANDS: You don't have to
3 mark anything? Okay.

4 MR. JONES: As long as it's
5 already been...

6 MS. FERNANDS: Oh, and if you
7 two would like a copy. And you have one as
8 well, so...

9 BY MS. FERNANDS:

10 Q. So you have in front of you what was
11 marked in the IPR 2024-00459 as Exhibit 1002,
12 correct?

13 And if you look at the second page of
14 it, I think you see it on the bottom.

15 A. Yes, that's correct.

16 Q. And that is the declaration that you
17 submitted in that IPR, correct?

18 A. That's correct.

19 Q. About how much time did you spend
20 preparing the declaration?

21 A. Oh, geez. I don't recall exactly. I
22 know that it was over a period of time from
23 the latter part of 2023 to the beginning of
24 2024. So it was probably a few dozen hours.

1 Q. And if you look at page 170 of your
2 declaration --

3 A. Yes.

4 Q. -- you see that that's dated as of
5 January 10, 2024; is that correct?

6 A. That's correct.

7 Q. And that's your signature there?

8 A. That is.

9 Q. Okay. So the declaration was
10 completed as of January 10 --

11 A. (Witness nodding.)

12 Q. -- of 2024?

13 A. Yes.

14 Q. Okay. You said you think you spent
15 probably a few dozen hours working on it?

16 A. I think that's fair.

17 Q. So I am going to hand you a document
18 that was already marked as Exhibit 1003.

19 And do you recognize that document?

20 A. I do.

21 Q. What is it?

22 A. It is my CV.

23 Q. And is this up to date still, this
24 CV?

1 A. Yes, more or less.

2 Q. If you turn to page 4 --

3 A. Do you mind if I get my glasses out?

4 Yes.

5 Q. If you turn to page 4, the top of
6 page 4 and then going on to page 5 -- page 3
7 where it begins, you see an entry for Exact
8 Sciences Corp.?

9 A. Yes.

10 Q. You were employed at Exact Sciences
11 from 2000 to 2005; is that correct?

12 A. That is correct.

13 Q. And you have two job titles listed for
14 Exact Sciences. The earlier is the director
15 of technology development, correct?

16 A. Yes.

17 Q. What generally were your
18 responsibilities as the director of technology
19 development at Exact?

20 A. So in that time frame, I was
21 responsible for leading a small team that was
22 working on methods to extract DNA from stool
23 samples and to optimize the yield that we were
24 able to get as well as downstream analysis

1 methodologies.

2 Q. And what do you mean by "downstream
3 analysis methodologies"?

4 A. Meaning also developing assays for
5 detection of specific mutations associated
6 with the DNA that we were recovering from the
7 samples as well as some other aberrant DNA
8 biomarkers.

9 Q. Was there a particular application for
10 which you were extracting DNA from stool
11 samples at that time at Exact?

12 A. So all of the work being done at Exact
13 Sciences was for the sake of developing and
14 ultimately commercializing a test for
15 screening of average-risk asymptomatic
16 patients for colon cancer.

17 Q. Okay. Is that also sometimes referred
18 to as CRC?

19 A. CRC, sure.

20 Q. So if I use CRC, that's colorectal
21 cancer?

22 A. I'm fine with that.

23 Q. Prior to working -- starting work at
24 Exact in 2000, had you had any experience

1 developing tests for CRC?

2 A. I had not specifically worked on CRC
3 prior to that time.

4 Q. Had you done any work with stool
5 samples prior to your work with Exact
6 Sciences?

7 A. No, I had not.

8 Q. When did you get promoted from
9 director of technology developments to VP of
10 technology development?

11 A. I don't recall exactly, but I'm going
12 to -- I'm going to guess that that was either
13 late 2023 or perhaps sometime -- I'm sorry.
14 Not 2023. Either 2004 or late 2003.

15 Q. Did your responsibilities change when
16 you were promoted?

17 A. I took on greater responsibilities,
18 yes.

19 Q. Throughout your entire time at Exact
20 Sciences, was the Exact Science focus on
21 developing a screening test for CRC?

22 A. There are many aspects to what's
23 involved in developing a test for CRC
24 screening, so I would say that everything we

1 were working on falls under that umbrella.

2 Q. In your CV, you state that, when you
3 were director of technology development, you
4 completed technology transfer of Exact's first
5 commercial assay, the PreGen-26. What is the
6 PreGen-26?

7 A. So that test was a single biomarker
8 test that we had developed which was based on
9 a marker referred to as BAT-26. That was a
10 test that we had completed enough of the
11 studies to be able to work with a partner as a
12 way to offer that commercially.

13 Q. You also refer to a PreGen-Plus assay
14 in your CV. What was the PreGen-Plus?

15 A. Okay. Yes. So PreGen-Plus at that
16 time was another configuration of a test for
17 screening patients. The BAT-26 test was more
18 specific to certain types of people that have
19 predisposition for colorectal cancer. The
20 PreGen-Plus was a test which would be more
21 applicable to the average-risk patient.

22 Q. Did the PreGen-Plus use different
23 biomarkers than the PreGen-26?

24 A. Yes, it did.

1 Q. What biomarkers did the PreGen-Plus
2 use?

3 A. So PreGen-Plus, in addition to BAT-26,
4 it included mutation analysis of a number of
5 different genes as well as an assay which we
6 refer to as DIA, which was an acronym for DNA
7 integrity assay.

8 Q. Do you remember how many different
9 genes it included mutation analysis for?

10 A. So I know that we tested for mutations
11 in KRAS gene, the p53 gene, and APC gene.
12 There were multiple mutation analyses across
13 those three genes. So I believe that, in
14 total, there was somewhere between 20 and 25
15 specific mutation analyses.

16 Q. When you were director of technology
17 development at Exact Sciences, did anyone
18 report to you?

19 A. Yes.

20 Q. Who reported to you?

21 A. Oh, geez. I don't -- I don't recall
22 all of the names. I know that -- let's see.
23 I can't remember everyone's names. I'm sorry.

24 Q. Can you remember anybody who reported

1 to you at the time?

2 A. At this point, no. I'm sorry.

3 Q. To whom did you report when you were
4 at Exact Sciences and were the -- in the role
5 of technology development?

6 A. I reported to a gentleman by the name
7 of Tony Shuber.

8 Q. When you were promoted to VP of
9 technology development, still the case you
10 cannot remember who reported to you?

11 A. It was basically the same people, and
12 we had hired some other folks. I -- sorry.
13 So I can remember somebody at this point. So
14 Lisa Kahn was the first person that I hired.
15 And so she reported to me in the director role
16 but not in the VP role.

17 Q. And when you became VP, did you still
18 report to -- is Tony Shuber Anthony Shuber?

19 A. Anthony Shuber.

20 Q. Did you still report to Anthony Shuber
21 when you became VP?

22 A. I did.

23 Q. And is that true the entire time you
24 worked at Exact Sciences?

1 A. I believe there may have been a short
2 period of time where I reported to the chief
3 financial officer, a guy by the name of John
4 McCarthy.

5 Q. The Shuber reference that -- there's a
6 patent application in this IP -- in connection
7 with your declaration in the IPR that we refer
8 to as the Shuber reference on which you and
9 Anthony Shuber are both inventors. Is that
10 the same Anthony Shuber?

11 A. That is, yes.

12 Q. And you are also a coauthor with
13 Anthony Shuber on some publications; is that
14 right?

15 A. Yes.

16 Q. Other than the PreGen-26 and
17 PreGen-Plus, did Exact Sciences commercialize
18 any products while you were at Exact?

19 A. Not that I recall.

20 Q. Was Exact Sciences working on
21 development of any other products while you
22 were at Exact?

23 A. Not that I'm aware of.

24 Q. What was the stage of development of

1 the PreGen-Plus assay when you joined Exact
2 Sciences?

3 A. When I had -- when I joined Exact,
4 PreGen-Plus was ultimately -- the point at
5 which it was ultimately developed did not
6 exist when I first joined the company. There
7 was still a lot of work being done to develop
8 that, and so the final configuration of what
9 that test became did not exist in 2000, when I
10 first joined.

11 Q. Were you involved in getting that test
12 to its final configuration?

13 A. Yes.

14 Q. What was your role in getting that
15 test to its final configuration?

16 A. So as I described earlier, a lot of
17 what I was working on was some of the
18 front-end work, being able to process stool
19 samples to -- there's a lots of optimization
20 that needs to be done in order to figure out
21 what size of a sample is required, what volume
22 of buffers might be added in order to prepare
23 a homogenate, what volume of the homogenate
24 might need to be taken in order to then

1 process that and get DNA out, as well as all
2 of the things that I was starting to describe
3 to you earlier about maximizing the yield of
4 DNA that one could get from a sample.

5 Q. Was there a sample collection device
6 associated with the PreGen-Plus assay?

7 A. Exact had developed a collection
8 device, yes.

9 Q. And had you had any role in developing
10 that collection device?

11 A. I did not.

12 Q. Were there particular performance
13 parameters that Exact was aiming for in
14 developing the PreGen-Plus assay?

15 A. Could you be more specific?

16 Q. Was there -- was there a measure of
17 diagnostic accuracy that Exact was aiming for
18 in the development?

19 A. I -- I believe there was. I couldn't
20 point to a document where that was recorded.

21 Q. Do you recall what it was?

22 A. I don't recall what the specific
23 parameters were, no.

24 Q. Do you have any understanding of why

1 Exact Sciences was focused on developing CRC
2 screening tests?

3 A. In the time frame that I was there?

4 Q. In the time frame that you were there.

5 A. Yes.

6 Q. And what is your understanding?

7 A. My understanding was that at that time
8 there was a relatively small number of people
9 who would get screened by colonoscopy and that
10 coming up with a noninvasive way of being able
11 to do something equivalent to what a
12 colonoscopy could deliver would be beneficial
13 for some percentage of people who were not
14 willing to go or not able to go into a
15 colonoscopy.

16 Q. The purpose of CRC screening is to
17 identify whether the person being screened has
18 indicia of having CRC; is that correct?

19 A. The purpose of CRC screening is really
20 to be able to get some indication as to who
21 may, in fact, have the disease. And with most
22 screening tests, there's usually a follow-on
23 procedure which is required in order to
24 confirm whether or not that disease exists.

1 Q. For CRC screening, the purpose of
2 screening is to determine whether someone has
3 the disease is or at risk because they have
4 adenomas polyps; isn't that correct?

5 MR. JONES: Objection to form.

6 A. I'm sorry. Could you restate the
7 question.

8 BY MS. FERNANDS:

9 Q. Sorry.

10 In your answer, you said the purpose
11 of CRC screening is really to be able to get
12 some indication as to who may, in fact, have
13 the disease. And isn't the purpose also to
14 identify who has polyps that may develop into
15 the disease?

16 MR. JONES: Objection to form.

17 A. I -- in my opinion, those are two
18 different things.

19 BY MS. FERNANDS:

20 Q. And in your opinion, it is not a
21 purpose of CRC screening tests to identify
22 whether or not there are adenomas in the
23 colon?

24 MR. JONES: Objection to form.

1 A. In my opinion, if one wants to
2 determine if someone has CRC, they would want
3 to have a test which, in fact, measures things
4 which are directly related to CRC.

5 BY MS. FERNANDS:

6 Q. So, in your opinion, a CRC screening
7 test should not test or identify whether or
8 not there's indicia of adenomas?

9 MR. JONES: Objection.

10 A. I'm not saying that. What I'm saying
11 is that it's a definition of terms, that if
12 one were looking to detect colorectal cancer,
13 one would come up with a test that is highly
14 associated with that disease of colorectal
15 cancer.

16 BY MS. FERNANDS:

17 Q. What -- advanced adenomas are an
18 indication of the likelihood of developing
19 colorectal cancer, correct?

20 A. Adenomas can progress to colorectal
21 cancer, but not all adenomas do progress to
22 colorectal cancer. And so that's why I say
23 it's a separate issue to be able to measure
24 adenomas compared to cancer itself.

1 Q. Would you agree that a purpose of CRC
2 screening is to detect cancer early?

3 MR. JONES: Objection to form.

4 A. I would say that the detection of --
5 well, the five-year survival rates of people
6 who are diagnosed with colorectal cancer
7 depends on the stage at which they are
8 diagnosed, and that early detection can
9 provide for better outcomes.

10 BY MS. FERNANDS:

11 Q. And the survival rate is better if
12 there is early detection?

13 MR. JONES: Objection to form.

14 A. Survival rate is improved if it is
15 detected at an earlier stage.

16 BY MS. FERNANDS:

17 Q. You left Exact Sciences in 2005?

18 A. Correct.

19 Q. When in 2005?

20 A. I don't recall. Sorry.

21 Q. Why did you leave Exact Sciences?

22 A. Exact had completed some studies that
23 did not provide for the level of performance
24 that we were anticipating. There were some

1 layoffs that had occurred after that point. I
2 was not impacted by the layoffs, but I took
3 that opportunity to look for other jobs.

4 Q. Since you left Exact Sciences in 2005,
5 have you had any further professional
6 experience with CRC screening?

7 A. Remind myself.

8 Not with CRC screening, but I did have
9 additional experience working with stool
10 samples.

11 Q. In what position was your additional
12 experience working with stool samples?

13 A. I was at U.S. Genomics.

14 Q. And that was from 2005 until 2007?

15 A. And also in 2009 as a consultant.
16 Most of my experience with stool samples was
17 in the 2009 time frame.

18 Q. What were you working on that had
19 experience -- from which you gained experience
20 with stool samples in the 2009 time frame?

21 A. So one of the technologies that
22 U.S. Genomics had developed was an early
23 version of a single-molecule detection
24 strategy where one could look at long

1 fragments of DNA and essentially map the
2 sequences of that DNA using specific markers
3 along the length and use that as a way of
4 identifying the source of the DNA.

5 Q. And since that work in 2009, that was
6 the last time you've had experience working
7 with stool samples?

8 A. Yes.

9 Q. Have you ever been an expert witness
10 before in any other capacity?

11 A. I've not been an expert witness, no.

12 Q. Have not submitted declarations for
13 any other IPRs?

14 A. I have not.

15 Q. Okay. And the one other time you've
16 been deposed was not as an expert, correct?

17 A. That's correct.

18 Q. And have you ever testified in
19 court?

20 A. No.

21 Q. Before you submitted the declaration
22 that is Exhibit 1002 here, had you had any
23 experience with IPRs before?

24 A. I have not.

1 Q. Do you have a general understanding of
2 what an IPR is?

3 A. I have a general understanding.

4 Q. And what is your understanding of what
5 an IPR is?

6 MR. JONES: Objection. Calls
7 for a legal conclusion.

8 A. I -- yeah, I'm not a lawyer, so my
9 understanding is very limited as to what that
10 is. So perhaps you could be more specific as
11 to what you're asking about.

12 BY MS. FERNANDS:

13 Q. You submitted a declaration in support
14 of Geneoscopy's IPR petition.

15 Do you understand that?

16 A. Yes.

17 Q. Okay. And do you understand that
18 Geneoscopy's IPR petition is seeking to
19 invalidate the '781 patent?

20 A. I do.

21 Q. Your declaration that's marked as
22 Exhibit 1002, who prepared this?

23 A. I did.

24 Q. You drafted it?

1 A. I drafted -- I drafted this in working
2 directly with counsel.

3 Q. I think you said you spent dozens of
4 hours working on it before you signed it in
5 January of 2024?

6 A. Yes, I said that.

7 Q. Do you have any -- can you be any more
8 specific as to how many dozens? Do you
9 know?

10 A. Probably not, no.

11 Q. Have you discussed your declaration
12 with anyone other than counsel for
13 Geneoscopy?

14 A. No.

15 Q. Have you discussed your work for
16 Geneoscopy at all with anyone other than
17 counsel?

18 A. No.

19 Q. Do you know someone named Don Hardison
20 (phonetic)?

21 A. I do.

22 Q. Do you keep in touch with
23 Mr. Hardison?

24 A. Occasionally.

1 Q. You have not discussed with him that
2 you're serving as an expert on behalf of
3 Geneoscopy in this case?

4 A. I have not discussed with him the IPR
5 specifically.

6 Q. Have you discussed with him that you
7 are serving as an expert for Geneoscopy?

8 A. I have not.

9 Q. And have you talked with -- are you
10 still in touch with Anthony Shuber?

11 A. Occasionally.

12 Q. And you have not discussed with him
13 your work for Geneoscopy?

14 A. I have not.

15 Q. In connection with your declaration,
16 you formed an opinion concerning the person of
17 ordinary skill in the art, correct?

18 A. Yes.

19 Q. And had you heard that term before
20 your work on this IPR?

21 A. Yes.

22 Q. And what is your understanding of what
23 a person of ordinary skill in the art is?

24 A. Well --

1 MR. JONES: Calls for a legal
2 conclusion.

3 A. -- let me go to that section of the
4 IPR where I think I recorded that. I can...

5 (Witness reviews document.)

6 Yes. So you're asking about what
7 my -- I'm sorry. Could you rephrase the
8 question?

9 BY MS. FERNANDS:

10 Q. So, in general, what is your
11 understanding of what it -- what it means to
12 be a person of ordinary skill in the art?

13 A. In general -- let me read from my
14 report -- that in response to the opinions on
15 the validity of the claims, that the person of
16 ordinary skill in the art would -- I'm sorry.
17 I'm on the wrong section.

18 Yes. That a person of ordinary skill
19 in the art would have awareness of the scope
20 and content of prior art, that they would be
21 aware of differences between the prior art and
22 the claims, that they would have a level of
23 skill in the art, and that they would be aware
24 of objective indicia of nonobviousness.

