

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 CASE NO. IPR2024-01330
4 U.S. PATENT 11,970,746
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6

7 GENEOSCOPY, INC.,

8 Petitioner

9 vs.

10 EXACT SCIENCES CORPORATION,

11 Patent Owner

12 *****

13 DEPOSITION OF:
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15

16 DUNCAN H. WHITNEY, PH.D.

17 QUINN EMANUEL URQUHART & SULLIVAN LLP

18 111 Huntington Avenue

19 Boston, Massachusetts

20 May 16, 2025 10:02 a.m.

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

Page 1

1 APPEARANCES: 2 Representing the Petitioner: 3 FOLEY HOAG LLP 4 Seaport West 5 155 Seaport Boulevard 6 Boston, MA 02210 7 BY: BRENDAN JONES, PH.D. 8 T 617.832.1000 9 E bjones@foleyhoag.com 10 11 Representing the Patent Owner: 12 QUINN EMANUEL URQUHART & SULLIVAN LLP 13 295 5th Avenue 14 9th Floor 15 New York, NY 10016 16 BY: ANASTASIA FERNANDS, ESQUIRE 17 T 212.849.7000 18 E anastasiafernands@quinnemanuel.com 19 20 21 (Continued on next page) 22 23 24 Page 2	1 INDEX 2 EXAMINATION 3 Witness Name Page 4 DUNCAN H. WHITNEY, PH.D. 5 Direct By MS. FERNANDS 5 6 7 EXHIBITS 8 Exhibit Description Page 9 Exhibit 2050 Duncan H. Whitney 9 10 deposition transcript 11 dated October 10, 2024 12 Exhibit 2051 Transcript of 12 13 videotaped deposition 14 of Duncan Whitney, 15 Ph.D., January 9, 2025. 16 Exhibit 2052 Declaration of Duncan 17 17 Whitney, Ph.D., dated 18 September 26, 2024 19 20 21 22 23 24 Page 4
1 APPEARANCES (Continued): 2 Representing the Patent Owner: 3 (Via Zoom) 4 QUINN EMANUEL URQUHART & SULLIVAN LLP 5 865 South Figueroa Street 6 10th Floor 7 Los Angeles, CA 90017 8 BY: SANDRA L. HABERNY, Ph.D., ESQUIRE 9 T 213.443.3000 10 E sandrahaberny@quinnemanuel.com 11 12 13 Also Present: 14 Alexandra M. Gorman, In-house Counsel, 15 Exact Sciences 16 Sarojini Adusumilli, Exact Sciences (Via Zoom) 17 18 19 20 21 22 23 24 Page 3	1 P R O C E E D I N G 2 3 (Commencing at 10:02 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. We've met in the past. My name is 21 Anastasia Fernands. I'm with Quinn Emanuel 22 Urquhart & Sullivan, and we represent Exact 23 Sciences. 24 A. Yes. Good morning. Page 5

1 Q. Could you please state your full name 2 for the record. 3 A. Yes. Duncan Harrower Whitney. 4 Q. What is your current address? 5 A. I split my time between 25 Channel 6 Center Street in Boston and 49 Quimby Lane in 7 Falmouth. 8 Q. And you have been deposed before? 9 A. Yes. 10 Q. And I believe this is Deposition No. 4 11 in connection with the Exact Sciences and 12 Geneoscopy matters; is that right? 13 A. Four or five, something... 14 Q. Something like that? 15 A. I'm not sure exactly. Yeah, it's at 16 least four. 17 Q. Okay. So you know the process. I 18 would ask that if you don't understand one of 19 my questions today, will you let me know? 20 A. Yes. 21 Q. And if you do answer a question today, 22 I will assume that you understood. Is that 23 fair? 24 A. Yes. Page 6	1 BY MS. FERNANDS: 2 Q. And in Exhibit 1002 on page 210, is 3 that your signature on page 210? 4 A. Yes, it is. 5 Q. And that's dated August 20, 2024; is 6 that right? 7 A. Correct. 8 Q. Since your last deposition in this 9 matter, which I believe was in January, has 10 anything changed for your job 11 responsibilities? 12 MR. JONES: Objection. 13 BY MS. FERNANDS: 14 Q. I'm sorry. That was an incorrect -- 15 since your last deposition in connection with 16 the Exact Science and Geneoscopy matters in 17 general, has anything changed in your job 18 responsibilities? 19 A. No. I still work for the same 20 company. 21 Q. And your title is still the same? 22 A. Correct. 23 Q. Have you been engaged in any -- as an 24 expert in any other matters other than for Page 8
1 Q. Is there any reason that you cannot 2 give complete and accurate testimony here 3 today? 4 A. No. 5 Q. I see you already have in front of 6 you -- 7 A. Yes. 8 Q. -- what is the declaration of Duncan 9 Whitney, and it is in Case No. IPR2024-01330, 10 correct? 11 A. Yes, that's what I have in front of 12 me. 13 Q. And then marked as Exhibit 1002 in the 14 bottom of the page; is that right? 15 A. That's correct. 16 Q. And is the copy that you have a clean 17 copy? 18 A. Yes. 19 MS. FERNANDS: Do you also have 20 a copy with you? 21 MR. JONES: I do. 22 MS. FERNANDS: So we've wasted 23 all of this paper for extra copies. Always 24 better to have them. Page 7	1 Geneoscopy in connection with the Exact 2 Sciences matters since your last depositions? 3 A. No, I haven't. 4 Q. So you've just been handed what has 5 been marked as Exhibit 1001. 6 Do you recognize this? 7 A. Yes. 8 Q. What is this? 9 A. This is the Exact Sciences patent 10 referred to as '746, if we can just call it 11 that. 12 Q. The '746 patent? 13 A. (Witness nodding.) 14 Q. Yes? 15 A. Yes. 16 Q. Is this the patent with respect to 17 which you offered opinions in your declaration 18 that is Exhibit 1002? 19 A. Yes, it is. 20 21 (Exhibit No. 2050 marked for 22 identification.) 23 24 BY MS. FERNANDS: Page 9

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1 Q. So we just handed you what we have 2 marked as Exhibit 2050. And it is a 3 deposition of Duncan H. Whitney dated October 4 10, 2024. 5 Do you recognize this? 6 A. Yes, I think I do. 7 MR. JONES: So just for the 8 record, I'd just like to object to this, or at 9 least portions of this, as under 401 through 10 403, and at least portions of it under 081 11 through 803. 12 MS. FERNANDS: I was hoping to 13 make today quicker by relying on this in some 14 part, but we might have to go through more in 15 that event. 16 BY MS. FERNANDS: 17 Q. Do you recall that you were deposed on 18 October 10, 2024 in connection with 19 IPR2024-00459? 20 A. I do. 21 Q. And do you recognize Exhibit 2050 as a 22 transcript of that deposition? 23 A. Yes, I do. 24 Q. You were under oath when you testified Page 10	1 corrections? 2 A. I believe I did. 3 4 (Exhibit No. 2051 marked for 5 identification.) 6 7 MR. JONES: Same objections with 8 respect to 2051 just for the record. 9 BY MS. FERNANDS: 10 Q. So you've been handed what we've 11 marked as Exhibit 2051. And this is a 12 videotaped deposition -- a transcript of a 13 videotaped deposition of Duncan Whitney, 14 Ph.D., taken Thursday, January 9, 2025. 15 Do you see that? 16 A. Yes. 17 Q. And you gave a deposition on 18 January 9, 2025 in connection with the 19 litigation that is in the district of 20 Delaware, Civil Action No. 231319, correct? 21 A. Sorry. Could you repeat the number. 22 Q. Yes. CA No. 231319 -- 23 A. Yes. 24 Q. -- correct? Page 12
1 on October 10, 2024? 2 A. Yes, I was. 3 Q. You testified truthfully in that 4 deposition? 5 A. Yes, I did, to the best of my ability. 6 Q. And you testified to the best of your 7 ability during the deposition on October 10, 8 2024? 9 A. Uh-huh, yes. 10 Q. Did you review the transcript of your 11 October 10, 2024 deposition after it was 12 taken? 13 A. I have reviewed it. 14 Q. Have you provided any corrections to 15 the transcript of your October 10, 2024 16 deposition? 17 A. I know -- I know that I reviewed the 18 transcript and was asked to make any 19 corrections that were necessary. I know -- 20 with counsel, I know that I had responded 21 back, but I don't recall exactly what the 22 content was at this point. I mean, that was 23 several months ago. 24 Q. Do you recall whether you did make any Page 11	1 A. I see that yes. 2 Q. And you have been handed a copy that 3 is -- has some redactions in it where this is 4 a copy that was filed as it was filed 5 publicly, so confidential information has been 6 redacted from this version. 7 And you were under oath when you 8 testified on January 9, 2025, correct? 9 A. Yes. 10 Q. You testified truthfully in that 11 deposition? 12 A. To the best of my ability, yes. 13 Q. Did you review the January 9 14 transcript after receiving it? 15 A. I believe I did, yes. 16 Q. Do you recall whether you made any 17 corrections to the January 9 transcript? 18 A. Again, I believe that I had at least 19 made comments back to counsel. And again, I 20 don't recall exactly what corrections there 21 may have been. 22 MR. JONES: Just let me remind 23 you, don't disclose -- talk about substantive 24 conversations -- Page 13

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1 THE WITNESS: Sorry. Yes. 2 MR. JONES: -- with counsel. 3 THE WITNESS: Yes. 4 MR. JONES: But you can answer 5 yes or no. 6 BY MS. FERNANDS: 7 Q. So in connection with this IPR -- IPR 8 No. 2024-01330, you have offered certain 9 opinions as to validity of the '746 patent, 10 correct? 11 A. Sorry. Which IPR are you referring 12 to? 13 Q. Sorry. So we're going back to the 14 declaration that is Exhibit 1002. 15 A. Yes. 16 Q. And this is for the IPR that is 17 IPR2024-01330, correct? 18 A. Yes. 19 Q. And in connection with IPR 01330, you 20 have offered certain opinions concerning 21 validity of the '746 patent, correct? 22 A. Correct. 23 Q. Do you know about how much time you 24 spent preparing the declaration that is Page 14	1 degradation than DNA? 2 A. I would say that RNA is more 3 susceptible to degradation in certain 4 conditions than DNA, yes. 5 Q. If RNA is more prone to degradation 6 than DNA in certain conditions, does that make 7 its preservation more difficult? 8 MR. JONES: Objection to form. 9 A. Preservation of any biomolecule for 10 use as a biomarker depends on where it's being 11 isolated from, what are the conditions in 12 which it's being handled, and a variety of 13 other things. And so we would have to qualify 14 those things in order to make any kind of 15 relative statement. 16 BY MS. FERNANDS: 17 Q. If the sample is stool, is RNA more 18 prone to degradation than DNA in a stool 19 sample? 20 A. I believe that the inherent properties 21 of RNA is that it can be more susceptible to 22 degradation and -- because it's single 23 stranded as opposed to the double strandedness 24 of DNA. But I also know that there is plenty Page 16
1 Exhibit 1002? 2 A. No. 3 Q. Do you know about how much time you 4 have spent total working for -- on matters for 5 Geneoscopy? 6 A. Many hours. 7 Q. More than 100? 8 A. I honestly couldn't say. I don't 9 know. Probably yes. 10 Q. In your opinion, Dr. Whitney, is use 11 of RNA as a biomarker challenging? 12 A. Use of RNA? 13 Q. RNA as a biomarker challenging. 14 MR. JONES: Objection. 15 A. Perhaps you could qualify that by 16 putting some bounds on that. There are many 17 commercially available RNA-based biomarkers. 18 BY MS. FERNANDS: 19 Q. Is it your opinion that RNA is 20 inherently unstable? 21 A. My belief is that RNA as a biomarker 22 has more challenges relative to DNA in terms 23 of stability. 24 Q. In your opinion, is RNA more prone to Page 15	1 of prior art before the 2009 prior art date to 2 suggest that RNA can be successfully isolated 3 from stool samples. 4 5 (Exhibit No. 2052 marked for 6 identification.) 7 8 MR. JONES: And I'll make the 9 same objections to at least portions of this 10 that -- under 401 through 403, the parts of 11 this are irrelevant, potential prejudicial. 12 BY MS. FERNANDS: 13 Q. You've been handed what's been marked 14 as Exhibit 2052, and it is a Declaration of 15 Duncan Whitney, Ph.D., in Civil Action 16 No. 23CV1319. 17 Do you see that? 18 A. Yes. 19 Q. And is this a declaration that you 20 prepared? 21 A. Yes. 22 Q. If you turn to page 111 in the back, 23 is that your signature on that page? 24 A. Yes. Page 17