1 Q. If you'd turn to Paragraph 12 of your
2 declaration, please --

3 A. Yes.

4 Q. -- and you state there that, in your
5 opinion, a POSA, a person of ordinary skill in
6 the art relevant to the '781 patent, would
7 have a Ph.D. in chemistry, biochemistry,
8 biology, or related field and at least five
9 years of experience designing and performing
10 diagnostic assays on --

11 A. I'm sorry. What page are you on?

12 Q. On Paragraph 12.

13 A. Oh, Paragraph 12. Sorry. I thought
14 it was page.

15 Q. It's on page --

16 A. Yes.

17 Q. Okay.

18 A. Yes, yes.

19 Q. Starting again on Paragraph 12, are
20 you with me?

21 A. Yes.

22 Q. Okay. Page 6, Paragraph 12, you state
23 that, in your opinion, "The person of ordinary
24 skill in the art relevant to the '781 patent

1 would have a Ph.D. in chemistry, biochemistry,
2 biology, or a related field and at least five
3 years of experience designing and performing
4 diagnostic assays on fecal samples,"
5 correct?

6 A. Yes.

7 Q. On what information did you rely to
8 develop that opinion concerning who was a
9 person of ordinary skill in the art?

10 A. Yes. So my understanding from talking
11 to counsel is that a person of ordinary skill
12 in the art would have a certain educational
13 level, would have encountered these types of
14 problems. They would be aware of prior art as
15 well as, you know, how -- the rapidity in
16 which innovations are made, the sophistication
17 of technology, and the educational level.

18 So, in short, they would have both
19 experience as well as educational training.

20 Q. Were there any particular facts about
21 the educational level of active workers in
22 this field that you've relied on in developing
23 your opinion about a person of ordinary
24 skill?

1 A. What -- what do you -- I'm not sure I
2 understand the question.

3 Q. So one of the factors that you
4 identified is the educational level of active
5 workers in the field, correct?

6 A. Yes.

7 Q. And are -- did you have in mind any
8 particular active workers in the field or
9 facts about their education level that you
10 relied on in forming your opinions?

11 A. My opinions about a POSA has to do
12 with the education level in terms of being
13 able to formulate a specific thesis of how
14 work should be done and being able to put
15 together plans to execute according to plan.

16 And the work experience, I believe, is
17 particularly important in a POSA opinion -- a
18 POSA definition because of the direct
19 experience that they may have with the subject
20 matter, in this case, related to these
21 patents.

22 Q. You do not identify here in your
23 discussion of a person of ordinary skill in
24 the art what was the educational level of

1 active workers in the field, do you?

2 MR. JONES: Objection.

3 A. Other -- I'm sorry. Let's...

4 (Witness reviews document.)

5 I do not here.

6 BY MS. FERNANDS:

7 Q. In forming your opinions that you set
8 forth in your declaration, did you apply the
9 definition of a POSA that you have in
10 Paragraph 12?

11 A. I did.

12 Q. Are you aware that the Patent Trial
13 and Appeal Board has instituted a decision
14 instituting this IPR?

15 A. I am aware.

16 Q. And are you aware that the Patent
17 Trial and Appeal Board disagreed with your
18 definition of the person of ordinary skill?

19 MR. JONES: Objection.

20 A. I'm not aware. I don't recall.

21 BY MS. FERNANDS:

22 Q. As of 2009, was Anthony Shuber a
23 person of ordinary skill in the art, in your
24 opinion?

1 A. According to the definition that I
2 have here, he would not have met those
3 requirements.

4 Q. And Anthony Shuber was an active
5 worker in the field, correct?

6 A. Yes.

7 Q. And someone who's a coinventor in one
8 of the patents on which you rely in your
9 declaration?

10 MR. JONES: Objection.

11 A. He is a coinventor, yes.

12 BY MS. FERNANDS:

13 Q. And he does not meet your definition
14 of a person of ordinary skill in the art?

15 A. He does not meet the definition that I
16 have documented here.

17 Q. Could you turn to Paragraph 27, which
18 is on page 12.

19 A. Uh-huh.

20 Q. In Paragraph 27, you state that
21 "Sensitivity and specificity are important
22 metrics of diagnostic assay performance,"
23 correct?

24 A. Yes.

1 Q. And that's an accurate statement?

2 A. Yes.

3 Q. So we understand what -- the terms
4 going forward, so sensitivity, as you describe
5 it in Paragraph 28, refers to what is the true
6 positive rate; is that right?

7 MR. JONES: Objection.

8 A. That's a shortened version of the
9 definition, yes.

10 BY MS. FERNANDS:

11 Q. So a sensitive -- a more sensitive
12 test has fewer false negatives; is that
13 right?

14 MR. JONES: Objection.

15 A. That's correct.

16 BY MS. FERNANDS:

17 Q. And then specificity refers to the
18 frequency at which the test result is negative
19 in subjects without the disease, correct?

20 A. That's correct.

21 Q. Or as you shorten it here, that's the
22 true negative rate?

23 A. Yes.

24 Q. You agree that having a high

1 specificity is desirable in fecal CRC tests
2 because patients who wrongly test positive
3 often are subjected to an unnecessary medical
4 procedure and potentially unnecessary
5 treatment?

6 A. I agree -- excuse me. I agree with
7 that, yes.

8 Q. Would you agree that for bowel cancer,
9 the tradeoff between sensitivity and
10 specificity should favor specificity because
11 the consequences of a positive test is an
12 expensive, uncomfortable, and potentially
13 harmful diagnostic workup for colonic
14 disease?

15 MR. JONES: Objection to form.

16 A. I'm sorry. Could you repeat the
17 question.

18 BY MS. FERNANDS:

19 Q. Would you agree that in CRC testing,
20 in the balance of sensitivity and specificity,
21 that the balance should weigh towards
22 specificity?

23 MR. JONES: Objection.

24 A. I think it depends on the specific

1 application of test that we're talking about
2 and what the specific balances are that we're
3 talking about, so...

4 BY MS. FERNANDS:

5 Q. We are talking about CRC screening
6 tests, correct?

7 A. Yes.

8 Q. In the context of CRC screening tests,
9 would you agree that the balance should weigh
10 towards specificity over -- in the
11 specificity/sensitivity balance?

12 A. Not -- not necessarily.

13 Q. It could, however?

14 MR. JONES: Objection.

15 A. Yeah, I don't think it's necessarily
16 true that one would always try to maximize
17 specificity over sensitivity. There may be
18 cases where the opposite is true, but we would
19 have to talk about those specific examples.

20 BY MS. FERNANDS:

21 Q. Would you turn to page 69. On
22 page 69, you discuss a reference called
23 Lenhard, correct?

24 A. Yes.

1 Q. Lenhard was a journal article
2 published in February of 2005?

3 A. That's correct.

4 Q. You were still with Exact Sciences in
5 February of 2005?

6 A. This was published in January of 2005,
7 so I believe I was still there at that time.

8 Q. So in the first line of Paragraph
9 1000 -- 109, you say "Lenhard is a journal
10 article published in February 2005," right?

11 A. Sorry. Yeah, online, January.

12 Q. I believe you said you don't recall
13 when in 2005 you left Exact Sciences?

14 A. That's correct.

15 Q. Do you recall what -- roughly what
16 time of year?

17 A. No, I don't. I apologize.

18 Q. You state that the journal in which
19 Lenhard was published is a well-regarded
20 journal that you consulted when doing research
21 on CRC diagnostics; is that correct?

22 A. That's correct.

23 Q. Do you recall whether you were aware
24 of Lenhard while you were at Exact Sciences?

1 A. Oh, geez. I don't recall if I was
2 aware at that time.

3 Q. When you refer to "when doing research
4 on CRC diagnostics," that was only when you
5 were at Exact Sciences; is that correct?

6 A. Correct.

7 Q. I'm going to hand you what's already
8 been marked as Geneoscopy Exhibit 1004 in the
9 IPR.

10 Is this a copy of the Lenhard
11 reference that you discuss in your
12 declaration?

13 A. Yes.

14 Q. In Paragraph 110 of your declaration,
15 you state that "Lenhard describes the combined
16 analysis of DNA methylation and FOBT in stool
17 samples to detect CRC," correct?

18 A. That's correct.

19 Q. In "Background and aims" of Lenhard on
20 the first page, Lenhard -- about eight lines
21 down, do you see the sentence that begins "We
22 explored"?

23 A. Are you talking about the abstract?

24 Q. Yes, in -- underneath the heading

1 "Background and aims" in the abstract.

2 A. Yes, I see that.

3 Q. And Lenhard states, "We explored the
4 potential of a single epigenetic marker in
5 comparison with fecal occult blood testing,
6 FOBT, for the discrimination of patients with
7 CRCs and adenomas from those without,"
8 correct?

9 A. I see that written here, yes.

10 Q. Lenhard is, in fact, comparing the DNA
11 marker with the FOBT marker, correct?

12 MR. JONES: Objection. Form.

13 A. Clearly, as stated in the abstract, he
14 describes this as a comparison. Later on in
15 the manuscript, he talks about the combination
16 of the DNA and the FOBT.

17 BY MS. FERNANDS:

18 Q. If you look at what Lenhard concludes
19 in the abstract, Lenhard concludes that the
20 marker HIC1 -- is that sometimes called HIC1?

21 A. (Witness nodding.)

22 MR. JONES: You need to --
23 sorry. You need to answer verbally.

24 A. Oh, sorry. Yes.

1 BY MS. FERNANDS:

2 Q. Lenhard concludes that the marker HIC1
3 promoter methylation carries high potential
4 for the remote detection of CRCs.

5 And he goes on, "We postulate that a
6 panel of merely a few genetic and epigenetic
7 markers will be required for the highly
8 sensitive and specific detection of CRCs and
9 adenomas in fecal samples from the affected
10 patients."

11 Do you see that?

12 A. I see that.

13 Q. So Lenhard's conclusion is to suggest
14 a panel of a few genetic and epigenetic
15 markers, correct?

16 MR. JONES: Objection to form.

17 A. That's what he has written under the
18 "Conclusion" section.

19 BY MS. FERNANDS:

20 Q. Now, you note in Paragraph 110 of your
21 declaration that "Lenhard states that the
22 combination of the HIC methylation with FOBT
23 resulted in detection of almost two-thirds of
24 CRCs," correct?

1 A. Let me review what I...

2 (Witness reviews document.)

3 Yes. So what I wrote is Lenhard
4 results led the authors to conclude the
5 combination of HIC1 with FOBT resulted in the
6 detection of almost two-thirds of CRCs.

7 Q. Those are the results -- the
8 individual results shown in Table 1 of
9 Lenhard?

10 MR. JONES: Objection.

11 A. Okay.

12 BY MS. FERNANDS:

13 Q. Well, what is your understanding of
14 what Table 1 is showing?

15 A. Let me review.

16 (Witness reviews document.)

17 A. So my understanding of what he is
18 showing here is a table of results for 26
19 subjects, all of who have colorectal cancer,
20 and indicating which of these patients had a
21 positive test with the HIC1 methylation as
22 well as who had a positive result with the
23 FOBT test.

24 Q. And the pluses there indicate the

1 positive results?

2 A. That's my understanding.

3 Q. And the negative signs reflect that
4 there was a negative result in these patients
5 known to have CRC?

6 A. Again, that's my understanding.

7 Q. With apologies, I'm going back and
8 forth.

9 In your declaration, in
10 Paragraph 11 -- 111, you state that "The stool
11 samples in Lenhard were collected from
12 patients in a healthcare facility before
13 they -- before they underwent endoscopy."

14 Do you see that?

15 A. Yes.

16 Q. Lenhard does not discuss at-home
17 collection, correct?

18 A. (Witness reviews document.)

19 Certainly, here, he does not.

20 Q. Okay. And if you look at the
21 "Materials and methods" on page 2, at the last
22 sentence under "Materials and methods," under
23 "Patients and stool samples" under "Materials
24 and methods," it states that "Samples were

1 received within ten hours after defecation at
2 the laboratory."

3 Do you see that?

4 A. Yes.

5 Q. So these were not home collection
6 tests, correct?

7 A. It would appear that they were not
8 home collected.

9 Q. Okay. Then in your Paragraph 111, the
10 third sentence, you state that "At the
11 laboratory, each sample was divided into at
12 least two portions."

13 Do you see that?

14 A. Yes.

15 Q. So the division of the sample in
16 Lenhard was also at the laboratory, correct?

17 A. That would appear to be true.

18 Q. The FOBT test that was used in Lenhard
19 was what was known as the guaiac FOBT; is that
20 right?

21 A. Let me refresh my memory.

22 Q. If you look at Paragraph 112 of your
23 report, that might help.

24 A. Yes.

1 Q. Okay. So, yes, the FOBT used in
2 Lenhard was the guaiac FOBT?

3 A. Yes.

4 Q. And the guaiac FOBT, the sample was
5 spread onto a card; is that correct?

6 A. The normal procedure for guaiac FOBT
7 is to spread stool sample on a card and then
8 develop it.

9 Q. The normal procedure in guaiac FOBT
10 did not involve putting the sample into a
11 stabilizing buffer; is that right?

12 A. That's my understanding.

13 Q. So -- so we have our terms right, so
14 there's -- you refer -- when you refer in your
15 report -- in your declaration to FOBT, are you
16 referring to both guaiac and immunochemical
17 FOBT if you do not put a "g" or an "i" in
18 front of it?

19 MR. JONES: Objection.

20 A. I think in many cases we tried to be
21 clear about that. And so in the context here,
22 obviously, it is describing the guaiac. So
23 all of the other references to FOBT which does
24 not have the "g" in front of it would imply

1 that it was that specific test. That may not
2 be true throughout the report.

3 BY MS. FERNANDS:

4 Q. And the immunochemical FOBT is
5 sometimes referred to as iFOBT; is that
6 right?

7 A. Yes.

8 Q. It's also sometimes referred to as
9 FIT; is that correct?

10 A. Yes.

11 Q. Now, in Lenhard, in the reference on
12 page 2, about five -- five lines down in the
13 first column on page 2, do you see the
14 sentence that starts with "of these
15 markers"?

16 A. Yes.

17 Q. And do you understand that's referring
18 to earlier studies evaluating several
19 potentially methylated genes identified
20 there?

21 A. What it says above that is "In one
22 study evaluating several potentially
23 methylated genes," SR -- "SFRP2, SFRP5, and
24 PGR were found to be methylated differentially

1 in the stool of patients with CRC." And they
2 reference Muller, et al. So, yes, an earlier
3 publication.

4 Q. Yes.

5 And of the markers tested in that
6 earlier publication, the SFRP2 was found to be
7 the most sensitive fecal methylation marker
8 detecting 77 percent to 90 percent of CRCs.

9 Do you see that?

10 A. That's what he has indicated, yes.

11 Q. Okay. So that single marker had a
12 higher sensitivity than the combined HIC1 and
13 FOBT as discussed in Lenhard, correct?

14 A. In this particular study, if one were
15 simply to compare those two numbers, then yes.

16 Q. Then, yes, the SFRPT had a higher
17 sensitivity, then.

18 A. I would not conclude that as a general
19 rule.

20 Q. If you look at the data reported in
21 Lenhard, that identifies a sensitivity that is
22 higher than the 66 percent of the HIC1 FOBT
23 combination of Lenhard, correct?

24 A. I'm sorry. Say that again. Ask that

1 again.

2 Q. Looking at the data that is reported
3 in Lenhard, the reported sensitivity of SFRPT
4 is higher than the 66 percent sensitivity of
5 the HIC1 FOBT combination?

6 A. The number that he is quoting here,
7 which is not from his study but from the
8 previously referenced study, that that 77 to
9 90 percent is a higher sensitivity than the
10 combination of HIC1 and FOBT in this
11 particular study of 26 patients.

12 Q. The specificity of that SFRPT
13 methylation marker was quite poor, though, at
14 77 percent according to what Lenhard reports,
15 correct?

16 A. That's what he indicates.

17 Q. So Lenhard goes on to state that
18 "Identification of both sensitive and highly
19 specific methylation markers is required
20 before MSP can be evaluated as a stool-based
21 screening procedure for CRC in prospective
22 studies," correct?

23 A. That's what he indicates.

24 Q. And so Lenhard is teaching that

1 markers will need to be both sensitive and
2 highly specific?

3 MR. JONES: Objection to form.

4 A. That's what he is saying.

5 BY MS. FERNANDS:

6 Q. Looking at Table 1 of Lenhard, the
7 majority of the CRC patients in Table 1 were
8 in either stage III or stage IV; is that
9 correct?

10 MR. JONES: Objection.

11 A. That appears to be true.

12 BY MS. FERNANDS:

13 Q. And if we look also at the -- whether
14 there is positive or negative for the HIC1 and
15 FOBT, numbers -- Patient Nos. 1, 2, and 3 all
16 both have over- -- overlapping negative tests,
17 correct?

18 A. Are you asking specifically about the
19 HIC1?

20 Q. In the HIC1 and FOBT, Patients 1, 2,
21 and 3 were incorrectly negative for both,
22 correct?

23 A. For both the HIC1 and the FOBT, that
24 appears to be true from this statement, yes.

1 Q. That's also true for Patient 7,
2 correct?

3 A. Geez, now you're testing my...
4 (Witness reviews document.)
5 Yes.

6 Q. And Patient 12?

7 A. Yes.

8 Q. And now I'm testing my own eyesight.
9 Patient 18?

10 A. Yes.

11 Q. Patients 20 and 21?

12 A. Yes.

13 Q. And Patient 23, correct?

14 A. Yes.

15 Q. So if I've counted those correctly,
16 that's 9 of the 26 patients with CRC were
17 incorrectly identified as negative as both --
18 from both HIC1 and FOBT in this study?