1 Q. And it's dated September 26, 2024, 2 correct? 3 A. That's correct. 4 Q. If you turn to Paragraph 32 of this 5 declaration, do you see, in the first sentence 6 of Paragraph 32, you state, "Use of RNA as a 7 biomarker is challenging because RNA is much 8 less stable than DNA"? 9 Do you see that? 10 A. I see that. 11 Q. Is that an accurate statement? 12 A. I think it's an accurate statement, 13 but again, I think it depends on the 14 conditions and where the RNA is being isolated 15 from. I didn't obviously get into all of the 16 details of that in this sentence here. 17 There's a broad set of literature that would 18 speak to that, so this is a shortened version 19 or shortened explanation. 20 Q. If you go to the fourth sentence in 21 that paragraph, do you see that sentence 22 beginning "the inherent"? 23 A. "The inherent stability of RNA"? 24 Q. And that sentence reads, "The inherent Page 18	1 Q. And then do you see Heading D1? 2 A. (Witness nodding.) 3 Q. Yes? 4 A. Yes, I see that. 5 Q. Heading D1 states, "Different 6 stabilization buffers are required for DNA and 7 RNA," correct? 8 A. I see that written, yes. 9 Q. You were employed by Exact Sciences at 10 one point, correct? 11 A. That's correct. 12 Q. And that was from 2000 until 2005; is 13 that right? 14 A. Yes. 15 Q. While you were employed at Exact 16 Sciences, one of the things you worked on was 17 a DNA stabilizing buffer; is that right? 18 A. Certainly we did -- yes, we did some 19 work on developing stabilization buffers, 20 correct. 21 Q. And were those stabilization buffers 22 for stool? 23 A. Yes, they were. 24 Q. During what time period did you work Page 20
1 instability of RNA, which is more prone to 2 degradation compared to DNA, makes its 3 preservation and extraction difficult, 4 especially from samples like stool that are 5 rich with other components and including 6 degrading enzymes, DNA, and bacteria." 7 Do you see that? 8 A. I see that. 9 Q. Is that an accurate statement? 10 A. I do believe that RNA certainly can be 11 difficult to isolate from stool and that 12 appropriate conditions need to be established 13 in order to show that it can be done, and I 14 also recognize that people have done that. 15 Q. If you turn to page 26 of your 16 declaration, the one that we've marked as 17 2052 -- 18 A. Yes. 19 Q. -- do you see Heading D? 20 A. Yes. 21 Q. And Heading D states "Fecal sample 22 processing is different for different 23 biomarkers," correct? 24 A. Yes. Page 19	1 on stabilization buffers for stool? 2 A. I would say probably for at least the 3 first year, perhaps more. 4 Q. So that's around 2000 to 2001? 5 A. Perhaps, yes. 6 Q. When you were working on 7 stabilizing -- stabilization buffers while at 8 Exact Sciences, what were you seeking to 9 stabilize? 10 A. So our primary objective at that point 11 was to stabilize DNA because of some of the 12 specific biomarkers that we were interested in 13 analyzing at that time. 14 Q. Do you recall any of the components of 15 the buffer that you were working on while you 16 were at Exact Sciences? 17 A. Yes, I do. 18 Q. What were those components? 19 A. I would say one of the primary 20 components was what I'll be call the EDTA, 21 which stands for ethylenediaminetetraacetic 22 acid. 23 Q. Do you recall any of the other 24 components of buffers that you were working at Page 21

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1 on at Exact Sciences for DNA stabilization? 2 A. There were certainly buffers like 3 Tris, which was used for establishing pH 4 bounds, yes. 5 Q. If you could, turn back to what we've 6 marked as Exhibit 2052, Paragraph 55 on 7 page 28. 8 You see that paragraph carries over on 9 to page 29? 10 A. Yes. 11 Q. Do you see the final sentence of that 12 Paragraph 55 on -- that carries to page 29 13 states, "Accordingly, RNA stabilization 14 buffers need to be specifically formulated to 15 address the unique challenges posted by RNA 16 fragility and susceptibility to degradation by 17 RNAses, and thus differ in composition from 18 DNA stabilizing buffers." 19 Did I read that correctly? 20 A. I read the same thing, yes. 21 Q. So if we could, turn back to the 22 declaration for IPR 1330, which is 23 Exhibit 1002, the one you brought with you 24 today. Page 22	1 Q. If you look at Paragraph 221, the 2 third -- the third sentence, do you see that 3 you refer to Example 1 of Kanaoka? 4 MR. JONES: Can you redirect me 5 or -- 6 MS. FERNANDS: So Paragraph 221, 7 the carryover 135 to 136. If I counted right, 8 it is the third sentence of that paragraph. 9 MR. JONES: Okay. 10 A. On the next page, yes, it refers to 11 Example 1. 12 BY MS. FERNANDS: 13 Q. So here in your Declaration 14 Paragraph 221, you refer to Example 1 of 15 Kanaoka, correct? 16 A. Yes. 17 Q. And you state that, "In Example 1, 18 Kanaoka reports that the disclosed fecal COX-2 19 RNA assay exhibited a sensitivity of 90 20 percent and specificity of 100 percent," 21 correct? 22 A. That's what I stated, yes. 23 Q. You go on to state in that paragraph, 24 "One of skill in the art would therefore have Page 24
1 A. Uh-huh. 2 Q. If you could, turn to Paragraph 220 of 3 that declaration. 4 Looking first at the heading of 5 Paragraph 220, Heading B states your opinion 6 that "Lenhard, Itzkowitz, and Vilkin, in 7 further view of Kanaoka, renders obvious 8 Claims 12 and 13," correct? 9 A. Yes, I read the same thing. 10 Q. And then Sub B1 refers to Claim 12, 11 correct? 12 A. It appears, yes, that that states the 13 Claim 12. 14 Q. And in this section, you discuss, 15 among the other references, a reference 16 referred to as Kanaoka; is that right? 17 A. I'm sorry. You're -- what part are 18 you referring to? 19 Q. In the Section B1 with the heading 20 that refers to "Lenhard, in view of Itzkowitz 21 and Vilkin, in further view of Kanaoka." 22 This section discusses the Kanaoka 23 reference, correct? 24 A. Yes. Page 23	1 been motivated to use Kanaoka's mRNA detection 2 assay either in place of or in addition to 3 Lenhard's HIC1 promoter methylation assay to 4 improve assay sensitivity." 5 Do you see that? 6 A. Yes, I see that. 7 Q. And is it your opinion that a person 8 of ordinary skill in the art in 2009 would 9 have been motivated to -- either to add the 10 COX-2 RNA assay to a combination of Lenhard, 11 Itzkowitz, and Vilkin? 12 A. It's my opinion that an expert at that 13 time would be looking for the most informative 14 nucleic acid markers to combine with fecal 15 occult blood testing in order to provide for 16 an overall assay with the best accuracy. 17 Q. When you refer to "an overall assay 18 with the best accuracy," what do you mean by 19 the "best accuracy"? 20 A. What I mean is to maximize the 21 sensitivity and specificity for detection of 22 colorectal cancer. 23 Q. And the person of ordinary skill in 24 the art would be interested in maximizing both Page 25

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1 sensitivity and specificity, correct? 2 A. It's -- it's my opinion that it's 3 important to have high sensitivity and high 4 specificity. That does not mean to say that 5 there's equal ramifications for having 6 suboptimal sensitivity or suboptimal 7 specificity. So there's always a requirement 8 to look at the balance of sensitivity and 9 specificity for these types of overall assays. 10 11 (Stenographer clarification.) 12 13 BY MS. FERNANDS: 14 Q. When you refer to "suboptimal," what 15 do you mean? 16 A. Less than perfect. 17 Q. So anything less than perfect is 18 suboptimal? 19 A. Not necessarily. 20 Q. In your -- in your previous answer, 21 when you used the word "suboptimal," were you 22 referring to less than perfect? 23 A. What I'm saying is that it's important 24 to -- let me rephrase in a different sort of Page 26	1 Q. In what way is -- should sensitivity 2 and specificity be balanced, in your opinion? 3 A. So I'll answer it in the sense that, 4 in my opinion, there's no such thing as a 5 perfect diagnostic test, and, therefore, 6 oftentimes if one were to try to increase the 7 sensitivity of an assay, it's usually at the 8 expense of specificity. And the opposite is 9 also true. And so in order to balance the 10 two, one must be cognizant of what is possible 11 with a given assay. 12 Q. In Paragraph 222 of Exhibit 1002, you 13 state your opinion that "Example 1 of Kanaoka 14 provides further motivation to combine 15 Kanaoka's 2 RNA COX assay with an iFOBT, like 16 the one disclosed in Vilkin." 17 Do you see that? 18 A. Yes. 19 Q. And that third sentence in that 20 paragraph states, "The iFOBT identified a CRC 21 patient as positive that was missed by COX-2 22 RNA assay, while the COX-2 RNA assay 23 identified three CRC patients missed by the 24 iFOBT," correct? Page 28
1 way to make my point more clear. 2 If one were looking at sensitivity of 3 a colorectal cancer assay, a stool-based 4 assay, one would want to make sure that 5 there's as few false negatives as possible 6 because those would be missed cancers. And 7 with a missed cancer in a negative test in 8 that case, they presumably would not go on to 9 a colonoscopy, and they may -- that may end up 10 impacting their mortality. 11 It's also important to have high 12 specificity, but in my opinion, it's less 13 important to have a very high specificity if 14 it's at the expense of a higher sensitivity 15 simply because a false positive test means 16 that those people would go on for a 17 colonoscopy and that colonoscopy may not be 18 required, but at least they would not be -- we 19 would not be talking about a missed cancer. 20 Q. So in your earlier answer, you said 21 that it was important to balance the 22 sensitivity and specificity; is that 23 correct? 24 A. Correct. Page 27	1 A. Correct. 2 Q. So the iFOBT identified one CRC 3 patient that was not identified by the COX-2; 4 is that right? 5 A. In this particular study, which was a 6 relatively small number and not represented -- 7 not representative of a population, that was 8 the result that they found. 9 Q. Why do you point out that this was a 10 relatively small number? 11 A. I point out the size of a study 12 because that dictates the representativeness 13 that that may have for the intended use 14 population. 15 Q. So that you have it, I'm going to hand 16 you Exhibit 1007, which is the Kanaoka 17 reference. 18 A. Okay. 19 Q. And if you'd turn to Paragraph 56 of 20 Exhibit 1007, does Paragraph 56 describe the 21 study population? 22 A. Let me read it. 23 (Witness reviews document.) 24 This -- yes, this paragraph describes Page 29

1 the cohort that they used for this study. 2 Q. Is cohort different than the study 3 population? 4 A. For this discussion, no. 5 Q. In this cohort, there were 30 cases 6 confirmed to have colon cancer; is that 7 right? 8 A. That's correct. 9 Q. And 22 cases with no tumor or 10 inflammatory alteration in their colon, 11 correct? 12 A. That's what it indicates, yes. 13 Q. The final sentence, going back to your 14 declaration in Paragraph 222, in the final 15 sentence of -- 16 MR. JONES: Which declaration? 17 MS. FERNANDS: The declaration, 18 Exhibit 1002. 19 BY MS. FERNANDS: 20 Q. Paragraph 222 that we were looking at 21 before -- 22 A. (Witness nodding.) 23 Q. -- that paragraph starts with 24 "Example 1 of Kanaoka," correct? Page 30	1 clarity, that in the Kanaoka reference itself, 2 that cohort of 30 cancers and 22 controls, my 3 point about a population earlier is that the 4 intended use population is one where -- a 5 screening population, the question would be 6 what is the prevalence of cancer in a 7 population such as that? And it's well known 8 that the number or the proportion of cancers 9 in an average risk population is 1 percent or 10 less, and so this particular cohort certainly 11 does not represent that proportion. 12 Q. You're saying that the proportion 13 of 30 cancer cases to 22 cases with no -- no 14 colon disorder is not representative of the 15 population? 16 A. No, I'm not saying that. What I said 17 is that that's not representative of the 18 intended use population for a screening test. 19 And this was a controlled study, and this is 20 the cohort that they selected to evaluate 21 certain biomarkers. 22 Q. In the Kanaoka reference, in 23 Paragraph 66 of Kanaoka, the results for the 24 immunological fecal occult blood test was 23 Page 32
1 A. Yes. 2 Q. In the final sentence there, you 3 state, "A skilled artisan would therefore have 4 been motivated to combine the Kanaoka fecal 5 COX-2 RNA assay with an iFOBT such as the one 6 disclosed in Vilkin to increase the 7 sensitivity of both assays." 8 Do you see that? 9 A. Yes, I see that. 10 Q. And so in your opinion, the motivation 11 to combine the COX-2 RNA assay with the iFOBT 12 of Vilkin would be increased sensitivity, 13 correct? 14 MR. JONES: Objection. 15 A. In this particular case, they've 16 already established that the specificity is 17 very, very high. And, in fact, with the COX-2 18 RNA assay, it's 100 percent. So to my 19 knowledge, they couldn't expand it any 20 further. So the focus of this sentence and 21 the point being is that they were looking at 22 combining the COX-2 with the FOBT to increase 23 the sensitivity. 24 Now, I'll also point out, just for Page 31	1 among 28 colon cancer cases, and 3 among 22 2 control cases were positive, correct? 3 A. Correct. 4 Q. And so the sensitivity of the iFOBT 5 was 82.1 percent there, correct? 6 A. If that's what that comes out to. I 7 would have to take that at face value. 8 Q. And the specificity is 86.3 percent, 9 correct? 10 A. The same comment. 11 Q. Did you check the math in Kanaoka when 12 you reviewed it? 13 A. I probably did. 14 Q. Do you have any reason to believe that 15 these numbers are incorrect? 16 A. Not to my recollection. 17 Q. So if the COX-2 test and the iFOBT 18 test of Kanaoka were combined, the specificity 19 would be lower than with COX-2 alone, 20 correct? 21 A. That -- in terms of how they ran this 22 particular study, that is one conclusion that 23 one could draw from this. To me, the bigger 24 learning was that the combination of an RNA -- Page 33

1 fecal RNA biomarker and a FOBT leads to 2 complementarity. And I would also note that 3 the FIT test can be adjusted in terms of 4 whatever the threshold that is used there to 5 provide for different levels of sensitivity 6 and specificity. 7 Q. What do you mean by "complementarity?" 8 A. What I mean is that these two types of 9 tests measure two completely different kinds 10 of things, that FOBT tests, in general, are 11 measuring blood in stool, which is indicative 12 of tumors that bleed. It was well known at 13 the time that not all tumors will bleed, and, 14 therefore, one way to be able to improve upon 15 that idea was to be able to look for DNA or 16 RNA coming from sloughed colonocytes. 17 It was also recognized that all tumors 18 will slough colonocytes on a continual basis, 19 and, therefore, the ability to potentially 20 pick up cases that are missed by the FOBT test 21 was there. So in that regard, I review these 22 as complementary. 23 Q. And in the Kanaoka reference, the 24 iFOBT test picked up one cancer that was not Page 34	1 Q. Then the next sentence there, you 2 state, "Example 1 of Kanaoka provides a 3 working example of the successful combination 4 of a COX-2 RNA assay with an iFOBT." 5 Do you see that? 6 A. Yes. 7 Q. What do you mean by "a working 8 example"? 9 A. What I mean by that is that it's not 10 just a -- that they provide data, in short. 11 Q. And I think you still have 12 Exhibit 1007, Kanaoka assay, the Kanaoka 13 reference there, correct? 14 A. Yes. 15 Q. And in Kanaoka, they discuss the COX-2 16 results and iFOBT results separately, 17 correct? 18 MR. JONES: Objection. 19 A. What do you mean by that? 20 BY MS. FERNANDS: 21 Q. At any point in Kanaoka, do they 22 discuss the combined results of COX-2 and 23 iFOBT? 24 A. In this particular -- I would have to Page 36
1 picked up by COX-2 in a cohort of 30 cancers, 2 correct? 3 A. Yeah. Again, in this -- in this 4 relatively small study, that's what they 5 found, but they also found that of the FIT 6 tests that were negative, the COX-2 assay 7 picked up three of the cases that were missed 8 by FIT. 9 Q. Going back to your declaration, which 10 is Exhibit 1002, you see in Paragraph 223 of 11 your declaration, the first sentence you 12 state, "One of skill in the art would have had 13 a reasonable expectation of successfully 14 incorporating the COX-2 fecal RNA assay" with 15 Kanaoka into the fecal -- sorry. Let me start 16 that again. I think I -- strike that one. 17 In Paragraph 223, you state, "One of 18 skill in the art would have had a reasonable 19 expectation of successfully incorporating the 20 COX-2 fecal RNA assay of Kanaoka into the 21 fecal processing method rendered obvious by 22 Lenhard, Vilkin, and Itzkowitz." 23 Do you see that? 24 A. Yes. Page 35	1 read that to be able to truthfully answer your 2 question. I know that there is an 3 accompanying paper from the same author that 4 talks about combining. 5 Q. You did not cite that paper in your 6 declaration, correct? 7 A. I don't recall if I did or -- 8 Q. Let me limit it to here in your 9 opinions in Paragraphs 220 to 224 concerning 10 Claim 12. You did not cite a paper by 11 Kanaoka, correct? 12 A. You're asking in this section alone? 13 Q. Correct. 14 A. It is not cited in that -- in this 15 section. 16 Q. And in this section concerning 17 Claim 12, you cite the Kanaoka reference that 18 is Exhibit 1007 and the Nechvatal reference 19 that is Exhibit 1024, correct? 20 A. Correct. 21 Q. Do you know how to say that name 22 that's in Footnote 304? 23 A. I don't. I say it the same way you 24 do. Page 37

1 Q. Okay. In your declaration at 2 Paragraph 223, what do you mean by "successful 3 combination of COX-2 RNA assay with an 4 iFOBT"? 5 MR. JONES: Objection to form. 6 A. Are you referring to the last 7 sentence -- 8 BY MS. FERNANDS: 9 Q. No. 10 A. -- of the paragraph? 11 Q. Sorry. Going back to where we were in 12 the second sentence where you state, 13 "Example 1 of Kanaoka provides a working 14 example of the successful combination of a 15 COX-2 RNA assay with an iFOBT," do you see 16 that? 17 A. Yes. 18 Q. What do you mean by "successful 19 combination"? 20 A. What I mean is that they provide 21 evidence to show that for cases that are 22 missed by one assay, the other assay can 23 detect cancers and that that goes both ways, 24 meaning when the COX-2 assay misses cancers, Page 38	1 priority date, it had been reported that, 2 'preserving fecal samples at room temperature 3 for a duration of five days, in a medium 4 suitable for DNA and RNA analysis is 5 feasible.'" 6 Do you see that? 7 A. I see that. 8 Q. I did read that correctly? 9 A. Yes. 10 Q. Then you have a footnote there, which 11 is Footnote 304, correct? 12 A. Yes. 13 Q. That Footnote 304 refers to the 14 Nechvatal reference -- 15 A. Yes. 16 Q. -- which is Exhibit 1024? 17 And you do not cite anything else in 18 this paragraph for that, correct? 19 A. We -- I did not, no. 20 Q. If you could, turn to Paragraph 272 of 21 your declaration that's Exhibit 1002. 22 Paragraph 272 on page 160, right above 23 it, there's a Heading D, "Shuber and Vilkin, 24 in view of Kanaoka, render obvious Claims 12 Page 40
1 the FIT test picks it up and vice versa. When 2 the FIT test misses cancer, the COX-2 assay 3 picks those up. 4 Q. Kanaoka does not describe an at-home 5 test, does it? 6 MR. JONES: Objection to form. 7 A. To my knowledge, they do not. 8 (Witness reviews document.) 9 BY MS. FERNANDS: 10 Q. You were just reviewing Kanaoka. 11 Kanaoka does not describe at-home sample 12 collection, correct? 13 A. I didn't see it described there. 14 Sorry. I didn't know you were waiting for me. 15 I thought I had already answered that. 16 Q. When you were reviewing the reference, 17 I wanted to give you an opportunity. 18 A. Oh. 19 Q. If you go back to your declaration at 20 the Exhibit 1002, still in Paragraph 223, do 21 you see a third sentence where you state, "A 22 person of skill in the art would reasonably 23 expect to be able to preserve the fecal RNA in 24 the sample without freezing because by the Page 39	1 and 13." 2 Do you see that? 3 A. Yes. 4 Q. And then D1 refers to Claim 12; is 5 that right? 6 A. Yes. 7 Q. In Paragraph 273, you refer in the 8 second sentence to Example 1 of Kanaoka, 9 correct? 10 A. Yes. 11 Q. And here in this section where you're 12 talking about the Shuber and Vilkin 13 combination in view of Kanaoka, which is 14 Paragraphs 272 through 276, you cite to the 15 Kanaoka reference, which is Exhibit 1007, and 16 the Nechvatal reference that is 1024, correct? 17 A. That's correct. 18 Q. And you do not rely on anything else 19 in this section concerning your opinions about 20 Claim 12 in light of the Shuber, Vilkin, and 21 Kanaoka combination, correct? 22 MR. JONES: Objection to form. 23 A. I'll answer the question that these 24 were the only things that were cited. There's Page 41