19 A. If that's the correct addition, yes.
20 I wasn't keeping track.

21 Q. Now, in your declaration, when you
22 discuss Lenhard, you don't discuss Table 2,
23 correct?

24 A. Table 2 of the publication?

1 Q. Table 2 of the Lenhard publication.

2 A. Let me refresh my memory what I talk
3 about.

4 (Witness reviews document.)

5 Are you talking about in this section
6 of the declaration or also in reference to
7 claims where we also talk about Lenhard?

8 Q. Are you aware of anywhere in the
9 declaration where you talk about Table 2 of
10 the Lenhard publication?

11 A. I -- let me review.

12 (Witness reviews document.)

13 In this section, I don't believe I
14 refer to Table 2.

15 Q. Do you recall discussing Table 2 at
16 all in your declaration?

17 A. I don't recall off the top of my head,
18 but I could review the declaration if you
19 would like.

20 Q. I can represent that I could not find
21 any reference to Table 2 anywhere in there.

22 MR. JONES: Objection.

23 BY MS. FERNANDS:

24 Q. If you look at Table 2, Table 2 is --

1 concerns patients with -- I'm not sure I know
2 how to say the word. Adenomatous?

3 A. Adenomatous.

4 Q. Adenomatous polyps?

5
6 (Stenographer clarification.)

7
8 MS. FERNANDS: Yes, that's what
9 I tried to say, adenomas, and not...

10 BY MS. FERNANDS:

11 Q. Table 2 of Lenhard discussing -- is
12 discussing patients with adenomatous polyps,
13 correct?

14 A. Yes.

15 Q. And in that, there was the -- there
16 was only one identified as positive by FOBT,
17 correct? That's Patient No. 30?

18 A. That is correct.

19 Q. And that same Patient No. 30 is
20 identified as positive with the HIC1
21 methylation, correct?

22 A. That is correct.

23 Q. So the FOBT added no sensitivity to --
24 with respect to the adenomas, correct?

1 MR. JONES: Objection to form.

2 A. In this small study, in this table, it
3 did not add any sensitivity.

4 BY MS. FERNANDS:

5 Q. And, in fact, Lenhard noted that, if
6 you'd go to page 6.

7 A. I'm sorry. Could you give me the
8 journal number?

9 Q. Oh, sorry. The journal --

10 A. Oh, it's here. Sorry. I've got it.
11 Yeah. You have them at the bottom.

12 Q. Right above the discussion, Lenhard
13 notes that "Although the combined test
14 detected all localized cancers, no increase in
15 the sensitivity for adenoma was seen,"
16 correct?

17 A. I see that, yes.

18 Q. The combination also reduced the
19 specificity of the HIC1 test alone, correct?

20 A. Let me review.

21 (Witness reviews document.)

22 MR. JONES: Objection to form.

23 BY MS. FERNANDS:

24 Q. If you turn to Table 3, that might be

1 helpful.

2 A. Table 3.

3 Q. And Table 3, the caption at the top is
4 "HIC1 Methylation Status of Healthy Controls
5 and Patients with Nonneoplastic Disease."

6 Do you see that?

7 A. Yes.

8 Q. Okay. And here, if there's a positive
9 sign, that's a false positive, correct?

10 A. Yes.

11 Q. And there is only one positive in the
12 HIC1 methylation column; is that right?
13 That's on Patient No. 81?

14 A. That's correct.

15 Q. Okay. And then that is also shown as
16 a false positive in the FOBT column,
17 correct?

18 A. That's correct.

19 Q. And then there are four more false
20 positives in the FOBT column; is that right?

21 A. That's correct.

22 Q. So the combination, therefore, reduced
23 the specificity with more false positives; is
24 that right?

1 A. That would seem to be the case, yes.

2 Q. In the discussion in Lenhard on
3 page 6 --

4 A. Uh-huh.

5 Q. -- Lenhard states, the first sentence
6 of the discussion, that "Highly sensitive,
7 specific, and easily analyzable markers are
8 required for noninvasive stool-based CRC
9 screening."

10 Do you see that?

11 A. I see that.

12 Q. Do you agree that that was the case in
13 2005?

14 A. I'm sorry. I don't understand the
15 question.

16 That that statement --

17 Q. Was --

18 A. -- is a true --

19 Q. Do you have -- do you agree with that
20 statement?

21 A. I agree with that statement.

22 Q. Okay. Was that statement still true
23 as of 2009 at the time of the '781 patent?

24 A. I believe that it's a generally true

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1 statement.

2 Q. If you'd turn to page 7, do you see
3 the conclusion paragraph that begins "in
4 summary"?

5 A. Yes.

6 Q. Lenhard summarizes, quote, This study
7 shows HIC1 as a sensitive and specific marker
8 well suited for stool-based CRC screening.

9 He goes on, "Combination of HIC1 with
10 a few additional sensitive and specific
11 methylation markers may allow for the highly
12 sensitive and specific stool-based detection
13 of CRCs and adenomas."

14 Do you see that?

15 A. Yes.

16 Q. So Lenhard's conclusion was that a
17 combination of specific methylation markers
18 may allow for highly sensitive and specific
19 stool-based detection of CRCs and adenomas,
20 correct?

21 MR. JONES: Objection to form.

22 A. I'm sorry. Repeat the question.

23 BY MS. FERNANDS:

24 Q. It was Lenhard's conclusion that a

1 combination of HIC1 with a few additional
2 sensitive and specific methylation markers may
3 allow for the highly sensitive and specific
4 stool-based detection of CRCs in adenomas,
5 correct?

6 MR. JONES: Objection to form.

7 A. I -- I don't know that that's a
8 conclusion. I think it's a suggestion.

9 BY MS. FERNANDS:

10 Q. Lenhard does not include a suggestion
11 to combine HIC1 with FOBT in this conclusory
12 paragraph of his --

13 MR. JONES: Objection to form.

14 BY MS. FERNANDS:

15 Q. -- of his article.

16 A. In that paragraph, he does not mention
17 FOBT.

18 MR. JONES: When you get a
19 chance, can we take a break? We've been going
20 an hour and 15.

21 MS. FERNANDS: I think just a
22 couple of more questions on Lenhard, and then
23 we can move on, if that's okay.

24 MR. JONES: Yes.

1 BY MS. FERNANDS:

2 Q. So in Lenhard, still in the methods,
3 under the "Patients and stool samples,"
4 right -- the last sentence of that subsection.

5 A. Okay.

6 Q. You see where it says that the samples
7 were stored at negative 80 degrees Celsius?

8 A. I see that, yes.

9 Q. Okay. So the samples in Lenhard were
10 frozen; is that right?

11 MR. JONES: Objection to form.

12 A. After the samples were received, they
13 appear to have been frozen.

14 MS. FERNANDS: We can take a
15 break.

16 MR. JONES: Sure. 11:25 a.m.

17
18 (Recess taken from 11:25 a.m.
19 to 11:42 a.m.)
20

21 MS. FERNANDS: I'm so unused to not
22 having a videographer.

23 BY MS. FERNANDS:

24 Q. Welcome back from break.

1 If we could, turn back to your
2 declaration in Paragraph 116 on page 74,
3 please.

4 A. Okay.

5 Q. And on page -- Paragraph 116, under
6 the section heading "B," you refer to a
7 reference called Vilkin.

8 Do you see that?

9 A. Yes.

10 Q. And Vilkin is a journal article that
11 was published in November of 2005 according to
12 the first sentence of Paragraph 116; is that
13 right?

14 MR. JONES: Objection.

15 A. Yes.

16 BY MS. FERNANDS:

17 Q. And you do state in Paragraph 116 that
18 "Vilkin is a journal article published in
19 2005," right?

20 MR. JONES: Objection.

21 A. What I've written is that "Vilkin is a
22 journal article published in November 2005."

23 BY MS. FERNANDS:

24 Q. And it was published in the "American

1 Journal of Gastroenterology"?

2 A. It was published in the "American
3 Journal of Gastroenterology."

4 Q. Was that a journal that you consulted
5 while you were doing research on CRC
6 diagnostics?

7 A. Yes, I'm quite sure it was.

8 Q. That says "CCR" diagnostics. Should
9 that be CRC?

10 A. Yes.

11 Q. Do you recall having been aware of the
12 Vilkin article in the 2005 time frame?

13 A. I don't recall off the top of my head.

14 Q. So you now have what's been marked as
15 Geneoscopy Exhibit 1005 in the IPR. Is this
16 the Vilkin article that you discuss in your
17 declaration?

18 A. Yes.

19 Q. If you look in the "Methods," which is
20 on -- I've been referring to the pages that
21 are marked with the exhibit number on the
22 bottom. If you'd look at page 3. You see the
23 "Methods" about the middle of the page.

24 A. Are you referring to the abstract?

1 Q. Yes.

2 A. Uh-huh.

3 Q. You see in the "Methods" in the
4 abstract, it states, "The desktop instrument,
5 OC-Sensor Japan, automatically develops and
6 quantitates 50 tests."

7 Do you see that?

8 A. Fifty tests per hour.

9 Q. So focused on the OC-Sensor from
10 Eiken -- Eiken Japan, were you familiar with
11 that when you worked at Exact Sciences?

12 A. I don't believe I was familiar with
13 that specific instrument.

14 Q. Were you aware of iFOBT testing when
15 you were working at Exact Sciences?

16 A. Yes.

17 Q. And were you aware of gFOBT testing
18 when you were working at Exact Sciences?

19 A. Yes.

20 Q. But you don't recall being aware
21 necessarily of the OC-Sensor from Eiken?

22 A. I do not recall.

23 Q. So, in your opinion, it would have
24 been obvious to a person of ordinary skill in

1 the art in 2009 to combine the iFOBT of Vilkin
2 with Lenhard and Itzkowitz; is that correct?

3 MR. JONES: Objection.

4 A. Let me go to my opinions.

5 (Witness reviews document.)

6 So on page 94 of my report, there's a
7 section entitled "A POSA would be motivated to
8 use the iFOBT of Vilkin in place of the gFOBT
9 of Lenhard."

10 BY MS. FERNANDS:

11 Q. So in your --

12 A. Also -- sorry. Go ahead.

13 Q. Sorry. Were you finished? I did not
14 mean to cut you off.

15 In your opinion, a person would
16 have -- of ordinary skill in the art in 2009
17 would have been motivated to combine the iFOBT
18 of Vilkin with Lenhard and Itzkowitz; is that
19 correct?

20 MR. JONES: Objection.

21 A. That is -- what my report states is
22 that a POSA would have been motivated to use
23 the iFOBT of Vilkin in place of the guaiac
24 FOBT of Lenhard, and the POSA would have been

1 motivated to use a sample collection
2 methodology of Itzkowitz in the process of
3 Lenhard.

4 BY MS. FERNANDS:

5 Q. So focusing on the iFOBT of Vilkin,
6 why did you choose the iFOBT of Vilkin?

7 A. The Vilkin reference describes work to
8 compare performance of a guaiac FOBT with an
9 iFOBT and provides for a direct comparison of
10 results of the two.

11 Q. Where in Vilkin is there a direct
12 comparison of the results of gFOBT and
13 iFOBT?

14 A. I'm sorry. I misspoke.

15 The Vilkin paper, I was confusing that
16 with another paper I had referred to.

17 The Vilkin paper refers to the
18 performance of the iFOBT test in fecal
19 samples. Apologies.

20 Q. And why, in particular, did you choose
21 the iFOBT of Vilkin?

22 A. This study does a good job of trying
23 to characterize the performance of an iFOBT
24 test in this one particular set of

1 experiments.

2 Q. And that particular set of experiments
3 used the OC-Sensor device from Eiken company
4 Japan, correct?

5 A. Yes, that appears to be the case.

6 Q. And for this one set -- sorry. Just
7 wanted to get...

8 In this particular set of experiments,
9 the patients prepared -- each patient prepared
10 three tests, correct?

11 A. Let me refresh my memory.

12 (Witness reviews document.)

13 Sorry. I'm having trouble locating...

14 Q. If you look in the abstract to
15 "Methods" perhaps. In the abstract, the
16 second sentence says, "Methods. States
17 patients prepared three tests."

18 A. Yes, I see that.

19 Q. Is your understanding that, for the
20 Vilkin reference, each patient prepared three
21 tests?

22 A. In this study, that is my
23 understanding, yes.

24 Q. Can you turn to Table 3 in Vilkin.

1 It's on page 7.

2 A. Yes.

3 Q. And Table 3, the caption is
4 "Sensitivity for significant colorectal
5 neoplasia, N equals 34, for each iFOBT
6 prepared."

7 Do you see that?

8 A. Yes, I see that.

9 Q. And then in the table, there are
10 results for each of the three samples,
11 correct?

12 A. I see that there are results for
13 Sample 1, Sample 2, Sample 3. Sample 1 and 2,
14 and then Samples 1, 2, and 3.

15 Q. And the results for -- the individual
16 results for each of Samples 1, 2, and 3,
17 those -- each of the samples had different
18 results; is that right?

19 A. In this table, yes, there are three
20 different percentages for Sample 1, 2, and 3.

21 Q. So the sensitivity for Sample 2, for
22 instance, was 66.7 for cancer?

23 A. In this study, yes.

24 Q. And then the third column, it's

1 "Cancer plus AAP." That's advanced
2 adenomatous polyps, correct?

3 A. That is -- the AAP refers to advanced
4 adenomatous polyps.

5 Q. So they're giving results here in
6 Table 3 for sensitivity for cancer alone and
7 cancer plus AAP, correct?

8 A. What they are showing in the third
9 column is reported as cancer plus AAP as a
10 percentage. So that would appear to be for
11 the combined sets of results for each of
12 these.

13 Q. And then in the discussion just a few
14 lines above, the second sentence of the
15 discussion, do you see that?

16 A. Yes.

17 Q. And that states, "The clinical
18 evaluation demonstrated a high sensitivity of
19 76.5 percent for all significant colorectal
20 neoplasia and acceptable specificity of 95.3
21 percent," correct?

22 A. That's what Vilkin is stating.

23 Q. And that result, if we look at the
24 table, the 76.5 is for the cancer plus AAP,

1 correct?

2 A. That's what they are indicating here,
3 yes.

4 Q. And that's with the combined results
5 of Samples 1, 2, and 3, right?

6 A. The 76.5 percent is -- corresponds to
7 the line on the table that is Samples 1, 2,
8 and 3.

9 Q. And the combined results for
10 Samples 1, 2, and 3 had 100 percent
11 specificity for cancer in this test; is that
12 right?

13 A. I'm sorry. Could you restate the
14 question?

15 Q. The combined results for Samples 1, 2,
16 and 3 showed 100 percent sensitivity for
17 cancer alone, correct?

18 A. Yes.

19 Q. So actually, if you turn to your
20 declaration, Paragraph 118 -- it's on
21 page 76 -- in Paragraph 118, you state in the
22 second sentence that "The device shown in
23 Figure 1 of Vilkin included a sample tube
24 filled with a hemoglobin (Hb) stabilizing

1 buffer."

2 Do you see that?

3 A. Yes.

4 Q. You don't state in your declaration
5 what that Hb stabilizing buffer was, do you?

6 MR. JONES: Objection. Form.

7 BY MS. FERNANDS:

8 Q. Do you state the composition of an Hb
9 stabilizing buffer?

10 A. In this section, I do not state what
11 the composition of the stabilizing buffer is.

12 Q. If you go back to Vilkin, the
13 reference which is Exhibit 1005, does Vilkin
14 identify the composition of the Hb stabilizing
15 buffer?

16 A. I would have to read the paper to
17 confirm whether or not that's true. Shall I
18 do that?

19 Q. If I -- if you look at the fecal
20 sampling methods on page 4 --

21 A. Page 4.

22 Q. -- do you see in fecal sampling, about
23 in the middle, it states that "The tip is then
24 put in a closed amount of Hb stabilizing

1 buffer."

2 Do you see that?

3 A. I see that.

4 Q. And it does not identify there what
5 the stabilizing buffer was?

6 A. Let me read the paragraph.

7 (Witness reviews document.)

8 In this section, it does not describe
9 what the stabilizing buffer is.

10 Q. And in your declaration where you
11 discuss Vilkin, which is from Paragraphs 116
12 through 121 in this section, you do not
13 identify what the Hb stabilizing buffer of
14 Vilkin was composed of?

15 A. I do not describe in here what the
16 stabilizing buffer composition is.

17 Q. So going back to Paragraph 118 of your
18 declaration, the sentence that's -- that
19 begins on the bottom of page 76 and carries
20 over to page 77, do you see where it begins
21 "Patients prepared"?

22 A. I see. Yes, I see that.

23 Q. You state, "Patients prepared three
24 separate samples prior to a scheduled

1 colonoscopy," correct?

2 A. That's what I've written, yes.

3 Q. And then you go on to state "which
4 were then refrigerated until they were
5 provided to the laboratory"; is that right?

6 A. That's what's written, yes.

7 Q. And it was the case that the samples
8 of Vilkin needed to be refrigerated; is that
9 right?

10 MR. JONES: Objection. Form.

11 A. I don't believe that there's any
12 statement to the effect that they needed to be
13 refrigerated.

14 BY MS. FERNANDS:

15 Q. Vilkin instructed that the samples be
16 refrigerated, correct?

17 MR. JONES: Objection. Form.

18 A. What it indicates in the method is
19 that "The examinee is requested to prepare
20 three consecutive daily samples during the
21 week before colonoscopy examination. Samples
22 are double closed in Ziploc bags and kept in
23 the refrigerator until returned to the
24 laboratory, where they are also kept at 4

1 degrees until development."

2 There is no -- to me, there is no
3 specific requirement for refrigerating other
4 than a request.

5 Q. If you go to page 8 of Vilkin, in the
6 second to the last paragraph before the
7 acknowledgment --

8 A. Yes.

9 Q. -- do you see that about halfway down
10 that second -- that paragraph, the sentence
11 that begins "the storage"?

12 A. Yes.

13 Q. Vilkin says there that "The storage of
14 the prepared iFOBT in a refrigerator until
15 development is important for maintaining the
16 testability," correct?

17 A. That's what he states.

18 Q. So Vilkin believed that refrigeration
19 was important for testability?

20 MR. JONES: Objection to form.

21 A. It's not clear to me how important he
22 thinks it is.

23 BY MS. FERNANDS:

24 Q. He uses the word "important" in his

1 publication, correct?

2 A. I see that.

3 Q. And he goes on in the next sentence to
4 say, "This is critical in countries with high
5 ambient temperatures even when homes are
6 air-conditioned," right?

7 A. He does say that here, yes.

8 Q. He continues there -- or the
9 publication continues there "The double Ziploc
10 bags we provided answered some of the
11 screenee's hesitancy about keeping the
12 prepared tests transiently in their home
13 refrigerator."

14 Do you see that?

15 A. I see that.

16 Q. He's referring there to patients using
17 this screening testing hesitant to keep these
18 samples in their refrigerators, right?

19 A. He does say that the intent of this
20 appears to be to keep -- yes, to address some
21 of the hesitancy about keeping the prepared
22 tests in their home refrigerator.

23 Q. If samples did not need to be
24 refrigerated, would screenees be asked to keep

1 them in their refrigerator, where they were
2 hesitant to do so?

3 MR. JONES: Objection to form.

4 A. I'm not sure how to answer that
5 question. Could you ask that again.

6 BY MS. FERNANDS:

7 Q. If a person was asking participants --
8 screenees to participate in the test and there
9 was no need for refrigeration, you wouldn't
10 ask them to refrigerate, right?

11 MR. JONES: Objection. Form.
12 Vague.

13 A. I don't -- yeah, I'm not sure that I
14 would say yes to that question.

15 BY MS. FERNANDS:

16 Q. Well, it was the case that these
17 people who took the test in the Vilkin --
18 referenced in the Vilkin article were asked to
19 refrigerate the tests, correct?

20 A. They were.

21 Q. And it is the case that the Vilkin
22 article states that the storage of the
23 prepared tests "in a refrigerator until
24 development is important for maintaining the

1 testability"?

2 A. Is there a question?

3 Q. Yes. The Vilkin article does say
4 that, correct?

5 A. It says that they -- yes, there was
6 request -- excuse me. There was a request to
7 refrigerate the samples after they had been
8 put in a stabilizing buffer.

9 Q. And in the second to the last
10 paragraph of the article, he states, "The
11 storage of the prepared iFOBT in a
12 refrigerator until development is important
13 for maintaining the testability"?

14 A. He does say it's important. It's
15 unclear if it's necessary.

16 Q. He goes on to say, "This is critical
17 in countries with high ambient temperatures,"
18 correct?

19 A. He states that.

20 Q. If you look on page 8 of Vilkin in the
21 first column, the last full paragraph in the
22 first column beginning "at present," do you
23 see that?

24 A. Yes.

1 Q. And it states, "At present, we will
2 continue with collecting three annual fecal
3 tests as we've confirmed the additive clinical
4 value of repeated occult blood testing in this
5 high-risk population."

6 Do you see that?

7 A. I see that.

8 Q. And so with respect to the test
9 described in Vilkin, the authors were going to
10 continue with collecting three fecal -- three
11 samples per year; is that correct?

12 A. What he is stating is that they will
13 continue to collect three annual fecal tests.
14 He also goes on to say that other countries
15 have different standards.

16 Q. So I'm going to hand you what's marked
17 Geneoscopy Exhibit 1006.

18 Exhibit 1006 is the Itzkowitz
19 reference; is that correct?

20 A. This is a publication where Stephen
21 Itzkowitz is the first author.

22 Q. And is this the reference that you
23 referred to as Itzkowitz --

24 A. Yes.

1 Q. Okay. And you discuss this reference,
2 including beginning at Paragraph 122 of your
3 declaration; is that right?

4 A. Yes.

5 Q. And Itzkowitz is a journal article
6 that was published in January of 2007; is that
7 right?

8 A. That's correct.

9 Q. You note in your declaration in
10 Paragraph 122 that Itzkowitz named several
11 Exact employees as coauthors, including the
12 senior author, Anthony Shuber?

13 A. Yes.

14 Q. And you've referred to Anthony Shuber
15 as Dr. Anthony Shuber there; is that
16 accurate?

17 A. That was a typo. That should be
18 Mr. Anthony Shuber.

19 Q. Who else in the authors was an Exact
20 employee?

21 A. Let me look at the author list.

22 So Joel Skoletsky, Kris Durkee, and
23 Anthony Shuber are the three Exact Sciences
24 employees.

1 Q. Was Joel Skoletsky at Exact when you
2 were there?

3 A. Yes.

4 Q. And was Kris Durkee at Exact Sciences
5 when you were there?

6 A. Yes.

7 Q. What was Joel Skoletsky's role at
8 Exact Sciences?

9 MR. JONES: Objection. Scope.

10 A. I -- I'm not sure how he described his
11 role, so I...

12 BY MS. FERNANDS:

13 Q. Did he work in -- was he one of the
14 people who reported to you when you were in --

15 A. He was not.

16 Q. Okay. And was Kris Durkee one of the
17 people who reported to you at Exact?

18 A. She was not.

19 Q. In your declaration in Paragraph 123,
20 you refer to Version 1 and Version 2 of
21 Exact's fecal sample DNA test for CRC
22 detection.

23 Do you see that?

24 A. Yes. The sentence reads, Itzkowitz

1 highlights several improvements over related
2 prior published assay using the same 22
3 mutations referred to in the abstract and
4 throughout as Version 1. The assay used
5 in Itzkowitz -- I'm sorry. I misread that.

6 "Itzkowitz highlights several
7 improvements over a related prior published
8 assay using the same 22 mutations referred to
9 in the abstract and throughout as Version 1.
10 The assay used in Itzkowitz is thus referred
11 to as Version 2 of Exact's fecal DNA test for
12 CRC detection."

13 Q. Is what is referred to in Itzkowitz as
14 Version 1 the same thing as the PreGen-Plus
15 assay that you worked on at Exact?

16 A. Let me refer to the publication.

17 (Witness reviews document.)

18 Yes, I would say that the Version 1
19 described here is very similar to the
20 PreGen-Plus.

21 Q. Is the Version 2 that is described
22 here something that you worked on before you
23 left Exact Sciences?

24 A. The Version 2 includes some of the

1 biomarkers that are in Version 1. So by
2 definition, some of the things that are in
3 Version 2 are things that I worked on when I
4 was at Exact.

5 Q. If you'd turn to Paragraph 126 of your
6 declaration, the last sentence, and this is
7 still discussing the Itzkowitz reference,
8 correct?

9 A. I'm sorry. Paragraph 126?

10 Q. 126.

11 A. The paragraph starts by saying,
12 "Itzkowitz articulates advances of fecal tests
13 for the samples collected at home, noting the
14 importance of a noninvasive screening test
15 that is convenient, safe, and easy to perform
16 at home without bowel preparation or dietary
17 restriction."

18 So this is still talking about
19 Itzkowitz.

20 Q. And one of the goals of Itzkowitz was
21 a noninvasive screening test that is
22 convenient, safe, and easy to perform at home,
23 correct?

24 A. What I just read is a noninvasive

1 screening test that is convenient, safe, and
2 easy to perform at home without bowel prep or
3 dietary restriction, and it goes on to say,
4 "has the potential to significantly increase
5 participation."

6 Q. The last sentence of that paragraph,
7 you state that "They also concluded that the
8 disclosed method of stabilizing DNA during
9 specimen transfer contributed to increasing
10 assay sensitivity from 52 percent to 72.5
11 percent."

12 Do you see that?

13 A. Yes, I see that.

14 Q. And that was with respect to the
15 Version 1 test, correct?

16 A. Which number are you referring to?

17 Q. That increase from 52 percent to 72.5
18 percent was with respect to the Version 1
19 test, correct?

20 MR. JONES: Objection. Vague.

21 A. So what the paper describes is a
22 number of changes to the Version 1 assay. And
23 what they conclude is that, due to those
24 number of changes, there is an increase in the

1 sensitivity.

2 BY MS. FERNANDS:

3 Q. And that's an increase in sensitivity
4 with respect to the Version 1 test, though,
5 correct?

6 MR. JONES: Objection. Vague.

7 A. In this -- what they -- what they are
8 talking about in this paper is results that
9 they got using a Version 1 test and comparing
10 that to a Version 2 test.

11 BY MS. FERNANDS:

12 Q. If you'd look at page 6 of Itzkowitz,
13 please, on page 6, in the first full
14 paragraph, do you see, about a third of the
15 way down, the sentence that begins "by using"?

16 A. I'm sorry. Which column?

17 Q. Column 1.

18 A. Yes.

19 Q. First paragraph.

20 A. Okay.

21 Q. About a third of the way down, right
22 after --

23 A. "By using," yes.

24 Q. Okay. And that sentence states that

1 "By using improved methods for stabilizing DNA
2 during specimen transport and better
3 extraction of DNA from stool, we now find that
4 the sensitivity for the Version 1 marker panel
5 is increased from 52 percent to 72.5 percent."

6 Do you see that?

7 A. Yes.

8 Q. So that the increase from 52 percent
9 to 72.5 percent was for the Version 1 marker
10 panel, correct?

11 A. Yes. Let me reread that.

12 (Witness reviews document.)

13 Yes.

14 Q. And the publication goes on to say,
15 "This improvement was a direct result of an
16 increase in DIA sensitivity from 3 percent
17 to 65 percent, confirming the observations of
18 Olson et al. that the low sensitivity of DIA
19 in the previous multicenter study was a result
20 of the DNA degradation."

21 Do you see that?

22 A. I see that.

23 Q. And so that -- that increase from
24 the 52 percent sensitivity to 72.5 percent

1 sensitivity was for the Version 1 marker
2 panel, right?

3 A. Yes, I see that that increase from 52
4 to 72 percent is for the Version 1 marker.

5 Q. The Itzkowitz reference goes on to
6 discuss other results in the next paragraph;
7 is that right?

8 A. (Witness reviews document.)

9 The next paragraph goes on to talk
10 about some methylation markers.

11 Q. About two-thirds of the way down that
12 paragraph, do you see the sentence that says
13 "the combination of vimentin plus DIA-DY"?

14 A. Yes.

15 Q. And that states, "The combination of
16 vimentin plus DIA-DY resulted in an optimal
17 sensitivity of 87.5 percent"; is that right?

18 A. What they state is "The combination of
19 vimentin plus DIA-DY resulted in an optimal
20 sensitivity of 87.5 percent."

21 Q. And you did not discuss that
22 combination in your declaration when you
23 discussed Itzkowitz, did you?

24 MR. JONES: Objection to form.

1 A. In this section of the declaration, we
2 do not talk about that part.

3 BY MS. FERNANDS:

4 Q. Do you talk about that part elsewhere
5 in the declaration?

6 A. I would have to refresh my memory to
7 answer that question.

8 Q. Go ahead.

9 A. Okay.

10 (Witness reviews document.)

11 Sorry. Could you rephrase the
12 question?

13 Q. So the question was whether you had
14 discussed that optimal sensitivity discussion
15 in Itzkowitz concerning the combination of
16 vimentin and DIA-DY in your declaration.

17 MR. JONES: Objection to form.

18 A. I don't believe I discuss the
19 combination of those two specific markers in
20 my report.

21 BY MS. FERNANDS:

22 Q. If you'd turn to the first page of
23 Itzkowitz, in the abstract, do you see the
24 conclusions?

1 A. Yes.

2 Q. And the conclusion in the abstract in
3 Itzkowitz is that "An improved fecal DNA test
4 that incorporates only two markers shows much
5 higher sensitivity for CRC. The new assay is
6 easier to perform and should be less costly,
7 thereby facilitating its use for noninvasive
8 CRC screening."

9 Do you see that?

10 A. I see that, yes.

11 Q. And do you understand that that is
12 referring to the two markers that have the
13 87.5 percent sensitivity?

14 A. I see that it mentions only two
15 markers, so -- they don't actually state in
16 the conclusion statement which two markers.

17 Q. If you'd look at the final paragraph
18 of the article on page 7, the second sentence
19 of the final paragraph says, "Our results
20 suggest that with only two markers (vimentin
21 plus DIA-DY) providing a sensitivity of 88
22 percent, the assay complexity can be reduced
23 significantly, thereby decreasing cost and
24 facilitating the development of an assay kit

1 that could be managed by local clinical
2 laboratories."

3 Do you see that?

4 A. Yes, I see that.

5 Q. So does that suggest the conclusion in
6 the abstract is referring to those two
7 markers?

8 MR. JONES: Objection to form.

9 A. That does -- what it would seem to
10 suggest is that they are referring to those
11 same two markers in this last paragraph in the
12 "Conclusions" statement.

13 BY MS. FERNANDS:

14 Q. In Paragraph 126 of your declaration,
15 the -- in the first sentence of Paragraph 126,
16 you state that "Itzkowitz articulates
17 advantages of fecal tests where the sample is
18 collected at home, noting the importance of 'a
19 noninvasive screening test that is convenient,
20 safe, and easy to perform at home without
21 bowel preparation or dietary restrictions,'
22 has the potential to significantly increase
23 participation."

24 Do you see that?

1 A. I see that.

2 Q. Would you agree with the statement
3 that inherent in the success of any screening
4 test is patient acceptance?

5 A. I think that for a screening test, as
6 part of the consideration for being used, it
7 needs to be accepted by the people being
8 screened.

9 Q. You continue in your Paragraph 126 to
10 discuss Itzkowitz's conclusion that
11 "Preliminary experience with the new fecal DNA
12 test in which patients add stabilization
13 buffer to the stool confirms a very high
14 degree of patient satisfaction."

15 Do you see that?

16 A. I see that.

17 Q. If you'd turn to page 6 of Itzkowitz
18 where that appears, the last sentence on the
19 second column of page 6, do you see the next
20 sentence in Itzkowitz is "These findings
21 support results from the previous multicenter
22 study in which subjects preferred fecal DNA
23 testing to both the fecal occult blood testing
24 and colonoscopy"?

1 A. I see that.

2 Q. Okay. And then that refers to
3 Footnote 16, which is Schroy, a 2005
4 publication.

5 Do you see that?

6 A. I see that.

7 Q. Are you familiar with the Schroy
8 publication?

9 A. Off the top of my head, I'm not
10 familiar with that.

11 Q. Do you recall while you were at Exact
12 Sciences a study -- a multicenter study in
13 which subjects preferred fecal DNA testing to
14 both fecal occult blood testing and
15 colonoscopy?

16 A. I am not aware.

17 Q. Would you agree that patients prefer
18 home fecal testing devices with which they do
19 not have to interact with the sample?

20 A. Not necessarily.

21 Q. That patients do not necessarily
22 prefer fecal testing devices where they don't
23 have to manipulate the fecal sample?

24 A. I have not run a study to determine

1 that. I'm not intimately familiar with the
2 details of other studies that have tried to
3 address that, so I'm -- I would say that
4 it's -- in my opinion, it's not necessarily
5 true.

6 MS. FERNANDS: Dr. Whitney,
7 we're having a very important discussion over
8 here about whether lunch had been delivered
9 yet.

10 THE WITNESS: Oh.

11 MS. FERNANDS: My apologies.

12 BY MS. FERNANDS:

13 Q. You've just been handed what has been
14 marked as Exhibit 1007 in the IPR.

15 Do you recognize this as another
16 document that you relied on in your
17 opinions?

18 A. I recognize this as the Kanaoka
19 exhibit.

20 Q. And if you'd turn to page 84,
21 Paragraph 127 of your declaration, is this the
22 Kanaoka exhibit that you discuss there?

23 A. Yes.

24 Q. Kanaoka is a patent application,

1 correct? Is that your understanding?

2 A. Yes.

3 Q. And Kanaoka -- in your declaration,
4 you state that Kanaoka was published in 2006;
5 is that right?

6 A. The publication date indicated here is
7 2006.

8 Q. So in Paragraph 129 of your
9 declaration...

10 In Paragraph 129, the last sentence,
11 you state, "Kanaoka notes that among three
12 COX-2 negative colon cancer cases, one was
13 positive in the immunological fecal occult
14 blood test."

15 Do you see that?

16 A. Yes.

17 Q. And then you go on to state, "While
18 COX-2 was detected in three among five colon
19 cancer cases negative to the immunological
20 fecal occult blood test," right?

21 A. Yes, I see that.

22 Q. So the FOB -- the iFOBT test in
23 Kanaoka detected one colon cancer that was not
24 detected by the COX-2, right?

1 A. In this very small study, yes, that's
2 true.

3 Q. So if you'd turn to the Kanaoka
4 reference on page 5, in Paragraph 65, that
5 paragraph begins that "COX-2 was detected
6 in 27 cases among 30 colon cancer cases."

7 Do you see that?

8 A. Yes, I see that.

9 Q. And then after the parens, it says
10 "but was not detected in any of the 22 cases
11 in the control group," correct?

12 A. "But was not detected in any of the 22
13 cases in the control group," yes, I see that.

14 Q. That was a sensitivity of 90 percent
15 and specificity of 100 percent for COX-2
16 alone, correct?

17 A. That's what this indicates in this
18 study.

19 Q. If you go to the next paragraph, 66,
20 in the iFOBT test, 23 of the 28 colon cancer
21 cases were detected, correct?