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1 a lot more known in the literature about these 2 types of assays. 3 BY MS. FERNANDS: 4 Q. You did not rely on any of that other 5 literature in your opinions expressed here in 6 Paragraphs 272 through 276, correct? 7 A. I did not -- 8 MR. JONES: Objection to form. 9 A. I did not cite them. 10 BY MS. FERNANDS: 11 Q. And then Paragraph 277 on page 163, do 12 you see that? 13 A. Yes. 14 Q. That concerns Claim 13, correct? 15 A. Yes. 16 Q. And in Paragraph 277, you have a 17 citation, Footnote 363, correct? 18 A. Yes. 19 Q. And that is in Id., which is back to 20 the Kanaoka referred to in Footnote 262; is 21 that right? 22 A. Yes. 23 Q. If you could, actually go back to 24 Paragraph 227 -- sorry -- 225. That's on Page 42	1 Exhibit 1002, you have a Heading No. 2 that 2 says "Claim 13," correct? 3 A. Wait. I'm sorry. 4 Q. Page 138. 5 A. Yes. 6 Q. Exhibit 1002, are you with me? 7 A. Yes. 8 Q. There's a heading that is "Claim 13," 9 correct? 10 A. Yes. 11 Q. Under the heading "Claim 13," you have 12 two paragraphs, correct? 13 A. Yes. 14 Q. Paragraphs 225 and 226? 15 A. Yes. 16 Q. And there is one footnote in those two 17 paragraphs. That's Paragraph 306 -- 18 Footnote 306, correct? 19 A. Yes. 20 Q. And that footnote refers -- cites to 21 Kanaoka, correct? 22 A. Yes. Again, I would qualify that, 23 however, by saying that this is not intended 24 to imply that this is the only literature Page 44
1 page 138. 2 In Paragraph 225 on page 138, there's 3 a Footnote 306, correct? 4 A. Yes. 5 Q. That also refers to the Kanaoka 6 reference; is that right? 7 A. This is also with respect to Claim 13, 8 as I read it. 9 Q. Yes. This is under the heading 10 "Claim 13"? 11 A. Yes. That -- so that's referring to 12 Kanaoka. I should point out that in these 13 discussions, talking about RT-PCR and the 14 previous one we were talking about with 15 respect to reverse transcription, generally 16 speaking, that these were well-known 17 methodologies. 18 And although we do refer to a 19 reference here, which is Kanaoka, that is not 20 intended to imply that that is the only 21 example of using RT-PCR or reverse 22 transcription, which was a well-known, 23 preestablished methodology. 24 Q. On page 138 of your declaration that's Page 43	1 showing the use of RT-PCR for detecting RNA. 2 This was a well-established methodology. 3 Q. The only literature that you cited in 4 Paragraphs 225 and 226 is Kanaoka, correct? 5 MR. JONES: Objection to form. 6 A. The -- as an expert witness and as -- 7 and to try to convey what was known at the 8 time by anyone skilled in the art, what I'm 9 suggesting is that there are things that do 10 not need to be cited simply because they were 11 well known in the art. 12 BY MS. FERNANDS: 13 Q. That is not my question, Dr. Whitney. 14 My question is the only reference that you 15 cited in Paragraphs 225 and 226 of your 16 declaration that is Exhibit 1002 is the 17 Kanaoka reference, correct? 18 MR. JONES: Objection to form. 19 A. There is one citation in this 20 paragraph. 21 BY MS. FERNANDS: 22 Q. And that is Kanaoka, correct? 23 MR. JONES: Objection to form. 24 A. That citation is to Kanaoka. Page 45

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1 BY MS. FERNANDS: 2 Q. And that's the Kanaoka that's marked 3 as Exhibit 1007, right? 4 A. Correct. 5 Q. So if we go back to where you discuss 6 the Shuber, Vilkin, and Kanaoka combination 7 starting on page 160 of your declaration, in 8 Paragraph 274, you -- again, Paragraph 274 9 with Example 1 of Kanaoka, correct? 10 A. Yes. 11 Q. And there in Paragraph 274, your 12 opinion is that "Example 1 of Kanaoka provides 13 further motivation to combine Kanaoka's COX-2 14 RNA assay with an iFOBT like the one disclosed 15 in Vilkin," correct? 16 A. Yes. 17 Q. In Paragraph 275 of Exhibit 1002, you 18 refer again to Example 1, correct, in the 19 second sentence? 20 A. Yes. 21 Q. And there you state, "Example 1 of 22 Kanaoka provides a working example of the 23 successful combination of a COX-2 RNA assay 24 with an iFOBT," correct? Page 46	1 Oh, yes, I guess it must be. 2 Q. Underneath that heading, you refer to 3 Claim 12 in Item 1 and Claim 13 in Item 2, 4 correct? 5 A. Yes. 6 Q. Heading G1 refers to claims -- 7 Claim 12, correct? 8 A. Yes, it does. 9 Q. And in Paragraph 330, does that 10 express your opinion with the references back 11 to the other sections concerning obviousness 12 of Claim 12 in light of Inbar, Shuber, Vilkin, 13 and Kanaoka? 14 MR. JONES: Objection to form. 15 A. I'm sorry. I missed the specific 16 question. 17 BY MS. FERNANDS: 18 Q. Sure. Paragraph 330 is the only 19 paragraph under your heading "Claim G1," 20 correct? 21 A. Yes. 22 Q. And Paragraph 330 refers back to 23 Sections 9F and 9B1, correct? 24 A. Yes. Page 48
1 A. Correct. 2 Q. And in Paragraph 275, you continue 3 with the statement "A POSA would be -- would 4 reasonably expect to be able preserve the 5 fecal RNA in the sample without freezing 6 because by the priority date, it had been 7 reported that 'Preserving fecal samples at 8 room temperature for a duration of five days 9 in a medium suitable for DNA and RNA analysis 10 is feasible.'" 11 Do you see that? 12 A. Yes, I see that. 13 Q. And that is -- there is a cite there 14 to Footnote 361, correct? 15 A. Yes. 16 Q. And that footnote is the Nechvatal 17 reference that is Exhibit 1024, correct? 18 A. Yes, it is. 19 Q. Could you turn to Paragraph 330. So 20 Paragraph 330 is under Heading G, "Inbar, 21 Shuber, and Vilkin in further view of Kanaoka 22 render obvious Claims 1 and 2." 23 Is that a typo? The 1 and 2? 24 A. (Witness reviews document.) Page 47	1 Q. And then on the next page, you have 2 Heading G2, correct? 3 A. Yes. 4 Q. And that's with respect to Claim 13, 5 correct? 6 A. Yes. 7 Q. And that's your opinion with respect 8 to Claim 13 concerning the Inbar, Shuber, 9 Vilkin, and Kanaoka combination, correct? 10 A. Let me read it quickly. 11 (Witness reviews document.) 12 Yes. 13 Q. If you could, turn back to 14 Exhibit 1007, the Kanaoka reference. 15 And Kanaoka is titled "Method of 16 detecting colon cancer marker," correct? 17 A. Yes. 18 Q. And in the abstract, in the first 19 sentence, it states, "It is intended to 20 provide a noninvasive and convenient method of 21 detecting a tumor marker for diagnosing colon 22 cancer which is superior in sensitivity and 23 specificity to the existing fecal occult blood 24 test," correct? Page 49

1 A. That's what the first sentence says. 2 Q. The intent was to provide something 3 that was better than fecal occult blood tests, 4 correct? 5 A. I -- I mean, as stated, that's -- 6 they're saying that they want something better 7 than fecal occult blood tests, but that does 8 not preclude the possibility of combining with 9 fecal occult blood test simply due to 10 complementarity that they show. 11 Q. The second sentence there in the 12 abstract says, "More specifically speaking, a 13 method of detecting a tumor marker for 14 diagnosing colon cancer which comprises 15 collecting biological sample which is 16 immediately frozen using liquid nitrogen in 17 some cases," and then the sentence goes on. 18 Do you see that? 19 A. Yes. 20 Q. Were the samples in Kanaoka frozen 21 using liquid nitrogen? 22 MR. JONES: Objection to form. 23 A. I know that some were. I don't 24 know -- I would have to review this to Page 50	1 over an hour. 2 MS. FERNANDS: Sure. We can 3 take a break. 4 THE STENOGRAPHER: We're off the 5 record. 6 7 (Recess taken from 11:07 a.m. 8 to 11:24 a.m.) 9 10 BY MS. FERNANDS: 11 Q. Before the break, we were talking 12 about Exhibit 1007, the Kanaoka reference, 13 correct? 14 A. Yes, among other things. 15 Q. In Paragraph 3 of Kanaoka, do you see 16 the first sentence states, "For the mass 17 screening of cancer, it is important that the 18 detection method is easy and noninvasive." 19 Do you see that? 20 A. Yes, I see that. 21 Q. Would you agree with that statement? 22 A. Not necessarily. 23 Q. In Paragraph 4, do you see the 24 statement "However, the fecal occult blood Page 52
1 determine at what point relative to defecation 2 and testing. I don't recall how much detail 3 they give in terms of exactly when that was 4 done or if that was done for all samples. 5 BY MS. FERNANDS: 6 Q. If you turn to Example 1 in 7 Paragraph 57 -- 8 A. Uh-huh. 9 Q. -- do you see Paragraph 57 states, "As 10 soon as possible after sampling feces, the 11 feces were separated into 5 ml. tubes. 12 About 1 gram each were frozen using liquid 13 nitrogen and were stored at negative 80 14 degrees Celsius." 15 Do you see that? 16 A. Yes, I see that. But I also recognize 17 this is one example, so I don't know that 18 that's representative of everything that 19 they're trying to claim. 20 Q. And there is only one other example, 21 Example 2, correct? 22 A. There is another example, 2, yes. 23 MR. JONES: When you get a 24 chance, can we take a break? We've been going Page 51	1 test has a rather low sensitivity and 2 specificity" -- then it refers in a parens -- 3 "(the sensitivity, 30 to 90 percent; the 4 specificity, 70 to 98 percent) because 5 appearance of hemoglobin in feces is not 6 specific to tumor." 7 Do you see that? 8 A. Yes. 9 Q. That is a statement with respect to 10 fecal occult blood tests, correct? 11 A. As stated, yes. 12 Q. In Paragraph 8, Kanaoka refers to 13 "Further, as an alternative method to the 14 fecal occult blood test, in order to detect 15 gene expression more directly, a method for 16 detecting mRNA of protein kinase C (PKC) or 17 the like in the feces has been developed," and 18 then it gives a citation. 19 Do you see that? 20 A. Yes. 21 Q. So then in the next paragraph, 9, it 22 begins, "However, the method making use of RNA 23 described above could not have the sensitivity 24 exceeding that of the fecal occult blood test Page 53

1 method because it was impossible to extract 2 RNA easily and efficiently from a small amount 3 of feces." 4 Do you see that in Paragraph 9? 5 A. Yes, of course, I see that written 6 there. It's -- it appears to be referring to 7 the reference in the previous paragraph, but 8 I'm not familiar with the data in that 9 reference as I sit here today. 10 Q. That was going to be my question. 11 Is -- Paragraph 9, to your understanding, 12 it -- does it appear to be referring to the 13 reference in Paragraph 8? 14 MR. JONES: Objection to form. 15 A. It's unclear, but it says, "However, 16 the method making use of RNA described above," 17 so I'm not exactly sure which part it's 18 referring to. 19 BY MS. FERNANDS: 20 Q. And in the eight preceding paragraphs 21 of Kanaoka, only Paragraph 8 refers to RNA, 22 correct? 23 A. Let me review. 24 (Witness reviews document.) Page 54	1 "Accordingly, it has been considered 2 impossible to extract RNA directly from feces 3 containing enormous amounts of RNases derived 4 from very large amount of microorganisms, and 5 a separation of the cell fraction has been 6 considered to be essential for removing at 7 least exogenous RNases derived from 8 microorganisms or the like." 9 Do you see that? 10 A. I see that. I'm not sure that I 11 completely agree with that. 12 Q. Based on what is -- Kanaoka states in 13 the background of the invention for what is 14 Exhibit 1007, correct? 15 A. That's what he seems to be stating, 16 yes. 17 Q. And then after providing that 18 background of the invention, Kanaoka states in 19 Paragraph 14, "Surprisingly, however, the 20 inventor of the present invention found in 21 some cases homogenization of frozen biological 22 materials in presence of RNase inhibitors can 23 resolve the problems described above and has 24 completed the present invention." Page 56
1 It does appear that that's the only 2 reference specifically to RNA. There are 3 other references to fecal DNA. 4 Q. And in Paragraph 11 of Kanaoka, 5 Kanaoka states, "However, since RNA is more 6 unstable compared with DNA and is always 7 subjected to a danger of decomposition by RNA 8 digesting enzymes, RNases, which are 9 ubiquitous in all the biological samples and 10 very stable. Strict control to avoid 11 contamination of RNases is necessary in the 12 RT-PCR method during and after purification 13 processes of RNA." 14 Do you see that? 15 A. I see that. 16 Q. And that's as stated in Paragraph 11 17 of Kanaoka, correct? 18 A. Yes. 19 Q. Kanaoka states in Paragraph 13, 20 "Accordingly, it has been considered 21 impossible to extract RNA directly from feces 22 containing enormous amounts of R" -- strike 23 that. Let me try that again. 24 Paragraph 13 of Kanaoka states, Page 55	1 Do you see that? 2 A. I see that. 3 Q. And in Paragraph 14, Kanaoka refers to 4 frozen biological samples, correct? 5 A. (Witness reviews document.) 6 He refers to frozen samples in that 7 paragraph. He also in the abstract, as we 8 reviewed earlier, talked about samples that 9 were frozen in some cases, suggesting that 10 freezing samples is not always required. 11 Q. The statement in the abstract is 12 that -- he states, "More specifically 13 speaking, a method of detecting a tumor marker 14 for diagnosing colon cancer which comprises 15 collecting biological sample which is 16 immediately frozen using liquid nitrogen in 17 some cases," correct? 18 A. Yes. What you have just read is in 19 the abstract. 20 Q. Is that the section of the abstract to 21 which you're referring? 22 A. Yes. 23 Q. Is it -- isn't it the case that the 24 "in some cases" could be referring to the use Page 57

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1 of liquid nitrogen? 2 MR. JONES: Objection to form. 3 A. You're asking is -- when the samples 4 are frozen, are some of those cases using 5 liquid nitrogen? 6 BY MS. FERNANDS: 7 Q. In your earlier answer, you referred 8 to the abstract and pointed out the "in some 9 cases" language, correct? 10 A. What I was pointing out is that he 11 talks about freezing samples immediately "in 12 some cases," which implies that samples are 13 not always immediately frozen. 14 Q. Well, he says "immediately frozen, 15 using liquid nitrogen in some cases," 16 correct? 17 A. That's what he's written. 18 Q. And you interpret that to mean that 19 "frozen in some cases," correct? 20 A. What I am -- what I interpret, which 21 is what I would also say is that people 22 skilled in the art would recognize is that it 23 doesn't have to be frozen. 24 Q. In Paragraph 15, the summary of the Page 58	1 done regularly in many different diagnostic 2 fields. 3 BY MS. FERNANDS: 4 Q. In Paragraph 15 of the Kanaoka 5 reference, the reference states that it is "an 6 object of the present invention to provide a 7 noninvasive and convenient tumor-marker 8 detecting method for diagnosing colon cancer, 9 which is superior in sensitivity and 10 specificity to the existing fecal occult blood 11 test," correct? 12 A. As is written -- you've read what's 13 written on the page. So I'm not disputing 14 what's written on the page. I'm offering my 15 further interpretation. 16 Q. Turning to Example 1, which begins at 17 Paragraph 55 -- 18 A. Okay. 19 Q. -- we discussed earlier in 20 Paragraph 56, "The cohort is 30 cases 21 confirmed to have colon cancer and 22 cases to 22 have no tumor or inflammatory alteration in 23 their colon," correct? 24 A. Yes, as determined by colonoscopy as Page 60
1 invention, Paragraph 15 states, "It is 2 therefore an object of the present invention 3 to provide a noninvasive and convenient 4 tumor-marker" detect -- "tumor-marker 5 detecting method for diagnosing colon cancer, 6 which is superior in sensitivity and 7 specificity to the existing fecal occult blood 8 test." 9 Do you see that? 10 A. Yes, I see that. 11 Q. And that was the object of Kanaoka's 12 work, is that correct, in this patent? 13 MR. JONES: Objection to form. 14 A. He certainly has -- he uses the word, 15 "It is therefore an 'object' of the present 16 invention," which I could presume means his -- 17 a -- objective. But my interpretation of this 18 and I think someone skilled in the art at the 19 time would interpret this as fecal occult 20 blood testing as being the standard at the 21 time for noninvasive fecal testing and that 22 one could use that as a reference to compare 23 results to, but it does not obviously preclude 24 the notion of combining the two things and is Page 59	1 the reference standard. 2 Q. In Paragraph 57, it states, "As soon 3 as possible after sampling feces, the feces 4 were separated into 5 mil. tubes. About 1 5 gram each were frozen using liquid nitrogen 6 and were stored at negative 80 degrees 7 Celsius," correct? 8 A. I see that written, yes. 9 Q. And Paragraph 57 goes on to state, 10 "Also for comparison and reference, human 11 hemoglobin (HB) in the feces of each sample 12 was measured by the immunological fecal occult 13 blood test." 14 Do you see that? 15 A. Yes. 16 Q. In Paragraph 65, it states that "COX-2 17 was detected in 27 cases among the 30 colon 18 cancer cases," correct? 19 A. That's what's written here, yes. 20 Q. And COX-2 was not detected in any of 21 the 22 cases in the control group, correct? 22 A. It does further describe that in this 23 example, yes. 24 Q. And this is Example 1, correct? Page 61

1 A. Yes. 2 Q. And this is the example that you 3 described as a working example in your 4 declaration, correct. 5 If you -- 6 A. My only hesitation is that we refer 7 many times to Kanaoka, so... 8 Q. Would you turn to Paragraph 223 of 9 your declaration. 10 A. 223. Yes. 11 Q. And in Paragraph 223, in the second 12 sentence, you state, "Example 1 of Kanaoka 13 provides a working example," correct? 14 A. Yes. But what I want -- what I want 15 to add just for context -- and I think I've 16 stated this before -- is that I do believe 17 that what -- what this example provides for is 18 an example of how -- in this particular study, 19 how the COX-2 test could be additive to the 20 FOBT test that they used and vice versa and 21 that that's a key learning, but that is not 22 intended to imply that this is representative 23 of a screening population. 24 Q. Would it be important to a person of Page 62	1 test all 30 cancer samples. 2 Q. And when you say why they didn't test 3 all 30 cancer samples, you're referring to 4 the 28 cancer cases referred to in 5 Paragraph 66? 6 A. Yes. 7 Q. In Paragraph 75 -- 8 MR. JONES: Of Kanaoka. 9 MS. FERNANDS: On Kanaoka still. 10 BY MS. FERNANDS: 11 Q. Paragraph 75, Exhibit 1007, do you see 12 the second sentence of Paragraph 75 where it 13 states, "Also the detection of COX-2 from the 14 feces by the RT-PCR technique had 90 percent 15 sensitivity and 100 percent specificity, and 16 it is proved the present invention is superior 17 to a conventional technique of the 18 immunological fecal occult blood test"? 19 Do you see that? 20 A. I see that, yes. 21 Q. So Kanaoka concluded that the COX-2 22 test was superior to the iFOBT, correct? 23 A. I believe that he seems to be 24 concluding that, that it proved that this is Page 64
1 ordinary skill in the art that the cohort be 2 representative of the screening population? 3 MR. JONES: Objection to form. 4 A. What I believe is important to someone 5 skilled in the art is to understand the limits 6 of any particular study design when they're 7 trying to interpret how that could be used in 8 a different population. 9 BY MS. FERNANDS: 10 Q. In the study population, in 11 paragraph -- as discussed in Paragraph 66 of 12 Kanaoka, the iFOBT detected 23 of 28 colon 13 cancer cases, correct? 14 A. That's what it states, yes. 15 Q. And Kanaoka does not explain why 16 it's 28 for the iFOBT and 30 for the CRC, does 17 it? 18 A. I would have to read this more 19 carefully again to refresh my memory to answer 20 your question. Shall I do that? 21 Q. Please go ahead and read Example 1. 22 A. (Witness reviews document.) 23 In my reading of just the Example 1, I 24 don't see any explanation of why they didn't Page 63	1 better than the FIT test that they used. But 2 again, I think this is a relatively small 3 study and is not representative of a screening 4 population, so the -- an expert would question 5 whether that was true, generally speaking, for 6 the intended use of this type of test. 7 Q. You've referred several times to 8 Kanaoka being a relatively small study. Did 9 you do anything to try to determine whether 10 the results of Kanaoka were statistically 11 significant? 12 A. I believe I may have looked at that, 13 yes. 14 Q. Did you include any calculations in 15 your report concerning whether the results of 16 Kanaoka were statistically significant? 17 A. Let me review quickly. 18 (Witness reviews document.) 19 I don't believe I did, but I know that 20 I had looked at some of those numbers myself, 21 and I know that I -- I recall convincing 22 myself that there were some statistically 23 significant differences of incorporating the 24 FOBT [sic] with the FIT test. Page 65

1 BY MS. FERNANDS: 2 Q. When you say you recall convincing 3 yourself that there were statistically 4 significant differences of incorporating FOBT 5 with the -- I think you said FOBT with the FIT 6 test? 7 A. Sorry. I misspoke. 8 Q. Okay. 9 A. COX-2 with the FIT test. 10 Q. When you say that you convinced 11 yourself they were statistically significant 12 differences combining COX-2 with the FIT test, 13 when did you -- when did you engage in that 14 analysis? 15 A. I don't recall. 16 Q. Do you recall if you calculated a 17 p-value? 18 A. I believe that that was probably part 19 of my convincing. 20 Q. Do you recall what that p-value is? 21 A. I recall calculating a p-value less 22 than .05. 23 Q. Is it important to calculate a p-value 24 that's less than .05? Page 66	1 together and that if one also recognizes that 2 as a sample study size was relatively small, 3 it could still provide motivation for -- for 4 doing other studies and recognizing the 5 learnings. 6 Q. Turning back to Exhibit 1007, the 7 Kanaoka reference, please -- 8 A. Yes. 9 Q. -- can you look at Paragraph 77 of 10 Kanaoka. 11 A. Yes. 12 Q. Paragraph 77 states that "While the 13 conventional technique of the fecal occult 14 blood test targets a general and indirect 15 event, 'bleeding' from the lesion, the method 16 of the present invention targets a specific 17 and direct event, the expression of a marker 18 of carcinogenesis COX-2." 19 Do you see that? 20 A. Yes, I see that. 21 Q. Kanaoka goes on to state, "Therefore, 22 the data obtained by the method of present 23 inventions provide diagnosis with higher 24 quality." Page 68
1 MR. JONES: Objection to form. 2 A. That's a very general statement. 3 BY MS. FERNANDS: 4 Q. Why did you bring up a p-value of less 5 than .05? 6 A. Typically, that threshold is used 7 as a -- as a measure of significance. It's 8 not necessarily the only p-value that could be 9 used, and there's also other means of 10 measuring significance. 11 Q. But you believe that when you 12 undertook to convince yourself that this was 13 statistically significant, that you would have 14 looked at the p-value? 15 A. I believe I would have, but even -- I 16 mean, I think that -- I don't want to focus 17 too much on p-values and significance either 18 in the sense that I think that one can look at 19 a result and see that -- even -- let me put it 20 this way. Even if a result were not 21 significant but one could clearly see that 22 cases were being picked up with one assay that 23 were missed by another, that there was some 24 additive nature to using those two assays Page 67	1 Do you see that? 2 A. I see that. 3 Q. And Kanaoka is concluding here that 4 "COX-2, unlike fecal occult blood test, is not 5 dependent on bleeding"; is that right? 6 A. Yeah, I don't know that it's a 7 conclusion, but he is certainly stating that 8 COX-2 is separate from bleeding. 9 Q. And going on to Paragraph 78, Kanaoka 10 states, "Accordingly, the method of the 11 present invention is clinically very useful as 12 a novel noninvasive screening method with high 13 specificity and high sensitivity," correct? 14 A. He states that. I don't -- I don't 15 necessarily agree with that. 16 Q. You chose to rely on the Kanaoka 17 reference in your opinions in your 18 declaration, correct? 19 A. Yes. My point of my earlier comment 20 is that he specifically mentions that this is 21 useful clinically. For all the reasons that 22 we were discussing earlier in terms of the 23 study cohort and whether or not that's 24 representative of the intended use population, Page 69