22 A. Yes, it indicates that 23 of the 28
23 colon cancer cases were positive by the iFOBT.

24 Q. Okay. And there seems to be a

1 discrepancy there because it referred to 30 in
2 Paragraph 65 and 28 in Paragraph 66.

3 A. (Witness nodding.)

4 Q. Is -- does there seem to be a
5 discrepancy there?

6 A. There -- there are different number of
7 cancers in Paragraph 65 than in Paragraph 66.

8 Q. And it was the same group being tested
9 in Kanaoka, correct?

10 A. My understanding is the same group.

11 Q. And Paragraph 66 continues that 3
12 among 22 control cases were positive from the
13 iFOBT, correct?

14 A. It does say that.

15 Q. So there were three false positives
16 from the iFOBT in this test?

17 A. The iFOBT had imperfect specificity.

18 Q. The specificity of the iFOBT was
19 86.3?

20 A. That's what they indicate.

21 Q. And the sensitivity of the iFOBT was
22 82.1 percent, correct?

23 A. 82.1 percent sensitivity.

24 Q. Did I misspeak?

1 The sensitivity of the iFOBT was 82.1
2 percent, correct?

3 A. Yes.

4 Q. And if one were to combine the COX-2
5 with the iFOBT, it would reduce the
6 specificity of the test, correct?

7 MR. JONES: Objection. Form.

8 A. The -- in this particular example,
9 what they're showing is the test results from
10 a very small set of samples, and I think what
11 you're asking about is getting at a more
12 generalizable result. So the only way I would
13 answer this is to quote you back what the
14 numbers are.

15 In this case, there appear to be no
16 false positives with the COX-2, and there
17 appear to be three false positives with the
18 iFOBT. Whether or not that's a generalizable
19 result is a question.

20 BY MS. FERNANDS:

21 Q. So there was only one true positive
22 from the iFOBT that was missed by the COX-2,
23 correct?

24 A. I'm sorry. Could you rephrase that?

1 Q. In --

2 A. Or could you say that again.

3 Q. In Paragraph 67, it says, "Among the
4 three COX-2 negative colon cancer cases, one
5 was positive in the iFOBT," correct?

6 A. That's what it indicates.

7 Q. So the iFOBT identified only one true
8 positive that was missed by the COX-2; is that
9 right?

10 A. In -- again, in this very small study,
11 that's what they're saying.

12 Q. Okay. So in your declaration, on --
13 in Paragraph 129, the last sentence of your
14 declaration there, you say, "Kanaoka notes
15 that 'among three COX-2 negative colon cancer
16 cases, one was positive in the immunological
17 fecal occult blood test' while 'COX-2 was
18 detected in three among five colon cancer
19 cases negative to the immunological fecal
20 occult blood test,' indicating that the
21 combination of the two tests had a higher
22 sensitivity than either test alone."

23 Do you see that?

24 A. I see that, yes.

1 Q. Okay. So based on the data in
2 Kanaoka, you concluded that the two tests have
3 a higher sensitivity than either test alone,
4 right?

5 MR. JONES: Objection.
6 Mischaracterizes.

7 A. What this is indicating is that
8 they're -- by combining the COX-2 and the
9 iFOBT tests, that more of the total cancers
10 would have been detected as positive.

11 BY MS. FERNANDS:

12 Q. At the same time, because there were
13 three false positives from the iFOBT, there
14 would have been more false positives if the
15 two were combined, correct?

16 A. Again, in this very small study, that
17 if one had combined those two, then, as the
18 data is showing, there would be more false
19 positives given that the COX-2 had zero false
20 positives.

21 MS. FERNANDS: Shall we break
22 for lunch?

23 MR. JONES: Sure.

24

1 (Recess taken from 12:39 p.m.
2 to 1:23 p.m.)
3

4 BY MS. FERNANDS:

5 Q. So I've just handed you what was
6 marked as Geneoscopy Exhibit 1009 in the IPR.
7 I believe your discussion with this starts on
8 page 88 at Paragraph 133.

9 So Exhibit 1009, is this what you
10 refer to as "Shuber" in your declaration?

11 A. Yes.

12 Q. And this is a patent application that
13 has -- under "Priority Date," it says May 14
14 of 2004; is that right?

15 A. This is a patent application with a
16 priority date of 2004.

17 Q. And then under the international
18 application number, it's P --
19 PCT/US2005/017046, correct?

20 A. Sorry. Where are you reading that
21 from?

22 Q. Item 21, the international application
23 number.

24 A. PCT/US2005-01.

1 Q. With an international filing date
2 under that of 16 of May of 2005, right?

3 A. That's what I see, yes.

4 Q. And you are a named inventor on this
5 patent; is that right?

6 A. I am.

7 Q. And the only other named inventor is
8 Anthony Shuber; is that right?

9 A. That is correct.

10 Q. And Mr. Shuber worked with you at
11 Exact Sciences; is that correct?

12 A. Tony and I worked together, yes.

13 Q. And you reported to Tony for most of
14 the five years you were at Exact Sciences?

15 A. Yes. As I indicated before, that's
16 true.

17 Q. And this -- on the face of the patent,
18 on Item No. 71, the applicant is Exact
19 Sciences Corporation, correct?

20 A. Exact Sciences Corporation.

21 Q. The title on the second page here is
22 "Method for stabilizing biological samples for
23 nucleic acid analysis," correct?

24 A. Yes, the title is "Method for

1 stabilizing biological samples for nucleic
2 acid analysis."

3 Q. The "Field of the invention" at
4 line 10, the paragraph underneath that states,
5 "The invention relates generally to assays to
6 detect nucleic acid markers indicative of
7 cancer and other diseases and more
8 particularly to preparing nucleic acid
9 containing biological samples for use in these
10 assays."

11 Do you see that?

12 A. I see that.

13 Q. Is that an accurate depiction of the
14 field of the invention for the Shuber
15 patent?

16 MR. JONES: Objection. Calls
17 for a legal conclusion.

18 A. I am -- I would read the same words.
19 BY MS. FERNANDS:

20 Q. And as an inventor of this patent, you
21 have no issue with that description of the
22 "Field of the invention"?

23 MR. JONES: Objection.

24 A. Could you be more specific what you

1 mean by "issues"?

2 BY MS. FERNANDS:

3 Q. Well, do you think this is an
4 appropriate description of the "Field of the
5 invention" for this Shuber patent on which you
6 are a named inventor?

7 MR. JONES: Objection. Calls
8 for a legal conclusion.

9 A. From a personal opinion, this one
10 sentence reasonably represents what this
11 patent field is.

12 BY MS. FERNANDS:

13 Q. Now, in your report, or your
14 declaration, rather, starting -- you discuss
15 this application starting at Paragraph 133 on
16 page 88, correct?

17 A. Yes, I see that.

18 Q. That discussion continues to Paragraph
19 136, on page 91?

20 A. Yes, it does.

21 Q. In Paragraph 135, in the last
22 sentence, you state, "Shuber also considers
23 combining multiple assays to improve the test
24 sensitivity for detection of CRC, noting that

1 'The invention may be useful to avoid or
2 reduce the number of false negative results in
3 a screen of a population of individuals for
4 one or more early stage of cancer (e.g., using
5 DNA integrity assay, a multiple mutation
6 assay, a hypermethylation assay, or any
7 combination thereof).'

8 Do you see that?

9 A. I see that.

10 Q. And the DNA integrity assay, multiple
11 mutation assay, and hypermethylation assay are
12 all nucleic acid assays, correct?

13 A. The DNA -- yeah, the DNA integrity
14 assay, multiple mutation assay, and
15 hypermethylation assay are all DNA-based
16 tests.

17 Q. There's no discussion in Shuber of
18 fecal occult blood testing, correct?

19 A. To my knowledge -- I'm sorry. Let me
20 review real quickly.

21 (Witness reviews document.)

22 Are you asking if there's any mention
23 of fecal occult blood testing anywhere in the
24 patent?

1 Q. Is there any discussion in Shuber of
2 using any fecal occult blood tests?

3 A. (Witness reviews document.)

4 I don't believe there's any
5 description of fecal occult blood tests.

6 Q. In Paragraph 134 of your declaration,
7 in your third sentence, you state that "Shuber
8 addresses this problem by describing a buffer
9 that stabilizes nucleic acids in the sample,
10 e.g., a method for preparing a fecal sample
11 for analysis."

12 Do you see that?

13 A. Yes, I see that.

14 Q. It continues, "Shuber reports that the
15 use of such buffers provides marked advantages
16 such that samples, 'Do not require
17 refrigeration or freezing.'"

18 Do you see that?

19 A. Yes, I see that.

20 Q. And one of the things discussed in
21 Shuber was the addition of stabilization
22 buffers for nucleic acids, correct?

23 A. One of topics of this patent
24 application was stabilization buffers.

1 Q. On -- in the Shuber reference, on
2 page 3 --

3 MR. JONES: Just for clarity,
4 are you referring to the pages on the top or
5 on the bottom?

6 MS. FERNANDS: Oh, I'm sorry.
7 Thank you. Page 4. Let's continue with the
8 pages on the bottom because that's what I have
9 been doing. And it would then be page 4 of
10 Shuber. Thank you.

11 BY MS. FERNANDS:

12 Q. So on page 4, using the Geneoscopy
13 exhibit number and the page, in the paragraph
14 that begins at line 11, do you see that
15 paragraph --

16 A. Yes.

17 Q. -- starting with "in general"?

18 A. (Witness nodding.)

19 Q. The final sentence of that paragraph
20 refers to a ratio of 7 milliliters to -- per
21 gram of stabilization solution to patient
22 sample.

23 Do you see that?

24 MR. JONES: Objection.

1 A. I see that there is a sentence that
2 says, "When the patient sample is a stool
3 sample and the stabilization solution is 10
4 millimolar Tris Cl 1 millimolar EDTA and 150
5 millimolar sodium chloride, a suitable ratio
6 stabilization buffer to patient sample is 7
7 milliliters per gram."

8 Q. Do you know the significance of that
9 ratio, if any?

10 A. There were many ratios that were
11 analyzed. This is one of the ones that we had
12 looked at. I'm not sure if you have a more
13 specific question.

14 Q. Is it one of the ones that you looked
15 at that was useful for stabilizing nucleic
16 acid in the stool sample?

17 A. This was one of the ratios that
18 appeared to be useful to us.

19 Q. If you turn to Paragraph 136 of your
20 declaration, you state that "Shuber also
21 discusses stool collection devices, e.g.,
22 where the sample can be combined with
23 stabilizing buffer sealed and shipped. Shuber
24 states that the stool sample may be directly

1 deposited into a container (e.g., a sealable
2 container) that also contains stabilization
3 solution stabilization may be added to a
4 container when (e.g., at the same time,
5 immediately after, or within minutes, hours,
6 or a day) of biological sample (e.g., a stool
7 sample) is deposited in the container."

8 Do you see that?

9 A. I see that.

10 Q. And that portion of Shuber in which
11 you rely does not state that the collection is
12 at home, does it?

13 MR. JONES: Objection to form.

14 A. As written within the quotations, this
15 does not specifically indicate that samples
16 are collected at home. However, as we can
17 also see at the beginning of the paragraph
18 where we say "Shuber discusses stool
19 collection devices where the sample can be
20 combined with stabilization buffers sealed and
21 shipped," the shipping, I think, is indicating
22 that a sample would be sent from a home to a
23 lab.

24 BY MS. FERNANDS:

1 Q. Shipping could also be from a doctor's
2 office to a lab, correct?

3 A. It doesn't specify.

4 Q. If you look at page 30, going from the
5 pages next to the exhibit numbers on Shuber,
6 and the quotations in your Paragraph 136 come
7 from that first full paragraph on page 30,
8 correct, the one beginning at line 8?

9 A. What's written in the patent
10 application is "In any of the aspects of the
11 invention described herein, including the
12 examples, a sample, e.g., a stool sample, can
13 be directly deposited into a container, e.g.,
14 a sealable container, that already contains
15 stabilization solution. The amount of
16 solution may be sufficient to cover the sample
17 or a portion thereof.

18 "Alternatively, stabilization solution
19 may be added to a container when, for example,
20 at the same time, immediately after, or within
21 minutes, hours, or a day, a biological sample,
22 for example, a stool sample, is deposited in
23 the container. The amount of solution added
24 may be sufficient to cover the entire sample

1 or at least a portion thereof, for example, 10
2 percent, 25 percent, 50 percent, or more. In
3 one embodiment, an amount of solution
4 sufficient to fill the container may be added.
5 In some embodiment, a container may be between
6 about 25 mls and about 1,000 mls," and it
7 continues.

8 Q. And so my question was the portions of
9 Shuber that you quote in Paragraph 136 come
10 from that paragraph on page 30 of the patent
11 application, correct?

12 A. Some of the portions in the
13 declaration are quoted as coming from this
14 patent.

15 Q. From that paragraph in the patent,
16 right, the one that you just read?

17 A. That is correct.

18 Q. And that paragraph does not refer to
19 home collection, correct?

20 MR. JONES: Objection. Form.

21 A. That particular paragraph in the
22 patent application does not refer to
23 collection of samples at home.
24

1 BY MS. FERNANDS:

2 Q. In your discussion of Shuber in your
3 declaration, you do not describe the
4 collection kit used for Shuber, do you?

5 MR. JONES: Objection.

6 A. I'm sorry. Could you restate the
7 question?

8 BY MS. FERNANDS:

9 Q. In your discussion of Shuber, do you
10 describe whatever device into which the stool
11 sample was collected?

12 A. In my declaration, you're asking?

13 Q. Yes, in your declaration.

14 A. I do not describe the physical
15 attributes of the container.

16 Q. Going back to page 92, Paragraph 138,
17 in Paragraph 138, in the second sentence, you
18 state, "Specifically, it is my opinion that it
19 would have been obvious for a POSA to use the
20 iFOBT of Vilkin and the fecal collection and
21 DNA stabilization process of Itzkowitz in the
22 screening method of Lenhard to arrive at the
23 method of the challenged claims."

24 Do you see that?

1 A. Yes.

2 MR. JONES: I'm sorry. Could
3 you -- I --

4 MS. FERNANDS: Paragraph 138,
5 second sentence beginning with "specifically."

6 MR. JONES: Oh, okay. I'm
7 sorry.

8 MS. FERNANDS: No worries.

9 MR. JONES: I was on the wrong
10 sentence.

11 BY MS. FERNANDS:

12 Q. And do you recall when we were
13 discussing Vilkin earlier today that Vilkin
14 included the collection of three different
15 samples from each patient?

16 A. I recall that in the description of
17 his study that's what he did in that study.

18 Q. So the iFOBT of the Vilkin reference
19 includes the collection of three samples,
20 correct?

21 A. As -- as he ran his study and as he
22 ran that test, he did run three different
23 studies -- or three different tests.

24 Q. And he also instruct- -- that

1 publication also instructed that the samples
2 be kept in the refrigerator over -- as they
3 were collected over three days, correct?

4 MR. JONES: Objection. Form.

5 A. As we discussed earlier and as we read
6 from the paper, there was a request to the
7 people that were being examined to refrigerate
8 the samples.

9 BY MS. FERNANDS:

10 Q. If one were to combine the iFOBT of
11 Vilkin with the DNA stabilization process of
12 Itzkowitz, in your opinion, would they also
13 collect three samples for the DNA sampling?

14 A. My learning from reading Vilkin is
15 that the iFOBT test has a high sensitivity and
16 specificity as a suitable test for, at least
17 in part, colorectal cancer screening and that
18 that is the takeaway learning for me in that
19 study. Whether or not the -- a POSA would
20 take away from that that the specific aspect
21 of running three separate tests per person or
22 not is not something that I have opined about.

23 Q. Did you consider what a POSA looking
24 at Vilkin and Itzkowitz and Lenhard would do

1 with respect to that teaching that -- in
2 Vilkin that three samples were used?

3 MR. JONES: Objection to form.

4 A. Could you rephrase that?

5 BY MS. FERNANDS:

6 Q. In reaching your opinion that "It
7 would have been obvious for a POSA to use the
8 iFOBT of Vilkin and the fecal collection and
9 DNA stabilization process of Itzkowitz in the
10 fecal screening method on Lenhard to arrive at
11 the method of the challenged claims," did you
12 consider how a POSA would view the three
13 sample -- collection of three samples in
14 Vilkin?

15 MR. JONES: Objection to form.

16 A. I did consider that, yes.

17 BY MS. FERNANDS:

18 Q. And would a POSA then collect three
19 samples from the DNA as well in combining the
20 tests?

21 MR. JONES: Objection to form.

22 A. My -- my opinions about the value of
23 the iFOBT test in Vilkin is based on the
24 results shown, which has a very high

1 sensitivity and a high specificity.

2 If we go back to the Vilkin reference,
3 we see that -- it was actually a question you
4 had asked about in terms of the results of
5 Tests 1, 2, and 3. And I would note that in
6 Table 3 indeed there are differences in terms
7 of the percentages of cancers detected, but
8 due to the small number of samples in this
9 test set, it's not clear that that's a
10 significant difference.

11 BY MS. FERNANDS:

12 Q. Considering the very high sensitivity
13 and high specificity of Vilkin, why would a
14 POSA combine Vilkin with another test?

15 A. When looking to screen for colorectal
16 cancer, I think that there was also a desire
17 to try to get as high a sensitivity and
18 specificity of a test as possible.