1 leads me to believe that that conclusion might 2 be a little premature, but it doesn't take 3 away from using this particular reference to 4 show that there is benefit in combining a 5 fecal RNA test with an FOBT test. 6 Q. So your potential disagreement with 7 Paragraph 78 [sic] of Kanaoka Exhibit 1007 is 8 with respect to the conclusions about clinical 9 usefulness; is that accurate? 10 A. You mean 0078? 11 Q. Yes, 0078, yes. 12 A. What he's stating is that 13 "Accordingly, the method of the present 14 invention is clinically very useful," and he 15 goes on. And my point is that I don't believe 16 that he has proven that this is clinically 17 useful here. I think what he has shown clear 18 evidence for is that there are advantages of 19 combining fecal RNA with FOBT. 20 Q. You can set Kanaoka aside. 21 Before 2009, had you ever developed a 22 buffer to stabilize hemoglobin in stool? 23 A. Have I developed a... 24 I had not specifically worked on Page 70	1 of DNA and are therefore used when long DNA, 2 mutated DNA, or methylated DNA is used as a 3 biomarker," correct? 4 A. That's what's written, yes. 5 Q. Then the footnote there is 6 Footnote 85, correct? 7 A. Yes. 8 Q. And you cite three references there; 9 is that correct? 10 A. There are references to Olson, Shuber, 11 and Itzkowitz. Yes, three. 12 Q. So the first item in your Footnote 85 13 is Olson, Exhibit 1022, correct? 14 A. Yes. In 84 and 85, yes. 15 Q. And I've just handed you what is the 16 Olson reference, marked as Geneoscopy 17 Exhibit 1022. Is that what you cite in your 18 Footnote 85? 19 A. Yes. 20 Q. And you are an author on the Olson 21 reference, correct? 22 A. Yes. 23 Q. And in your Exhibit 85, you cite Olson 24 at page 183; is that right? Page 72
1 stabilizing hemoglobin from stool. 2 Q. Have you at any time worked on 3 stabilizing hemoglobin in stool? 4 A. I don't believe so. 5 Q. If you could, go back to your 6 declaration, which is Exhibit 1002, and 7 Paragraph 75 of your declaration. 8 In Paragraph 75, you state, "As a 9 result of the above concerns, many assays used 10 different stabilizing buffers to minimize loss 11 of sample integrity between at-home sample 12 collection and laboratory analysis without 13 freezing." 14 Do you see that? 15 A. Yes. 16 Q. And then your footnote there is 17 Footnote 84, correct? 18 A. Correct. 19 Q. And Footnote 84 refers to Olson, 20 Shuber, Vilkin, Lapidus 178, and Itzkowitz, 21 correct? 22 A. That's correct. 23 Q. In the next sentence, you state, "For 24 example, certain buffers prevent degradation Page 71	1 MR. JONES: In your 2 Exhibit 85... 3 BY MS. FERNANDS: 4 Q. I'm sorry. In your Footnote 85. 5 Thank you. 6 In your Footnote 85 on page 50 of 7 Exhibit 1002, you cite Olson at page 183, 8 correct? 9 A. That appears to be correct. 10 Q. Does Olson at page 183 provide the 11 components of a stabilization buffer? 12 A. Let me read. 13 (Witness reviews document.) 14 So your question is specifically about 15 components within a stabilization buffer? 16 Q. Yes. 17 A. I don't see anywhere on this 18 particular page the description of 19 stabilization buffers. There are certainly 20 several mentions of using a buffer to 21 stabilize samples, and it's possible that 22 there are descriptions of the components in 23 subsequent pages. 24 Q. If you turn to the next page, which is Page 73

1 page 184 as numbered in the reference, page 2 2 of the exhibit, in the "Materials and Methods" 3 section, the second paragraph -- 4 A. Uh-huh. 5 Q. -- do you see the third sentence -- 6 fourth sentence of the second paragraph begins 7 "stabilization buffer"? 8 A. Yes, I see that. 9 Q. And that sentence reads, 10 "Stabilization buffer consisted of 0.5 mole 11 per liter Tris, 0.15 mole per liter EDTA, 12 and 10 millimole per liter NaCl (pH 9.0)." 13 Do you see that? 14 A. I see it. 15 Q. Do you recall whether those are the 16 components of a buffer that you worked on 17 while you were with Exact Sciences? 18 A. I believe this is one of the buffers 19 that we had worked with. 20 Q. Do you know whether that buffer would 21 also stabilize hemoglobin in stool? 22 A. As I stated earlier, I wasn't working 23 on buffers to stabilize hemoglobin in stool, 24 so I don't recall testing this particular Page 74	1 may not be maintained at a sufficiently low 2 temperature to preserve indicia of disease." 3 Do you see that? 4 A. Yes. 5 Q. In that page 10, lines 10 to 15, it 6 does not discuss the components of a 7 stabilization solution, correct? 8 A. What -- what it's discussing is the 9 amount of buffer that's added to different 10 quantities of stool sample. I don't see in 11 that particular section any mention of the 12 component of a buffer. 13 Q. Were you looking at lines 10 to 15 14 when you referred to the amount of buffer to 15 be added to stool sample? 16 A. Sorry. It's talking about the amount 17 of stool sample. 18 Q. If you turn to what I believe is -- 19 page 33 of the application, the page number at 20 the top, 33 -- there are page numbers at the 21 top, so the page numbered 33 at the top. 22 A. Oh, okay. 23 Q. And if you need to orient, these are 24 claims that begin on page 30 of this patent Page 76
1 buffer on stability of hemoglobin. 2 Q. I'm handing you what's been marked as 3 Exhibit 1008, and Exhibit 1008 is an 4 International Patent Publication 5 No. WO 2005/113769. 6 Is this the reference that you refer 7 to as the Shuber reference? 8 A. Yes, I believe it is. 9 Q. And that Shuber reference is cited in 10 a variety of places, including in Footnote 85 11 on page 50 of your declaration, correct? 12 A. Certainly it's cited in Citation 85, 13 yes. 14 Q. And Citation 85, you cite to page 10 15 at lines 10 to 15; is that right? 16 A. Yes, I think that's what that 17 annotation means. 18 Q. That annotation is 10:10-15, right? 19 A. Yes. 20 Q. And at page 10, lines 10 to 15, it 21 begins, "In one aspect of the invention a 22 stabilization solution may be particularly 23 useful when samples are not refrigerated or 24 frozen or when there is a risk that a sample Page 75	1 application. 2 Do you see that? 3 A. Yes. 4 Q. So on page 33, there is a Claim 5 No. 30; is that correct? 6 A. Yes, there is. 7 Q. And in Claim No. 30, the claim begins, 8 "a method for preparing nucleic acid for an 9 assay for diagnosing a carcinoma or adenoma, a 10 method comprising," there's a colon there, and 11 it goes on, correct? 12 A. That's what's written. 13 Q. And then continuing on in that claim 14 at about line 14, it begins, "Wherein said 15 stabilization solution is about pH 7.5 to 16 about pH 8.5." 17 Do you see that? 18 A. Yes, I see that. 19 Q. And it continues on, "and comprises 20 0.5 millimolar to 25 millimolar Tris"; is that 21 right? 22 A. Comprises 0.5 millimolar to 25 23 millimolar Tris, yes. 24 Q. Then 0.01 to 2.5 millimolar EDTA, Page 77

20 (Pages 74 - 77)

1 correct? 2 A. Yes. 3 Q. And then it continues, "and 100 4 millimolar to 200 millimolar NaCl," correct? 5 A. Yes. 6 Q. Does that describe a stabilization 7 solution that you were working on while you 8 were with Exact Sciences? 9 A. I mean, again, this is one set of 10 embodiments of a buffer that we were working 11 on -- that I was working on. 12 Q. And you are a named inventor on this 13 patent application that is Exhibit 1008, 14 correct? 15 A. Yes. 16 Q. And the applicant for this patent 17 application was Exact Sciences Corporation, 18 right? 19 A. Yes. 20 Q. So I've just handed you what has been 21 marked as Geneoscopy Exhibit No. 1006, a 22 reference with first author Itzkowitz. 23 Do you recognize this? 24 A. (Witness reviews document.) Page 78	1 declaration that is marked as Exhibit 1002, in 2 Paragraph 75, the final sentence of 3 Paragraph 75, you state, "Other buffers 4 stabilize blood proteins and are therefore 5 used when blood proteins are used as a 6 biomarker." 7 Do you see that? 8 A. I see that. 9 Q. And then you have Footnote 86 there, 10 correct? 11 A. Correct. 12 Q. The first reference cited in 13 Paragraph 86 is Vilkin; is that right? 14 A. Yes. 15 Q. That's Exhibit 1005? 16 A. Yes. 17 Q. And I've just handed you Exhibit 1005, 18 the Vilkin reference. 19 Your citation to Vilkin is to 20 pages 2520 to 2521, correct, in exhibit -- in 21 Footnote 86? 22 A. 2520 to 2521. 23 Q. And Vilkin does not identify the 24 components of a buffer solution, does it? Page 80
1 Yes, I do. 2 Q. And if we look back at Footnote 85 on 3 page 50, Itzkowitz is the third reference 4 cited there, correct? 5 A. Yes. 6 Q. You cite there page 111 to 112 of 7 Itzkowitz, right? 8 A. In Citation 85, yes. 9 Q. Itzkowitz does not describe the 10 components of any buffer solution on pages 111 11 to 112, correct? 12 A. Give me a minute to review. 13 (Witness reviews document.) 14 I don't see on page 111 or 112 the 15 specific description of the buffer 16 composition, but I do see that they refer to 17 the addition of a DNA stabilizing buffer to a 18 stool sample with a reference to the Olson 19 paper that we were looking at previously. 20 Q. And that's -- the Footnote 7, correct, 21 refers to Olson, which is Exhibit 1022, also 22 cited in your Footnote 85? 23 A. Correct. 24 Q. So if you look back at your Page 79	1 A. (Witness reviews document.) 2 I don't see that they specify what's 3 in the buffer. They talk about using a 4 hemoglobin-stabilizing buffer, and that seems 5 to be to the extent of the description. 6 Q. And that's on page 2520 in fecal 7 sampling. They state, "The tip is then put in 8 a closed amount of Hb stabilizing buffer," 9 correct? 10 A. That's what they say. 11 Q. And is that what you were referring to 12 when you referred to them describing the use 13 of a hemoglobin-stabilizing buffer? 14 A. Yes. 15 Q. So in your declaration, Exhibit 1002 16 at Footnote 86, the next reference you cite is 17 Grow, Exhibit 1041, correct? 18 A. Correct. 19 Q. And I you've just been handed a 20 reference that is Patent No. 5,198,365, first 21 inventor, Grow. That's been marked as 22 Geneoscopy Exhibit 1041. 23 Is that the Grow reference that you 24 cite in Footnote 86? Page 81