19 What's described in Vilkin I think is
20 directional in terms of indicating what the
21 benefit of that iFOBT test provides for, and
22 larger studies may be required to be able to
23 prove the benefit of that.

24 Q. I've just handed you what's been

1 marked as Geneoscopy Exhibit 1013 in the IPR.
2 And this is a reference titled "Screening and
3 surveillance for the early detection of
4 colorectal cancer and adenomatous polyps,
5 2008: A joint guideline from the American
6 Cancer Society, the U.S. Multi-Society Task
7 Force on Colorectal Cancer, and the American
8 College of Radiology."

9 This is one of the references that you
10 consulted in preparation of your declaration,
11 correct?

12 A. Yes, this paper is one of the
13 references.

14 Q. And this was a 2008 publication; is
15 that right?

16 A. This was published in 2008.

17 Q. And you understand that this contains
18 recommendations for CRC screening?

19 A. As the title indicates, "Screening and
20 surveillance for the early detection of
21 colorectal cancer and adenomatous polyps," a
22 joint guideline of the -- this is intended as
23 a guideline for practitioners.

24 Q. If you'd turn to page 4, the first

1 full paragraph in the first column on page 4,
2 do you see the paragraph beginning "It is the
3 strong opinion"?

4 A. Yes.

5 Q. And that sentence states, "It is the
6 strong opinion of this expert panel that colon
7 cancer prevention should be the primary goal
8 of CRC screening."

9 Do you see that?

10 A. Yes.

11 Q. And that was a statement in a
12 guideline in 2008, correct?

13 A. This is a statement within this paper
14 in 2008, yes.

15 Q. And your understanding is that a
16 person of ordinary skill in the art is
17 presumed to be aware of the literature that's
18 available at the time, correct?

19 MR. JONES: Objection. Calls
20 for a legal conclusion.

21 A. A POSA should be familiar with the --
22 what's in the art.

23 BY MS. FERNANDS:

24 Q. Would you agree that a POSA in 2009

1 seeking to develop a CRC screening test would
2 consider that a primary goal should be
3 prevention of colorectal cancer?

4 A. I actually would not agree with that.
5 I think that this is one opinion by this
6 guideline group that is an important
7 consideration. I don't think it's the only
8 consideration. I think that detection of
9 existing cancers is also a primary concern.

10 Q. It was your opinion that a person of
11 ordinary skill in the art would substitute the
12 gFOBT of Lenhard with the iFOBT of Vilkin,
13 correct?

14 A. I'm sorry. Could you say that again.

15 Q. Yes.

16 It was your opinion that a person of
17 ordinary skill in the art as of 2009 would,
18 looking at Lenhard and Vilkin, substitute the
19 gFOBT of Lenhard with the iFOBT of Vilkin,
20 correct?

21 A. I think I have an opinion to that
22 effect on here. Let me read what I wrote.

23 (Witness reviews document.)

24 So there is a section entitled "A POSA

1 would be motivated to use the iFOBT of Vilkin
2 in place of the gFOBT of Lenhard."

3 Q. And one of the reasons that you give
4 for that in Paragraph 144 is that iFOBT has a
5 higher sensitivity than gFOBT; is that
6 correct?

7 A. What I write is that "Vilkin itself
8 expressly teaches numerous advantages of using
9 iFOBT instead of gFOBT, including that iFOBT
10 has a higher sensitivity than gFOBT,
11 eliminates the need for the diet restrictions
12 associated with gFOBT, and is quantitative,
13 which allows a physician to choose the optimal
14 fecal hemoglobin threshold level for a
15 patient."

16 Q. And is one of the reasons that you
17 believe, in your opinion, that a person of
18 ordinary skill in the art would have used the
19 iFOBT of Vilkin in place of the gFOBT of
20 Lenhard is because of higher sensitivity?

21 A. One of the reasons is because of the
22 higher sensitivity.

23 Q. Vilkin was a 2005 reference, correct?

24 A. That's correct.

1 Q. If you could, turn back to the Levin
2 reference, which is Exhibit 1013, and to
3 page 7 of that.

4 In the second column, the first full
5 paragraph that begins "a number of studies,"
6 do you see that?

7 A. "A number of studies," yes.

8 Q. And that -- that first sentence
9 states, "A number of studies over the" last --
10 "over the past 20 years have compared the
11 diagnostic accuracy of various FIT with gFOBT
12 (most often Hemoccult II or Hemoccult SENSEA)."

13 Do you see that?

14 A. I see that.

15 Q. And FIT is the same thing as iFOBT,
16 correct?

17 A. I would agree.

18 Q. Yes.

19 This continues, "In this review, we
20 have focused on studies that compared
21 different FIT with Hemoccult SENSEA since at
22 present it has the highest sensitivity of
23 currently marketed gFOBT."

24 Do you see that sentence?

1 A. I see that.

2 Q. And Hemoccult SENSE was, at least
3 according to this reference, the most
4 sensitive gFOBT as of -- at the time,
5 correct?

6 A. I'm sorry. Could you --

7 Q. At least according to this reference,
8 Hemoccult SENSE was the most -- had the
9 highest sensitivity of --

10 A. According -- sorry.

11 Q. -- of marketed gFOBT at the time?

12 A. According to what they are saying
13 here, Hemoccult SENSE at present has the
14 highest sensitivity of currently marketed
15 gFOBT is what they state.

16 Q. And then the last sentence in that
17 paragraph states, "Based on data from these
18 six studies, it appears that there are no
19 clear patterns of superior performance in
20 overall test performance between a
21 high-sensitivity guaiac-based test (Hemoccult
22 SENSE) and a variety of FIT."

23 Do you see that?

24 A. I see that.

1 Q. So at least for purposes of this Levin
2 reference, they had concluded that there was
3 no pattern of superior performance of gFOBT
4 over iFOBT?

5 MR. JONES: Objection.
6 Mischaracterizes.

7 A. Is there a question?

8 BY MS. FERNANDS:

9 Q. No. There was, but I'll say it again.
10 At least for purposes of this Levin
11 reference, they had concluded that there was
12 no pattern of superior performance of the
13 high-sensitivity gFOBT to Hemoccult SENSА over
14 a variety of iFOBT?

15 MR. JONES: Objection.

16 A. If you're asking me did they come to
17 that conclusion, I assume that, based on their
18 review of the six studies which are
19 referenced, that is the conclusion that they
20 come to.

21 I don't know that that's a generalized
22 result or conclusion.

23 BY MS. FERNANDS:

24 Q. This was however one of the references

1 that you cited in your declaration, correct?

2 A. It was.

3 Q. On the same page, right under the
4 "FIT" heading, do you see where it states that
5 "The use of FIT in the United States has
6 lagged behind some other countries, mostly due
7 to higher costs associated with FIT compared
8 with gFOBT"?

9 A. I see that.

10 Q. Was it also the case that in 2008 FIT
11 had higher costs than gFOBT?

12 A. I don't know the answer to that
13 question.

14 Q. Do you have any reason to doubt what
15 was reported in this Levin reference?

16 A. I do not have a reason to doubt that.

17 Q. Will you turn to page 142 of your
18 declaration.

19 A. I'm sorry. Page 142?

20 Q. Page 142, Paragraph 244.

21 And in Paragraph 244, you cite to this
22 Levin reference that we're looking at, right,
23 Exhibit 1 -- 1013?

24 A. I cite to Levin at the end of the

1 paragraph, yes.

2 Q. And it's just a one-sentence
3 paragraph, right?

4 A. It is one sentence.

5 Q. That starts with "Indeed, the 2008
6 joint guideline from the American Cancer
7 Society, the U.S. Multi-Society Task Force on
8 Colorectal Cancer, and the American College of
9 Radiology proposed investigating whether" --
10 and then you quote, "including a sensitive
11 gFOBT or FIT [another acronym for iFOBT] at
12 the time of testing would improve sensitivity
13 [of DNA-based assays] without adversely
14 affecting specificity."

15 Do you see that?

16 A. I see that.

17 Q. Then you cite to what is page 1578 on
18 the reference page 9 in the exhibit numbering
19 in Levin?

20 A. Yes.

21 Q. The paragraph beginning "as noted"
22 toward the bottom of that paragraph, I believe
23 that's where that comes from.

24 A. (Witness reviews document.)

1 Q. Have you located it?

2 A. I have.

3 Q. And so the quote in your declaration
4 begins with the word "including," correct?

5 A. I'm trying to locate it.

6 Q. In -- back to your declaration, the
7 portion that you quoted, you began with the
8 word "including," correct?

9 A. Yes.

10 Q. And the sentence that that comes from,
11 about two-thirds of the way down, do you see
12 the sentence beginning "another question"?

13 A. I'm having trouble locating it.

14 Q. Do you see the "SVNA" heading?

15 A. Yes.

16 Q. If you go up -- I think it's ten lines
17 from there -- there's a sentence that begins
18 "another question."

19 A. Okay. I've located it.

20 Q. Okay. So that sentence reads,
21 "Another question worthy of consideration is
22 whether or not including a sensitive gFOBT or
23 FIT at the time of testing would improve
24 sensitivity without adversely affecting

1 specificity," correct?

2 A. Correct.

3 Q. And you did not include the beginning
4 of that sentence in your declaration where it
5 says "A question worthy of consideration is
6 whether or not including the sensitive gFOBT
7 at" -- correct?

8 A. I did not include those words.

9 Q. And what Levin states here is it's
10 worth considering whether or not including an
11 FOBT at the time of testing would improve
12 sensitivity without adversely affecting
13 specificity, correct?

14 MR. JONES: Objection to form.

15 A. What he says is "Another question
16 worthy of consideration is whether or not
17 including a sensitive gFOBT or FIT at the time
18 of testing would improve sensitivity without
19 adversely affecting specificity."

20 BY MS. FERNANDS:

21 Q. Going back to your declaration, in
22 Paragraph 241 on page 140, your footnote on
23 Paragraph 241 is to a reference called
24 Nishikawa, correct?

1 A. Reference 335 is to Nishikawa.

2 Q. And Nishikawa is Geneoscopy Exhibit
3 1011, correct?

4 A. Geneoscopy Exhibit 1011, yes.

5 Q. Nishikawa was published in 2002; is
6 that right?

7 A. It was indeed published in 2002.

8 Q. So that's seven years before the
9 priority date of the '781 patent?

10 MR. JONES: Objection. Calls
11 for a legal conclusion.

12 A. 2002 is before 2007 -- 2009.

13 BY MS. FERNANDS:

14 Q. And for purposes of your report, you
15 assumed that the priority date of the '781
16 patent was 2009, correct?

17 A. I assume that the priority date is
18 February of 2009.

19 Q. And so Nishikawa was seven years
20 before that; is that right?

21 A. Nishikawa would appear to be seven
22 years before that.

23 Q. So the final paragraph of Nishikawa on
24 the last -- on what is page 6 of the exhibit,

1 is that the paragraph in which you rely in the
2 citation and quote in page -- on page 140 in
3 Paragraph 241?

4 A. What I wrote in the quote is that "For
5 example, Nishikawa, a 2002 paper reporting a
6 fecal DNA assay similar to the ones disclosed
7 in Shuber, concluded that the disclosed assay
8 should provide a more sensitive and specific
9 tool for mass screening of a colorectal cancer
10 than is currently available, especially if
11 used in combination with fecal occult blood
12 testing and other methods for detecting
13 genetic abnormalities."

14 Q. And was your source for that that
15 final paragraph of Nishikawa?

16 A. The -- sorry. Let me see what I put
17 in here specifically.

18 (Witness reviews document.)

19 The quoted portion of that is in the
20 last paragraph of Nishikawa.

21 BY MS. FERNANDS:

22 Q. And Nishikawa does not provide any
23 data concerning any combination of the KRAS
24 point mutation test of Nishikawa with any

1 other form of testing, does it?

2 A. If you go to the "Method" section, the
3 testing of the samples in Nishikawa related to
4 DNA-based markers.

5 Q. And there's no data concerning any
6 comparison of or combination with FOBT
7 testing?

8 A. In this particular paper, there is no
9 data on the FOBT test itself.

10 Q. Going to Paragraph 243 of your
11 declaration, in Paragraph 243, you discuss a
12 reference called Kutzner, correct?

13 A. Yes, we reference Kutzner in this
14 paragraph.

15 Q. If you could go to page 8 of Kutzner,
16 on page 8 of Kutzner, at the bottom of the
17 first column, do you see the sentence "this
18 leads"?

19 A. Yes. At the end?

20 Q. Yes. And that sentence says, "This
21 leads to the question of whether both
22 methods" -- that's referring to MD and FOBT;
23 is that right?

24 A. The paragraph starts by saying, "This

1 is one of the first studies which evaluates
2 and directly compares the potential of the two
3 noninvasive methods, MD and FOBT, in the
4 diagnosis of colorectal carcinomas."

5 Q. And so when it refers to both methods,
6 it's referring to the MD and FOBT, correct?

7 A. That is my understanding.

8 Q. And the MD of Kutzner was molecular
9 diagnosis, correct? It's in the abstract
10 where they define it.

11 A. They define "MD" as molecular
12 diagnosis.

13 Q. So going back to that final -- that
14 page 8, Kutzner states, "This leads to the
15 question of whether both methods should be
16 used together in a broad diagnostic -- in
17 broad diagnostic screening programs."

18 Do you see that?

19 A. "This leads to the question" -- yes, I
20 see that sentence.

21 Q. And now, Kutzner is a retrospective
22 study, correct?

23 A. They describe it as a retrospective
24 study.

1 Q. And Kutzner goes on to state there on
2 page 8, "We are aware that our retrospective
3 data do not allow any conclusion on the
4 potential of this approach in diagnostic
5 screening."

6 Do you see that?

7 A. I see that.

8 Q. Kutzner then states, "Prospective
9 comparative studies, which include a very high
10 number of individuals, have to prove the value
11 of the combined application of MD and FOBT."

12 Do you see that?

13 A. I see that.

14 Q. Kutzner states that no conclusions can
15 be drawn from this retrospective data,
16 correct?

17 MR. JONES: Objection.

18 A. What he states is "The final result of
19 this study will allow further conclusions
20 about the effectiveness of the two methods and
21 their combined applications."

22 BY MS. FERNANDS:

23 Q. When you say the final -- the sentence
24 before what you just read says, "Preliminary

1 results of a large study were presented in an
2 abstract form, ACG and AG annual meetings.
3 The final results of this study will allow
4 further conclusions about the effectiveness of
5 the two methods and their combined
6 applications," correct?

7 A. Taken together, yes.

8 Q. And that large -- you did not discuss
9 the results of that large study in your
10 declaration?

11 A. My discussion in the declaration is
12 relative to this.

13 Q. And this reference, Kutzner states
14 that "This retrospective data do not allow any
15 conclusion on the potential of this approach
16 in diagnostic screening," correct?

17 A. What he is -- what Kutzner is
18 describing is that there is a potential
19 benefit to providing these two types of assays
20 and therefore, speaks to the motivation for
21 doing additional studies.

22 Q. And a person to do those additional
23 studies would want to improve sensitivity
24 without adversely affecting specificity,

1 correct?

2 MR. JONES: Objection.

3 A. I think one would have to define the
4 reference points for relative statements about
5 sensitivity and specificity.

6 BY MS. FERNANDS:

7 Q. If you could, turn back to the Exhibit
8 1013, the Levin reference. It's the...

9 A. Sorry. Which page?

10 Q. Also on page 9.

11 A. Okay.

12 Q. Do you recall on page 9 of Levin that
13 sentence that states, "Another question worthy
14 of consideration is whether or not including a
15 sensitive gFOBT or I -- FIT at the time of
16 testing would improve sensitivity without
17 adversely affecting specificity"?

18 A. I see that that is written there.

19 Q. And then Levin goes on to refer to a
20 recent retrospective analysis, correct?

21 A. He states, "In a recent retrospective
22 analysis of stool samples from patients with
23 CRC and donor controls, combined results from
24 a standard gFOBT and a panel of DNA markers

1 (APC, BAT-26, and LDna) resulted in a combined
2 sensitivity for cancer of 93 percent and
3 specificity of 89 percent."

4 Q. And if we look at Footnote 76, which
5 is the citation there, that is to the Kutzner
6 reference, correct?

7 A. That is to the Kutzner reference.

8 MS. FERNANDS: We've been going
9 about an hour. Can we take a quick break?

10 MR. JONES: Sure.

11
12 (Recess taken from 2:22 p.m.
13 to 2:33 p.m.)
14

15 BY MS. FERNANDS:

16 Q. If you could, go to your declaration,
17 and let's start on page 34, Paragraph 62.

18 A. Okay.

19 Q. In Paragraph 62, your final sentence
20 which is on the carryover page to 35, you
21 state, "The fact that colonoscopy is a
22 low-risk, routine procedure as balanced
23 against mortality from false negative" --

24 A. Sorry. I must be in the wrong place.

1 Q. Paragraph -- sorry. Did I say the
2 wrong one? Paragraph 62.

3 A. Yeah.

4 Q. Paragraph 62, the final sentence.

5 MR. JONES: It's a long
6 paragraph.

7 A. Oh, sorry. Okay.

8 BY MS. FERNANDS:

9 Q. So just so we're all -- so Paragraph
10 62, on page 35, the final sentence of the
11 paragraph.

12 And that states, "The fact that
13 colonoscopy is a low-risk, routine procedure,
14 as balanced against mortality from false
15 negative diagnoses, favors the development of
16 CRC screening tests with higher sensitivity
17 even if some tradeoff against specificity is
18 required."

19 Do you see that?

20 A. Yes, I see that.

21 Q. You do not include any citations for
22 that statement, do you?

23 A. There are no citations on that
24 statement.

1 Q. If you could, turn now to
2 Paragraph 65. Paragraph 65, on page 38, in
3 the second sentence of that paragraph, you
4 say, "Use of multiple biomarkers directly
5 increase sensitivity where any positive result
6 was considered a positive diagnosis and
7 increase specificity where multiple positive
8 results were required for a positive
9 diagnosis."

10 Do you see that?

11 A. Yes.

12 Q. And there's no citation for that
13 sentence, correct?

14 A. That sentence is following the
15 sentence before that, which was "It was widely
16 understood that one method for increasing
17 sensitivity and/or specificity of CRC
18 screening would be to combine the use of
19 multiple biomarkers, including both fecal DNA
20 and FOBT."

21 So the sentence follows, then, that
22 use of multiple biomarkers directly increase
23 sensitivity where any positive result was
24 considered a positive diagnosis. And the

1 intent of that statement is to indicate that
2 being able to detect more cancers was a good
3 thing.

4 Q. And you also say "an increased
5 specificity where multiple positive results
6 were required for a positive -- where multiple
7 positive results were required for a positive
8 diagnosis."

9 Why is that increased specificity
10 where multiple positive results were required?

11 A. The -- what's required of a good test,
12 as we were discussing before, is to have high
13 specificity in order to avoid false positives
14 and to have high sensitivity to avoid false
15 negatives. These are relative terms, and so
16 the combination of specific biomarkers and the
17 benefit of what happens when you combine
18 different biomarkers is something that would
19 need to be explored.

20 Q. And your final sentence there is
21 "Under either approach, increasing the number
22 of biomarkers used in such a diagnostic test
23 results in an improved assay."

24 Do you see that?

1 A. I see the sentence, yes.

2 Q. And there's also no footnote on that
3 sentence, correct?

4 A. Again, this follows the first sentence
5 of the paragraph, which is referenced.

6 Q. Is it an improved assay if sensitivity
7 is increased at the expense of specificity?

8 A. That's a general statement, which I
9 wouldn't answer at this point. I think that
10 in order to adjudicate what is the extent to
11 which the sensitivity increases and the extent
12 to which a specificity might decrease is
13 something that needs to be evaluated.

14 Q. I'm sorry. These are huge.

15 You have now been handed what was
16 marked as Exhibit No. 1026. And if you turn
17 to page 40, Paragraph 69, I believe this is
18 cited in Footnote 70. Sorry. Not of the
19 exhibit, of your declaration. My apologies.
20 I was unclear. Page 40, Paragraph 69 of your
21 declaration.

22 A. Okay.

23 Q. And the footnote in page 40,
24 Paragraph 69 is to Footnote 70, which is

1 Melvin Exhibit 1026, correct?

2 A. Melvin is the reference of
3 Paragraph 69, first sentence.

4 Q. And there aren't any other footnotes
5 in that paragraph, right?

6 A. There are not any other footnotes.

7 Q. And this Exhibit 1026 is Melvin that
8 is referenced there, correct?

9 A. Yes, that's correct.

10 Q. So in Footnote 70, you cite page 12 of
11 Melvin; is that right?

12 A. The citation is to page 12.

13 Q. Which corresponds with page 32 of the
14 exhibit -- exhibit page numbers.

15 Is that figure on page 12 of Melvin
16 the figure that you have as Figure 1 on
17 page 42 of your declaration?

18 A. These two figures are the same.

19 Q. And on page 42 of your declaration,
20 the title of the figure on Melvin, "Use of PVA
21 fixative and formalin for submitting stool
22 specimens to be examined for parasites," is
23 missing in your declaration, correct?

24 A. It is not included there.

1 Q. And according to this title on the
2 figure in the Melvin reference in Exhibit
3 1026, this -- these stool samples were taken
4 to be examined for parasites; is that right?

5 A. The topic of this collection was for
6 microorganisms, I believe, and parasites.

7 Q. In the title, it says "to be examined
8 for parasites" in the reference; is that
9 right?

10 A. Yes.

11 Q. And in that reference, the stool was
12 put into two separate containers, neither of
13 which were direct defecation containers,
14 correct?

15 MR. JONES: Objection.

16 BY MS. FERNANDS:

17 Q. Let me ask that differently.

18 There are two sealed containers shown
19 in No. 6 in Figure 1, right?

20 A. Yes.

21 Q. And neither of those two sealed
22 containers in Figure -- in No. 6 of Figure 1
23 was a container into which the user would
24 directly defecate?

1 A. I would agree with that.

2 Q. If you turn to page 45 and 46 --

3 MR. JONES: What are you --

4 BY MS. FERNANDS:

5 Q. I'm sorry. In your declaration.

6 You can put Melvin away. I apologize.

7 So going back to your declaration, on
8 page 44 of your declaration, Paragraph 71
9 begins, and it refers to a stool collection
10 device described and claimed in a patent
11 application filed in 1997; is that correct?

12 A. This is -- it's referencing the Inbar
13 patent application of -- as stated, filed in
14 1997.

15 Q. Okay. And then is Figure 3 in your
16 declaration, which appears on page 46, a
17 device shown -- a figure from Inbar?

18 A. I don't have the Inbar --

19 Q. Can you tell -- if you turn to
20 Figure 3, is your citation that this is from
21 Inbar?

22 A. What we are citing is that this --

23 MR. JONES: He's looking at the
24 wrong figure.

1 MR. FERNANDS: Okay.

2 THE WITNESS: I'm sorry.

3 BY MS. FERNANDS:

4 Q. So I think you're looking at Figure 2,
5 right? So that's -- it's confusing because
6 we're on --

7 A. Oh, I'm sorry. I'm sorry.

8 Q. So that's Figure 2, and then
9 Paragraph 71 refers to Figure 3, which comes
10 later.

11 A. Oh, sorry. Sorry, sorry.

12 Q. So is Figure 3 of your declaration a
13 figure that you took from the Inbar patent?

14 A. Yes.

15 Q. And would you agree that Figure 3 is
16 not a device for direct defecation into the
17 device?

18 A. I think the important thing to
19 recognize here is that the concept of taking
20 whole stool samples and sampling from the
21 whole stool samples and then preserving that
22 is what I'm trying to describe here.

23 And so these particular devices are
24 not the devices for which the whole stool

1 sample was collected.

2 Q. And so Figure 3 is not a device for
3 direct defecation into the device?

4 A. This is not a device for defecation
5 directly into it.

6 Q. If you'd turn to page 49,
7 Paragraph 74, you state in Paragraph 74 that
8 "Many assays use different stabilizing buffers
9 to minimize loss of sample integrity between
10 at-home sample collection and laboratory
11 analysis without freezing."

12 Do you see that?

13 A. I see that.

14 Q. Okay. And then you go on "For
15 example, certain buffers prevent degradation
16 of DNA and are, therefore, used when long DNA,
17 mutated DNA, or methylated DNA is used as a
18 biomarker," correct?

19 A. I see that sentence.

20 Q. And then that has Footnote 84, and you
21 have three references cited for that, right?

22 A. The three -- yes, the references are
23 Olson, Shuber, and Itzkowitz.

24 Q. And you go on in that paragraph to

1 state, "Other buffers stabilize blood proteins
2 and are, therefore, used when blood proteins
3 are used as a biomarker," correct?

4 A. That's what I say.

5 Q. Okay. And for that, you have
6 Footnote 85, and you cite Vilkin, Grow, Karl,
7 and Hirata; is that right?

8 A. I do reference Vilkin, Grow, Karl, and
9 Hirata.

10 Q. You do not here describe the
11 composition of either -- of buffers for -- to
12 prevent degradation of DNA; is that right?

13 MR. JONES: Objection. Vague as
14 to what you mean by "here."

15 BY MS. FERNANDS:

16 Q. In your declaration --

17 MS. FERNANDS: I think -- you
18 know, I'm pretty sure the PTAB -- I'm not a
19 PTAB expert, but I'm pretty sure the PTAB's
20 rules say that you're not supposed to do long
21 speaking objections.

22 MS. HABERNY: Object to form.
23 That's it.

24 MR. JONES: Sorry. Your -- you

1 say, "You do not here describe." I was trying
2 to give you a chance to be more specific as a
3 courtesy. I'll refrain.

4 BY MS. FERNANDS:

5 Q. In -- in your declaration, in this
6 discussion where you say "Certain buffers
7 prevent degradation of DNA and are, therefore,
8 used when long DNA, mutated DNA, or methylated
9 DNA is used as a biomarker," you do not
10 describe the composition of any such buffers
11 in your declaration, correct?

12 A. In this paragraph, if that's what
13 you're asking about, we do not describe the
14 compositions of the buffers. However, we do
15 reference -- provide references where
16 compositions of buffers are described.

17 Q. Do you describe anywhere in your
18 declaration the composition of buffers that
19 prevent degradation of DNA?

20 A. I would have to read it to confirm to
21 answer that question.

22 Q. If you can, point me to anywhere where
23 you describe the composition of the buffers in
24 your declaration.

1 A. I know that we provide references that
2 describe compositions of buffers.

3 (Witness reviews document.)

4 In Paragraph 44 and 45, we talk about
5 buffers that contain EDTA.

6
7 (Stenographer clarification.)

8
9 BY MS. FERNANDS:

10 Q. And there are no citations to those
11 paragraphs, are there?

12 A. There are not citations here.

13 Q. Is there anywhere else where you
14 describe the composition of buffers?

15 A. (Witness reviews document.)

16 I don't believe there are any other
17 places.

18 Q. So going back to Paragraph 74 on
19 page 49, you do not identify any differences
20 between buffers that prevent degradation of
21 DNA and buffers that stabilize blood proteins,
22 do you?

23 MR. JONES: Objection to form.

24 A. Are you asking me if I describe

1 specific buffers?

2 BY MS. FERNANDS:

3 Q. I'm asking you whether, in your
4 opinion here, you have -- in your declaration,
5 in the opinions you have offered, whether you
6 have identified any reason why a buffer that
7 prevents degradation of DNA could not be used
8 to stabilize blood proteins.

9 MR. JONES: Objection to form.

10 A. I believe I do. I could try to find
11 it, but I believe that the -- well, let me not
12 paraphrase.

13 (Witness reviews document.)

14 One of the things I talk about on the
15 section in the technical background starting
16 on Paragraph 34, which is a section entitled
17 "Diagnostic analysis require well-preserved
18 samples," one of the things that I describe in
19 here is that "Precautions must be taken to
20 preserve analytes in the specimen so that they
21 do not degrade."

22 I go on to describe different
23 degradation mechanisms, including activity of
24 certain enzymes.

1 On Paragraph 36, I talk about, for
2 instance, there are naturally occurring
3 nucleases that cleave the chains of
4 nucleotides of nucleic acids into smaller
5 units and that these nucleases can be specific
6 to DNA, referred to as DNases, or to RNA,
7 referred to as RNases.

8 I go on to say that endonuclease
9 activity cleaves nucleic acids in well-defined
10 locations and that there are other
11 exonucleases which can act on these molecules
12 leading to degradation.

13 I go on on page 38 to describe how,
14 similarly, naturally occurring proteases,
15 which are a different kind of naturally
16 occurring enzyme, can act on protein analytes
17 to cleave polypeptide chains and denature of
18 proteins.

19
20 (Stenographer clarification.)
21

22 A. "Denaturation can also occur from
23 storage of samples for extended periods of
24 time at ambient or elevated temperatures.

1 Detection methods that rely on intact
2 functional proteins will be negatively
3 impacted by any denaturation of protein
4 analytes."

5 BY MS. FERNANDS:

6 Q. That paragraph that you read concerns
7 stabilization buffers for preserving DNA,
8 correct?

9 A. I'm sorry --

10 MR. JONES: Objection to form.

11 BY MS. FERNANDS:

12 Q. What you just referred to are your
13 discussion of stabilization buffers for
14 preferring -- for preserving DNA in a sample,
15 correct?

16 MR. JONES: Objection to form.

17 A. So --

18 BY MS. FERNANDS:

19 Q. Sorry. Let me ask the question again.
20 The paragraphs on which -- that you've
21 just read concern preserving nucleic acids in
22 samples, correct?

23 A. One of the paragraphs that I read
24 about is relative to preserving DNA based on

1 nucleic acid enzymes that will act on those
2 DNA molecules.

3 The other paragraph that I read is
4 specifically about proteins.

5 Q. So each of those addresses what is
6 being preserved separately.

7 Have you, in your report, offered any
8 opinion that the buffer used to stabilize DNA
9 could not also stabilize blood protein?

10 MR. JONES: Objection to form.

11 A. My opinion as to what preservation
12 activity a particular buffer composition might
13 have on DNA and protein at the same time would
14 be based on the composition of that specific
15 buffer.

16 BY MS. FERNANDS:

17 Q. And you have not offered a categorical
18 opinion that buffer solutions for
19 preserving -- for preventing degradation of
20 DNA are mutually exclusive from buffers that
21 stabilize blood proteins?

22 MR. JONES: Objection to form.

23 A. I'm sorry. Could you repeat the
24 first -- well, repeat the whole question.

1 BY MS. FERNANDS:

2 Q. You have not offered any opinion that
3 a buffer that prevents degradation of DNA
4 necessarily would not preserve blood
5 proteins?

6 MR. JONES: Objection to form.

7 A. My -- my opinions have been centered
8 around the concept that buffers must be
9 selected in order to confirm the stability of
10 specific analytes that are of interest. My
11 opinions are not based on the possibility of
12 things that I have considered otherwise and
13 would have considered otherwise.

14 BY MS. FERNANDS:

15 Q. In your opinion, is it possible that
16 the same buffer could stabilize both nucleic
17 acids and a protein?

18 MR. JONES: Objection.

19 A. Which buffer are we talking about?

20 BY MS. FERNANDS:

21 Q. Is it -- in your opinion, is it
22 possible that someone could formulate a buffer
23 that would stabilize both nucleic acids and a
24 protein?

1 MR. JONES: Objection to form.

2 A. My opinions, in general, are formed on
3 scientific evidence and interpreting that
4 evidence. I have not formed an opinion on the
5 costabilization of DNA and protein.

6 BY MS. FERNANDS:

7 Q. So you're not, then, saying that it
8 would not be possible to form a buffer that
9 would stabilize both nucleic acids and
10 proteins?

11 MR. JONES: Objection to form.

12 BY MS. FERNANDS:

13 Q. Let me ask again.

14 Is it -- in your opinion, would it be
15 impossible to form a buffer that would
16 stabilize both nucleic acids and proteins?

17 MR. JONES: Objection to form.

18 A. Again, my opinions are formed by
19 reviewing data which illustrates to me what is
20 possible. I have not viewed data, in my
21 recollection, that would allow me to answer
22 that question.

23 BY MS. FERNANDS:

24 Q. So you have no opinion as to whether

1 or not it is possible -- as you sit here
2 today, you have no opinion as to whether or
3 not it is possible to -- to develop a buffer
4 that would stabilize both nucleic acids and
5 proteins?

6 MR. JONES: Objection to form.

7 A. Part of my opinion would be based on
8 evidence, as I have already indicated, but I
9 also need to -- I think it's important to
10 refine the question.

11 What you're asking about is a very
12 general phenomenon of DNA and protein. If one
13 were to look at specific proteins or specific
14 DNA, then it would -- it would provide for a
15 more refined context to be able to address
16 that question.

17 BY MS. FERNANDS:

18 Q. You said that part of your opinion
19 would be based on -- is it correct that you do
20 not, as you sit here today, have an opinion on
21 whether it is possible to create a buffer that
22 stabilizes both nucleic acid and blood
23 protein?

24 MR. JONES: Objection to form.

1 A. As I sit here today, I don't recall a
2 set of experiments that I would refer to to be
3 able to allow me to conclude that there are
4 buffers that could simultaneously stabilize
5 DNA and protein.

6 BY MS. FERNANDS:

7 Q. Is it likewise the case that you
8 cannot, as you sit here today, identify
9 anything that would say that you could not
10 create such a buffer?

11 MR. JONES: Objection. Form.

12 A. I'm not forming an opinion on whether
13 or not it's possible.

14 BY MS. FERNANDS:

15 Q. You don't have an opinion as to
16 whether or not it's possible?

17 MR. JONES: Objection to form.

18 A. I'll stick with my same answer. I --
19 I am not forming an opinion as to whether or
20 not that is possible.

21 BY MS. FERNANDS:

22 Q. So in your expert report on page 57,
23 Paragraph 91 -- and if you need to read for
24 context, Paragraph 90, I think, provides

1 context for that.

2 A. (Witness reviews document.)

3 Okay.

4 Q. In Paragraph 91, you list what you
5 identify as some exemplary rationales that may
6 support obviousness that you've been informed
7 of, correct?

8 A. What I've written in 91 starts with "I
9 have been informed that exemplary rationales
10 that may support obviousness include," and I
11 list a number of examples.

12 Q. In your opinion, is the combination of
13 nucleic acid testing and FOBT, does it result
14 in a predictable result?

15 MR. JONES: Objection to form.

16 BY MS. FERNANDS:

17 Q. Let me rephrase that.

18 A. Yeah.

19 Q. Is it your opinion that as of 2009 the
20 result of combining iFOBT and nucleic acid
21 testing was predictable?

22 MR. JONES: Objection to form.

23 A. I believe what was known in 2009 is
24 that the combination of FOBT and DNA was --

1 that there was an increase in detectability of
2 cancers, which would provide for a motivation
3 to combine those using the appropriately
4 chosen sets of biomarkers within those two
5 categories.

6 BY MS. FERNANDS:

7 Q. In your opinion, would a person of
8 ordinary skill in the art have a reasonable
9 expectation that the combination would result
10 in an improved assay?