1 A. Yes, I believe it is. 2 Q. In Footnote 86, you cite Grow, 3 Exhibit 1041, abstract, correct? 4 A. That's what we cite, yes. 5 Q. Can you identify in the abstract the 6 reference to a buffer that will stabilize 7 blood proteins? 8 A. Sorry. Could you repeat the specific 9 question. 10 Q. What in the abstract are you referring 11 to as other buffers that stabilize blood 12 proteins, the sentence for which you use Grow 13 as a footnote? 14 A. Well, there's a couple of mentions of 15 buffers. The very first line reads, "A method 16 for preparing a fecal sample for immunoassay 17 testing, comprising the steps of dispersing a 18 sample of from 1 to less than 10 percent 19 weight of a stool sample in an aqueous fecal 20 test solution formulated with one or more 21 preservatives and a light stabilizing agent 22 and endogenous interference-reducing agents." 23 Q. And is it your understanding that that 24 is a buffer that could be used to preserve Page 82	1 test solution is a buffer that stabilizes 2 blood proteins? 3 A. The last part of the abstract talks 4 about "for determining human hemoglobin in a 5 sample of human stool." 6 Q. And that last sentence refers to 7 "determining human hemoglobin in a sample of 8 human stool, the aqueous fecal test solution 9 preferably contains..." correct? 10 A. I can read the full sentence, if you'd 11 like. 12 Q. Well, it refers to a fecal test 13 solution. Is it your understanding that a 14 fecal test solution and a buffer for 15 stabilizing blood proteins are the same 16 thing? 17 MR. JONES: Objection to form. 18 A. Not generally speaking, no. 19 Q. So continuing with Footnote 86 on 20 page 50 of Geneoscopy Exhibit 1002, your 21 declaration, the next reference that's cited 22 is cited as Karl, correct? 23 A. In Citation 86, yes, it's Karl. 24 Q. And Karl is Exhibit No. 1045, right? Page 84
1 blood proteins for purposes of transporting a 2 sample? 3 MR. JONES: Objection to form. 4 A. For the sake of this particular 5 reference, which it's talking about fecal 6 sample immunoassay methods for testing 7 hemoglobin, my understanding is that it's 8 describing solutions which could be used to 9 stabilize the analytes of interest, just 10 judging from that sentence alone. 11 BY MS. FERNANDS: 12 Q. Is there anything else in the abstract 13 on which you're relying for the buffers that 14 stabilize blood proteins? 15 A. The abstract goes on to say, "Fecal 16 test solutions contain suitable stool 17 stabilizers such as buffers and antimicrobial 18 agents, analyte protecting agents such as 19 proteolytic, reductive or oxidative enzyme 20 inhibitors, endogenous assay interference 21 enzyme inhibitors such as a reducing agent, 22 and nonspecific binding inhibitors such as 23 animal proteins." 24 Q. And is it your understanding that that Page 83	1 A. Correct. 2 Q. And you have in front of you now 3 Exhibit 1045, the Karl reference that you 4 cite? 5 A. Yes. 6 Q. And your citation in Footnote 86 is to 7 Karl at page 1127, correct? 8 A. Yes. 9 Q. I understand you'll probably need an 10 minute to look. Can you identify for me on 11 page 1127 the buffer that stabilizes blood 12 proteins that you're referring to in Karl? 13 A. (Witness reviews document.) 14 I don't see a description of the exact 15 buffer that I was citing to. It's possible I 16 cited to the wrong page. There is a 17 description on the right-hand side about 18 halfway down on page 1127 where the authors 19 talk about -- or they say, "Because patients 20 in a screening situation are likely to collect 21 stool samples at home, the sampling procedure 22 and analyte stability are crucial. Novel 23 sampling devices that are prefilled with 24 extraction buffer and can be mailed to the Page 85

1 laboratory at ambient temperature have been 2 introduced." 3 And in this context, although they 4 refer to that as an extraction buffer, they're 5 clearly describing, at least functionally, a 6 buffer which I would take to be a 7 stabilization buffer. 8 Q. And in that discussion in Karl, they 9 do not identify the components of any of those 10 extraction buffers, correct? 11 A. In that part which I was just reading 12 from, they certainly do not describe the 13 components. I could review the materials and 14 methods to see if they describe that any 15 further. 16 Q. Well, if you look at the fecal 17 analysis on page 1124, that refers to "stool 18 samples processed in a single laboratory with 19 a modification of a recent procedure using a 20 freshly prepared extraction buffer." 21 Does that appear to be the same 22 extraction buffer that they're talking about 23 later? 24 MR. JONES: Objection to form. Page 86	1 Q. On page 1573, at the top of the page, 2 left-hand column, it states that "Hemoglobin 3 is likely to be degraded by bacteria or 4 enzymes contained in feces." 5 Do you see that, the beginning of that 6 paragraph? 7 A. Yes. 8 Q. The third sentence in that paragraph 9 says, "In this study, feces were collected 10 into a buffer fluid." 11 Do you see that? 12 A. Yes. 13 Q. Other than that reference to the 14 buffer fluid -- and take whatever time you 15 need to look at it -- is there anything else 16 to which you were referring in Hirata as 17 showing a buffer that stabilizes blood 18 proteins? 19 A. (Witness reviews document.) 20 After reading, I don't believe there's 21 any other mentions of buffers on this page. 22 This is also -- again, it's also possible that 23 I may have not referenced the correct page. 24 There might be other details about buffers on Page 88
1 A. I have no idea. I mean, they use the 2 same description as an extraction buffer, 3 which in this case I believe is a true and 4 accurate description of the buffer because 5 they're processing the stool sample. 6 In the other reference which I read 7 from on page 1127, as I indicated before, they 8 describe it as an extraction buffer, but the 9 functional use of that buffer in that context 10 acted as a stabilization buffer. 11 Q. So still -- or going back to 12 Exhibit 1002, your declaration, Footnote 86, 13 the last reference there is Hirata, 14 Exhibit 1070, correct? 15 A. Correct. 16 Q. And you've just been handed a 17 reference with first author Hirata that's 18 marked as Geneoscopy Exhibit 1070. 19 Is that a reference that is cited in 20 your declaration? 21 A. Yes. 22 Q. You cite page 1573 of Hirata, 23 correct? 24 A. Yes. Page 87	1 other pages. 2 Q. Feel free to look at the "Materials 3 and Methods" and whatever else you need to see 4 if there's any description of the buffer or 5 other reference to it. 6 A. (Witness reviews document.) 7 Yes, after reviewing "Materials and 8 Methods," I don't see any other detail on the 9 specific buffers, but the primary reason for 10 citing this paper is to -- and as evidenced 11 from that initial paragraph you were drawing 12 attention to, which is to say that buffers can 13 be added to stool samples to stabilize the 14 hemoglobin as well as in this case some of the 15 other proteins that they were looking at, and 16 that that is what the reference is to, that 17 the -- that provides a precedent for doing 18 that. 19 Q. Do you know whether a buffer 20 containing Tris and EDTA can be used to 21 stabilize hemoglobin in stool? 22 MR. JONES: Objection to form. 23 A. I think it depends -- as I indicated 24 before, I've not done experiments myself to Page 89

23 (Pages 86 - 89)

1 look at stabilizing hemoglobin from stool. 2 I -- I'm trying to recall other papers that I 3 may have read about this in order to answer 4 your question. 5 I think certainly some of it would 6 depend on what kind of measurement is being 7 done and that the stability of a protein could 8 certainly impact different types of assays in 9 different ways. 10 BY MS. FERNANDS: 11 Q. Do you know whether a buffer 12 containing Tris and EDTA could be used to 13 prevent the denaturation and degradation of 14 hemoglobin in stool? 15 MR. JONES: Objection to form. 16 A. I think it also probably depends on 17 the concentrations of the Tris and the EDTA. 18 I don't -- I'm not trying to represent what's 19 known in the field as far as the -- the ranges 20 that are used for stabilizing hemoglobin. 21 BY MS. FERNANDS: 22 Q. You have personally not done any study 23 of the stabilization of hemoglobin in stool? 24 A. I have not run experiments to test Page 90	1 include parasites, bacteroides, but also I 2 think they mentioned occult blood in here 3 somewhere. 4 BY MS. FERNANDS: 5 Q. And if you look at Inbar page 2 -- the 6 number is at the top of the page, page 2 -- 7 A. Uh-huh. 8 Q. -- line 3. At the bottom of page 2, 9 do you see where it states, "A stool sample is 10 typically subjected to two different tests, 11 one being a bacteriological test and the other 12 a parasitological test." 13 Do you see that? 14 A. I see that. 15 Q. And Inbar continues, "The medium 16 required to obtain viable bacteria and a 17 medium required to maintain viable parasites 18 are not only different but are mutually 19 exclusive, i.e., one type of median damages 20 the other type of microorganisms." 21 Do you see that? 22 A. I see that. 23 Q. Would you agree that Inbar does not 24 describe at-home collection of the stool Page 92
1 that. 2 MS. FERNANDS: Is now a good 3 time for a break? Off the record. 4 5 (Recess taken from 12:36 p.m. 6 to 1:14 p.m.) 7 8 BY MS. FERNANDS: 9 Q. So I'm going to hand you what is 10 marked as Geneoscopy Exhibit 1009, PCT 11 application with Inventor Inbar. 12 Do you recognize this? 13 A. Yes. 14 Q. And what is this? 15 A. This is the Inbar patent, Exhibit 16 1009, as you mentioned, that we reference in 17 the declaration. 18 Q. And Inbar discusses collecting stool 19 samples to be tested for bacteria and 20 parasites, correct? 21 MR. JONES: Object to form. 22 A. What they -- what they talk about is 23 collecting two separate aliquots from a stool 24 sample for subsequent analysis, which does Page 91	1 sample? 2 MR. JONES: Object to form. 3 A. One of the focuses of this paper is to 4 collect a sample, take two aliquots, as I 5 indicated, to be able to preserve those 6 aliquots in order to then transport that 7 sample back to a laboratory. So although it 8 may or may not mention the word "home," I 9 think it could certainly be -- it's certainly 10 consistent with collecting at home and could 11 be implied that that was the intent. 12 BY MS. FERNANDS: 13 Q. It's also consistent with collecting 14 at a doctor's office and sending to a 15 laboratory, correct? 16 A. As I said, it's consistent with 17 collecting remote from a laboratory and being 18 able to ship that sample from wherever the 19 sample is collected to the testing facility. 20 And although I think it's certainly possible 21 it could be collected from a doctor's office, 22 I would think, for the sake of convenience, 23 the most logical place would be to collect it 24 at home. Page 93

24 (Pages 90 - 93)

1 Q. And Inbar itself does not specifically 2 state collection takes place at home, 3 correct? 4 A. I would have to read through this to 5 verify whether or not it does, but I think 6 that that's beside the point from the message 7 that I'm trying to convey, which is that it 8 certainly does not exclude the possibility of 9 collecting a sample from home and, 10 furthermore, setting up for preserving samples 11 so that you could, in fact, collect it at 12 home. 13 Q. You think it is beside the point 14 whether or not Inbar says that you can collect 15 a sample at home? 16 A. What I meant by that is that whether 17 or not he specifies the actual word "home," 18 what he is clearly indicating is a method for 19 collecting a sample remote from the testing 20 laboratory and being able to ship that sample 21 to that laboratory. And so it might use the 22 word "home." It might use the word "abode." 23 It might use a number of other descriptions. 24 It does not exclude the possibility of Page 94	1 some problems of ease of collecting samples 2 for sending to a testing facility. And as 3 part of that ease of collecting, I would think 4 the easiest way to do that is to collect a 5 sample at home as opposed to going somewhere 6 else to defecate. 7 Q. I hand you now what's marked as 8 Exhibit 1010. My apologies. I copied the 9 whole thing, which is quite long. It is -- 10 "Laboratory procedures for the diagnosis of 11 intestinal parasites" is the title. 12 Do you see that? 13 A. Yes. 14 Q. And is this a document on which you 15 relied in your declaration? 16 A. Yes. 17 Q. And if you go to page 43 of your -- of 18 Exhibit 1002, your declaration, all right, on 19 page 43, there's an image. I think the 20 footnote of the citation is actually two pages 21 earlier, Footnote 71. 22 So do you see -- in Paragraph 70, you 23 see "Reproduced below as Figure 1, a schematic 24 included in a 1985 laboratory manual, which, Page 96
1 collecting a sample from home, and, indeed, I 2 think that's the primary intent. 3 Q. You said it might use the word "home"; 4 it might use the word "abode." Can you point 5 anywhere in Inbar where it uses the word 6 "home" or any synonym for "home" with respect 7 to the location of the sample collection. 8 A. I could read through the whole thing, 9 if you would like. 10 Q. Yes. 11 A. Okay. 12 (Witness reviews document.) 13 So I've read through this document 14 very quickly, at least as quick as I can read, 15 and I did not see a mention of the word "home" 16 or any synonyms for "home," but again, my 17 reading of this and my interpretation of this 18 is that what he is teaching is a methodology 19 and a device for collecting samples remote 20 from a testing laboratory, which certainly 21 does not preclude the idea of collecting a 22 sample at home. 23 And further, he does go on to talk 24 about -- in an earlier part, about solving Page 95	1 in turn, was adapted from a 1949 publication." 2 Do you see that? 3 A. Yes. 4 Q. And then that footnote is 71 to 5 Melvin, Exhibit 1010, correct? 6 A. Yes. 7 Q. And then the Figure 1 is on page 43 of 8 your declaration, correct? 9 A. That's correct. 10 Q. And it cites to page 12 of Melvin; is 11 that right? 12 A. Cite -- Reference 71 is to page 12 of 13 Melvin, correct. 14 Q. So if you turn to page 12 of Exhibit 15 1010, the Melvin reference -- and it's page 12 16 at the top numbering. So page 12 of Melvin is 17 the same figure as on page 43 of your 18 declaration, Exhibit 1002, correct? 19 A. It appears to be very similar, yes. 20 Q. And it was page 12 of the Melvin 21 reference that you cited for this figure, 22 Figure 1, of your declaration, correct? 23 A. Yes. 24 Q. And Figure -- what is called Figure 1 Page 97