11 A. My belief -- my opinion is that there
12 have been sufficient evidence provided in
13 prior art to suggest that combinations of
14 biomarkers could lead to increased
15 detectability of cancers and therefore, would
16 provide for some probability of success in
17 being able to demonstrate that.

18 Q. Paragraph 93 of your declaration.

19 You state in Paragraph 39, "I
20 understand that the use of hindsight in an
21 obviousness analysis is impermissible."

22 Do you see that?

23 A. I see that.

24 Q. And you state in the third sentence,

1 "I have not used hindsight in my analysis,"
2 correct?

3 A. That's what I state.

4 Q. What did you do to avoid using
5 hindsight in your analysis?

6 MR. JONES: Objection to form.

7 A. As I've written here, my understanding
8 is that it is not hindsight to rely on
9 knowledge that was within the level of
10 ordinary skill, and so I relied on information
11 from prior art and combined combinations of
12 prior art to form my opinions.

13 BY MS. FERNANDS:

14 Q. Had you read the '781 patent before
15 you started combining pieces of prior art?

16 A. Have I read the '781...

17 MR. JONES: Objection to form.

18 A. Are you asking about the order of the
19 way I did things?

20 BY MS. FERNANDS:

21 Q. I am asking about the order of steps.

22 Had you read the '781 patent that you
23 assert is obvious based -- before you looked
24 at the prior art references?

1 A. I believe I did.

2 Q. And you had read the claims of the
3 '781 patent before you looked at the prior art
4 references?

5 A. Yes.

6 Q. And what did you do to avoid using the
7 claims as a road map to find specific pieces
8 of prior art that fit those claims?

9 MR. JONES: Objection to form.

10 A. Before I would look for prior art, I
11 would want to be aware of what's in the patent
12 and what is being claimed. And so reviewing
13 the claims and looking to see what is the
14 content of whether or not there's prior art,
15 one has to start with that information in
16 order to look to see what else has been
17 described in the literature.

18 BY MS. FERNANDS:

19 Q. And you understand the person of
20 ordinary skill in the art in 2009 did not have
21 the benefit of the claims?

22 MR. JONES: Objection to form.

23 A. Could you rephrase that?

24 BY MS. FERNANDS:

1 Q. A person of ordinary skill in the art
2 in 2009 looking to develop a CRC screening
3 test would not have known what was in the
4 claims. They didn't exist yet, correct?

5 A. I -- the -- I'm not aware of when the
6 patent was publicly available.

7 Q. Your analysis was based on what a
8 person of ordinary skill in the art would have
9 known at the time of the invention, right?

10 A. Yes.

11 Q. So taking ourselves back to
12 immediately before the time of the invention,
13 the person of ordinary skill in the art at
14 that time would not -- could not know the
15 content of the claims?

16 A. Oh, immediately before --

17 Q. Right.

18 A. I see what you're asking.

19 I would say that if the patent was not
20 available for part of prior art, then it would
21 not be possible for them to know what was in
22 there.

23 Q. And when you, having looked at the
24 patent to understand what the patent was

1 about, then looked at the prior art, already
2 knowing what the claims were, how did you try
3 to avoid using the claims as a road map to
4 which pieces of prior art to select?

5 MR. JONES: Objection to form.

6 A. I -- when I -- when I read the
7 claims -- I'm trying to think of what you're
8 actually asking.

9 If I want to understand what is in the
10 prior art, I need to be able to know what the
11 reference point is in order to compare that
12 to. And so, for me, having an awareness of
13 what is in that patent is what I use to be
14 able to try to understand what was in the
15 prior art.

16 BY MS. FERNANDS:

17 Q. Turning to Paragraph 190 on page 117,
18 in Paragraph 190, you state, "The DNA
19 methylation assay disclosed in Lenhard and
20 Itzkowitz and the automated iFOBT disclosed in
21 Vilkin are each complicated molecular biology
22 assays requiring specialized equipment and
23 expertise," correct?

24 A. That's what's stated in the paragraph.

1 Q. And those assays, the methylation
2 assay and the iFOBT, require different
3 equipment to analyze, correct?

4 A. The iFOBT and the methylation assays
5 would be run on different pieces of
6 instrument -- equipment.

7 Q. And the person -- the people running
8 that specialized equipment would have to have
9 different expertise for the two different
10 types of tests, correct?

11 A. Not necessarily.

12 Q. Are the -- is that specialized
13 equipment run in exactly the same way?

14 A. They are not run in the same way.

15 Q. So persons running them would have to
16 have different knowledge for each set of
17 tests?

18 A. I think that a lab technician that was
19 trained on running both of those kinds of
20 tests could easily do that.

21 Q. How did you identify the prior art
22 references on which you rely?

23 MR. JONES: Objection to form.

24 A. Are you referring to --

1 MR. JONES: Just don't answer
2 anything that would reveal communications with
3 counsel.

4 A. Are you referring to any specific
5 reference?

6 BY MS. FERNANDS:

7 Q. Well, let's start with the -- the ones
8 that you used in combination, the Vilkin,
9 Lenhard, Itzkowitz, Shuber, Kanaoka, and Derks
10 references that you used in your grounds. Did
11 you identify those references?

12 A. I have identified -- I identified the
13 majority of those references.

14 Q. You went and did research after seeing
15 the patent and identified those references
16 without them being provided to you by anybody?

17 A. Some of these are papers that I have
18 already been familiar with. As you recall,
19 Itzkowitz publication is from the Exact
20 Sciences group, and even though it was after
21 the time I left, I was familiar with that, and
22 I was familiar with some of the others.

23 And I also am able to do searches in
24 literature to find references that I needed.

1 Q. You said you identified the majority
2 yourself.

3 Which ones did you identify
4 personally?

5 A. Of -- of which list?

6 Q. Of the list in your grounds to begin.

7 A. So the ones I'm certainly familiar
8 with are Lenhard, Itzkowitz, Shuber, and
9 Kanaoka.

10 Q. How did you decide to rely on
11 Vilkin?

12 MR. JONES: Objection.

13 To the extent your answer would reveal
14 conversations with counsel, don't answer. If
15 you can answer without revealing conversation
16 with counsel, you may.

17 A. I can't answer without revealing
18 conversations with counsel.

19 BY MS. FERNANDS:

20 Q. Vilkin was not something that you
21 identified in research that you personally
22 did?

23 MR. JONES: Objection to form.

24 A. That was not one that I had found

1 directly.

2 BY MS. FERNANDS:

3 Q. But you did do some of your own
4 research for references in connection with
5 your work for this IPR; is that right?

6 A. That's correct.

7 Q. And in doing that, did you also look
8 for any references that would weigh against
9 the combinations?

10 A. Could you be more specific?

11 Q. Did you look to see whether there was
12 teaching in the art that would have taught
13 away from the claimed invention of the '781
14 patent when you were doing your research?

15 A. My research was to look for prior art,
16 and so I've read many papers. And my approach
17 was to then take the learnings from those
18 papers to put together this IPR.

19 Q. The list of exhibits at the back of
20 your declaration, does that list all of the
21 papers that you identified in your research in
22 connection with this?

23 MR. JONES: Objection to form.

24 A. It certainly lists many of them.

1 BY MS. FERNANDS:

2 Q. As you sit here today, is there
3 anything that you came up with in your
4 research that is missing from this list that
5 you can think of?

6 MR. JONES: Objection to form.

7 A. Not that I recall off the top of my
8 head.

9 BY MS. FERNANDS:

10 Q. So I've just handed you what's been
11 marked as Geneoscopy Exhibit 1033.

12 This is a reference that you reviewed
13 in connection with your declaration,
14 correct?

15 A. Yes.

16 Q. The author here is Simon; is that
17 right?

18 A. Yes, Jerome Simon.

19 Q. Do you recall earlier we discussed
20 that lower specificity results in more
21 unnecessary medical procedures?

22 MR. JONES: Objection to form.

23 A. I don't recall the exact context, but
24 I know that we have talked about tradeoffs

1 between sensitivity and specificity. Perhaps
2 you could remind me of the specific mention
3 that you're referring to.

4 BY MS. FERNANDS:

5 Q. I believe this is on Paragraph 29 of
6 your declaration on page 13, the last sentence
7 there where you state, "Having a high
8 specificity is desirable in fecal CRC test
9 because patients who wrongly test positive are
10 often subjected to unnecessary medical
11 procedures and potentially unnecessary
12 treatment."

13 Do you see that?

14 A. I see that.

15 Q. That's what I was referring to for
16 context.

17 In addition to the unnecessary medical
18 procedures, would you agree there are also
19 other costs to the false positives in
20 screening tests?

21 MR. JONES: Objection to form.

22 A. Before I address that question, I'd
23 like to perhaps put this statement into
24 context.

1 BY MS. FERNANDS:

2 Q. There's not a question pending, sir.

3 A. Sorry.

4 MR. JONES: Actually, there is a
5 question pending. You just asked a question.

6 MS. FERNANDS: I said, Would you agree
7 there are also other costs to false positives
8 in the screening tests? And he said, before
9 he addresses that question, he'd like to put
10 his statement into context. It's not
11 responsive to the question that he was asked.

12 MR. JONES: That's not what you
13 said.

14 BY MS. FERNAND

15 Q. Okay. There is not a question pending
16 about the statement that you're seeking to
17 make a speech about. I'd like to talk about
18 the Simon reference.

19 A. Okay.

20 Q. In the Simon reference, if you could,
21 turn to page 12. Do you see the section
22 called "Costs" here?

23 A. Yes.

24 Q. And there's a "Direct costs" section

1 within "Costs," right?

2 A. There is a section there, yes.

3 Q. And that refers to the costs of the
4 hemoccult kit; is that accurate?

5 Among other things, it refers to
6 direct costs -- sorry. That was not accurate.
7 Let me step back.

8 Under "Direct costs," it lists "Costs
9 of hemoccult kits, which are cheap; sig fees
10 for sigmoidoscopy; air-contrast; barium enema;
11 or colonoscopy."

12 Do you see that?

13 A. I see that.

14 Q. And those are -- then they have a
15 section for "Indirect costs," correct?

16 A. Yes, there is a section for that.

17 Q. And about halfway down that section,
18 do you see the sentence that begins
19 "additional indirect costs"?

20 A. Yes.

21 Q. And that states, "Additional indirect
22 costs arise from public education programs,
23 such as media charges and publicity. These
24 expenses can be high."

1 Do you see that?

2 A. I see that.

3 Q. Would you agree with that?

4 MR. JONES: Objection to form.

5 A. Are you asking me specifically about
6 the indirect costs statement?

7 BY MS. FERNANDS:

8 Q. Do you agree that "With respect to CRC
9 screening, additional indirect costs arise
10 from the need for public education
11 programs"?

12 A. That's outside of my expertise. I
13 don't have an opinion on that.

14 Q. Then there's also a section on "Hidden
15 costs."

16 Do you see that?

17 A. Yes.

18 Q. And Item 1 there is "Patient time and
19 inconvenience."

20 A. Yes.

21 Q. And would you agree that patient time
22 and inconvenience is a hidden cost of false
23 positive tests?

24 MR. JONES: Objection to form.

1 A. Let me read the context.

2 (Witness reviews document.)

3 So could you rephrase the question in
4 the context of what this is talking about?

5 BY MS. FERNANDS:

6 Q. So this Simon reference is titled
7 "Occult blood screening for colorectal
8 carcinoma: a critical review," correct?

9 A. Uh-huh.

10 Q. And so, in general, the context here
11 is CRC screening, right?

12 A. Yes.

13 Q. And one of the things included in this
14 discussion of CRC screening is the cost of
15 such screening, right?

16 A. Yes, they were talking about the
17 costs.

18 Q. And they've split up costs into direct
19 costs -- indirect costs and what he calls
20 "hidden" costs, right?

21 A. Yes.

22 Q. And in your opinion, is -- patient
23 time and inconvenience, do you agree that that
24 is a hidden cost of false positive testing in

1 screening?

2 MR. JONES: Objection to form.

3 A. My opinion is that costs should always
4 be weighed against the benefits, and the
5 benefits of screening are to detect cancer and
6 to save lives, and so I think that there's
7 costs associated with any tests that are run.

8 BY MS. FERNANDS:

9 Q. Is another -- his Item 2 is "The
10 physical hazard of unnecessary colonic
11 investigations."

12 Do you see that?

13 A. Which section are you --

14 Q. Still in "Hidden costs," Item No. 2 on
15 the next page.

16 A. Okay. Oh, sorry.

17 Q. Would you agree that's another cost of
18 false positive tests?

19 MR. JONES: Objection to form.

20 A. Again, I think that the costs are
21 relative to the benefits. And so the benefits
22 for somebody that may have had a positive
23 screening test is that one could pick up
24 cancer very early, and the costs that are

1 associated with that are relative.

2 MS. FERNANDS: Can we take a
3 quick break? I want to go through my notes.

4 MR. JONES: Okay.

5

6 (Recess taken from 3:33 p.m.

7 to 3:45 p.m.)

8

9 MS. FERNANDS: Thank you very
10 much for your time today. Appreciate it. I
11 have no further questions today.

12 THE WITNESS: Thank you.

13 MR. JONES: So I have a couple
14 of questions. Should I wait for Sandy to get
15 back?

16 MS. FERNANDS: Yes, I guess.

17

18 (Brief pause.)

19

20 MR. JONES: Can we go off the
21 record for a second.

22

23 (Recess taken from 3:46 p.m.

24 3:46 p.m.)

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CROSS-EXAMINATION

BY MR. JONES:

Q. Dr. Whitney, if you could, turn to the section of your declaration that's Paragraphs 27 through 29.

A. Yes.

Q. This section that is -- sorry.

You previously indicated that you wanted to provide context to an answer with respect to Paragraph 29. And could you please provide what context you feel is appropriate?

A. Yes. The context that I wanted to provide is that -- it was part of what we did talk about, which is that sensitivity and specificity, in my opinion, should always be looked at in combination, and although there is a strong desire to maximize specificity to avoid false positives and therefore, not to compromise specificity too much at the expense of the sensitivity, that an increase in sensitivity still could tolerate a relatively small decrease in specificity and end up with a very useful test.

1 Q. So if you turn to page -- Paragraph 62
2 of your declaration --

3 A. Yes.

4 Q. -- you see the last sentence of that
5 paragraph?

6 A. The one that starts "the fact of"?

7 Q. Yes. It reads, "The fact that a
8 colonoscopy is a low-risk, routine procedure,
9 as balanced against mortality from false
10 negative diagnoses, favors the development of
11 CRC screening tests with higher sensitivity
12 even if the [sic] tradeoff against specificity
13 is required."

14 MS. FERNANDS: Objection. That
15 wasn't exactly the words.

16 BY MR. JONES:

17 Q. Okay. I'll try and read again.

18 "The fact that colonoscopy is a
19 low-risk, routine procedure, as balanced
20 against mortality from false negative
21 diagnoses, favors the development of CRC
22 screening tests with higher sensitivity even
23 if some tradeoff against specificity is
24 required."

1 Do you see that?

2 A. Yes.

3 Q. Is that still your opinion as you sit
4 here today?

5 A. Is it my opinion, and I think that one
6 of the things that we have to remind ourselves
7 is that colonoscopy, in fact, is the standard
8 of care for CRC screening. And today, without
9 any screening tests other than colonoscopy,
10 the majority of people who get a colonoscopy
11 do not have CRC. So any screening tests that
12 could be used in front of that to -- if you
13 don't mind the nontechnical term --
14 eliminating the people who do not have cancer
15 would be a benefit to screening overall. That
16 doesn't mean that there has to be perfect
17 specificity.

18 MR. JONES: I have no further
19 questions.

20 MS. FERNANDS: I have nothing
21 further.

22 THE STENOGRAPHER: I've got a
23 standing order for an expedite. Do both
24 parties need it expedited.

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MS. FERNANDS: We need expedited
and a rough draft.

MR. JONES: We'll take it
expedited and we'll take a rough since you're
doing it.

THE STENOGRAPHER: Thank you.
We're off the record.

(Deposition concluded at 3:50 p.m.)

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CERTIFICATION

I, DARLENE M. COPPOLA, a Notary Public, do hereby
certify that DUNCAN H. WHITNEY, PH.D., after having
satisfactorily identifying himself, came before me on
the 10th day of October, 2024, in Boston,
Massachusetts, and was by me duly sworn to testify to
the truth and nothing but the truth as to his
knowledge touching and concerning the matters in
controversy in this cause; that he was thereupon
examined upon his oath and said examination reduced to
writing by me; and that the statement is a true record
of the testimony given by the witness, to the best of
my knowledge and ability.

I further certify that I am not a relative or
employee of counsel/attorney for any of the parties,
nor a relative or employee of such parties, nor am I
financially interested in the outcome of the action.

WITNESS MY HAND THIS 10th day of October, 2024.

Darlene M. Coppola

DARLENE M. COPPOLA	My commission expires:
NOTARY PUBLIC	November 2, 2029
REGISTERED MERIT REPORTER	
CERTIFIED REALTIME REPORTER	

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
CASE NO. IPR2024-00459
U.S. PATENT 11,634,781

GENEOSCOPY, INC.,

Petitioner

VS.

EXACT SCIENCES CORPORATION,

Patent Owner

I, DUNCAN H. WHITNEY, PH.D., say that I have
read the foregoing deposition and hereby declare under
penalty of perjury the foregoing is true and correct:
(as prepared) (as corrected on errata.)

Executed this _____ day of _____,
2024, at _____, _____.

DUNCAN H. WHITNEY, PH.D.

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CASE: GENEOSCOPY, INC. VS. EXACT SCIENCES
CORPORATION

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