1 in your declaration, the first word at the top 2 of the figure is adapted from Brooke and 3 Goldman in 1949, correct? 4 A. Yes. 5 Q. And in the Melvin reference, Exhibit 6 1010, on page 12, above the words adapted from 7 Brooke and Goldman, 1949," it states, "Use of 8 PVA fixative and formalin for submitting stool 9 specimens to be examined for parasites," 10 correct? 11 A. Correct. 12 Q. Why did you omit that heading from 13 your declaration? 14 A. I don't know that it was intentional, 15 and I don't know that any information was 16 specifically lost in the sense that 17 Figure 1 -- or the Part 1 of Figure 1 18 indicates PVA fixatives and formalin in these 19 two different vials. So I think the 20 information is still retained. 21 Q. And so in these two separate vials, 22 one contains PVA fixative. 23 What is PVA fixative? 24 A. (Witness reviews document.) Page 98	1 Q. And so -- oh, actually, it is -- the 2 page is on the bottom. See, they -- the page 3 is on the bottom there for -- so it's page 59 4 of the reference, Geneoscopy Exhibit 1010, 5 page 85. 6 Do you see that? 7 A. Yes. 8 Q. Okay. The top of this page, it says, 9 "Preservation of specimens," correct? 10 A. Yes. 11 Q. And the second paragraph at the 12 beginning -- at the top says, "A single 13 solution is not available" per -- "for 14 preserving all of the diagnostic forms," and 15 there's a paren that I'll exclude -- "and 16 for providing" -- and after the paren -- "and 17 for providing material that can be both 18 concentrated and permanently stained." 19 Do you see that? 20 A. Yes. 21 Q. And it continues on, "Therefore, more 22 than one preservative solution may be needed 23 to permit reliable diagnosis." 24 Do you see that? Page 100
1 I don't know that they actually 2 described what the PVA fixative is in this 3 section, at least that I'm looking at. 4 Q. And the other vial contains formalin; 5 is that right? 6 A. Formalin. 7 Q. Formalin. 8 A. Yes. 9 Q. And what is formalin? 10 A. Formalin is another name for 11 formaldehyde. 12 Q. If you turn to what is marked as 13 page 85 in the footnote, the Geneoscopy 14 page 1010, page 85 in Melvin, still in 15 Melvin -- 16 A. Page? 17 Q. 85. 18 And page 85 at the bottom, that -- 19 using the numbering that's in the footer -- 20 this page doesn't have a page at the top. 21 That's why I'm using the page that goes with 22 Geneoscopy Exhibit 1010. Then you see the 23 page numbers at the bottom. 24 A. Oh, I'm sorry. Okay. Page 99	1 A. Yes. 2 Q. And this is for diagnosing parasites 3 in stool specimens, correct? 4 A. I believe that's true. 5 Q. The reference itself is titled 6 "Laboratory Procedures for the Diagnosis of 7 Intestinal Parasites," correct? 8 A. That's the name of the manual, yes. 9 Q. So you can put Melvin away. 10 And we're going back to your 11 declaration, which is Exhibit 1002. And if 12 you could, turn to page -- Paragraph 344 of 13 your declaration. 14 MR. JONES: I'm sorry. Did you 15 say 334 or 344? 16 MS. FERNANDS: 344. 17 A. Okay. 18 BY MS. FERNANDS: 19 Q. In Paragraph 344, you discuss certain 20 patents that are identified on the Exact 21 Sciences website; is that correct? 22 A. Yes. 23 Q. Okay. And those are grouped with 24 bullet headings in this Paragraph 344; is that Page 101

1 accurate? 2 A. What follows, yes, is some bullet 3 headings, yes. 4 Q. And so the first bullet in 5 Paragraph 344 is "Patents related to general 6 use of stool and CCR [sic] screening." 7 Do you see that? 8 A. Yes. Probably a typo. 9 Q. And so that should be "CRC 10 screening"? 11 A. Yes. 12 Q. Okay. Who characterized the listed 13 patents as patents related to the general use 14 of stool in CRC screening? 15 A. Are you asking how were these 16 particular patents listed under this 17 particular heading? 18 Q. Well, first, I'm asking who determined 19 that these patents listed here were related to 20 general use of stool in CRC screening? 21 A. I looked at these patents to try to 22 come up with a categorization system. I 23 didn't read all of these exhaustively, I guess 24 it's safe to say, but enough to get a sense Page 102	1 A. Yes. 2 Q. Others related to methods of preparing 3 DNA from methylation analysis? 4 A. Yes. 5 Q. And then others related to the methods 6 of testing for methylated DNA? 7 A. Yes. 8 Q. And others related to methods of 9 detecting DNA mutation, correct? 10 A. Yes. 11 Q. And then the last category is "Patents 12 related to control molecules used with DNA 13 assays," correct? 14 A. Yes. But as I said, it's entirely 15 possible that these patents are not exclusive 16 to the categorization I put these into. 17 Q. What do you mean that it's possible 18 they're not exclusive to that 19 categorization? 20 A. Meaning it's possible that any given 21 patent that I had indicated as an example 22 hypothetical that was related to testing 23 methylated DNA may also have some relevance to 24 methods for preparing DNA for methylation Page 104
1 for what was in the patents. 2 Q. Okay. 3 A. There's always a possibility that 4 there might be some overlap from one category 5 to another. 6 Q. But you personally looked at all of 7 these patents to determine into what category 8 to place them; is that accurate? 9 A. That was my goal. 10 Q. And so you determined that certain of 11 those patents were related to general use of 12 stool in CRC screening; is that right? 13 A. Correct. 14 Q. And then some of those patents related 15 to containers for collecting and storing stool 16 samples, correct? 17 A. Correct. 18 Q. And some related to DNA stabilizing 19 buffer? 20 A. Yes. 21 Q. And then some related to DNA isolation 22 methods, correct? 23 A. Yes. 24 Q. Others related to DNA markers? Page 103	1 analysis even though I listed those as two 2 separate categories. 3 Q. Have you done any further analysis of 4 any of these patents listed in Paragraph 344 5 since you prepared this declaration? 6 A. I don't believe so. 7 Q. Do you have Exhibit 1001 in the pile 8 over there? It's the '746 patent. 9 A. Yes. 10 Q. If we turn to the claims of the '746 11 patent, if you look at B and C of Claim 1, 12 would you agree that both B and C of Claim 1 13 relate to containers for collecting and 14 storing stool samples? 15 A. What's described is a sealable vessel 16 in B as well as in C. So, yes, I would agree 17 that this claim at least includes a mention of 18 containers. 19 Q. And Item 1B also refers to a 20 stabilizing buffer, correct? 21 A. Yes. As part of the sealable vessel, 22 it mentions combining a first portion of the 23 fecal sample with the stabilization buffer. 24 Q. If you look at Item 3B, 3B refers Page 105

27 (Pages 102 - 105)

1 extracting nucleic acid from the first portion 2 of fecal sample, correct? 3 A. Yes. 4 Q. Would you agree that Claim 3B, which 5 incorporates Claim 1, concerns -- or is 6 related to a DNA stabilizing buffer? 7 A. I'm sorry. Could you say that 8 again. 9 MR. JONES: Object to form. 10 BY MS. FERNANDS: 11 Q. Would you agree with me that Item 3B 12 of Claim 3, which refers to extracting nucleic 13 acid from the first portion, read in the 14 context of 1B, sealable vessel, combining a 15 first portion of the fecal sample with a 16 stabilizing buffer relates to a DNA 17 stabilizing buffer? 18 MR. JONES: Object to form. 19 A. So 3B talks about extracting nucleic 20 acid from the first portion of the fecal 21 sample wherein that portion is obtained, 22 according to Claim 1. And in Claim 1, we're 23 talking about -- I'm sorry -- the patent claim 24 talks about a stabilizing buffer. Page 106	1 specified at all. 2 Q. In 3B, "Extracting a nucleic acid from 3 the first portion of the fecal sample," is 4 that related to a nucleic acid isolation 5 method? 6 A. Extracting nucleic acid, yes, I 7 would -- I would assume that that's a 8 similar -- as isolating. 9 Q. And then 3C is testing nucleic acid 10 extracted from the first portion of the fecal 11 sample for an amount of human nucleic acid, 12 correct? 13 A. Correct. 14 Q. So that is related to testing for 15 nucleic acid, yes? 16 MR. JONES: Objection to form. 17 A. It's indicating that it's testing 18 nucleic acid. It does not specify what the 19 test is other than to say that it's related to 20 the amount of the nucleic acid. 21 BY MS. FERNANDS: 22 Q. In Paragraph 347 of your declaration, 23 Exhibit 1002, you referred to a U.S. Patent 24 No. 9,163,278, correct? Page 108
1 BY MS. FERNANDS: 2 Q. And is it your understanding that that 3 is a nucleic acid stabilizing buffer? 4 MR. JONES: Objection to form. 5 A. It's really not clear. What they talk 6 about is extracting nucleic acid. The 7 stabilizing buffer that's mentioned in 8 Claim 1B does not indicate what's being 9 stabilized. 10 BY MS. FERNANDS: 11 Q. What is your understanding of the 12 stabilizing buffer referred to in Claim 1B? 13 A. It's not specified. 14 Q. And when you read Claim 1 in the 15 context of Claim 3, what is your understanding 16 of the stabilizing buffer? 17 A. My understanding is that we've got a 18 stool sample which is combined with a buffer 19 which is stabilizing -- intended to stabilize 20 something, and in Claim 3, there's an aim to 21 extract the nucleic acids from that portion of 22 the fecal sample. So it's entirely possible 23 that the stabilization buffer is intended to 24 stabilize a nucleic acid, but it's not Page 107	1 A. Yes. 2 Q. Have you reviewed the '278 patent? 3 A. Yes. 4 Q. And so I've just handed you what's 5 been marked as Geneoscopy Exhibit 1028. And 6 is this the '278 patent that you refer to in 7 Paragraph 347 of your declaration? 8 A. Yes. 9 Q. If you'd turn to the claims on the 10 back of the '278 patent, the '278 patent 11 claims a system for isolating a target human 12 DNA from a human stool sample; is that 13 correct? 14 MR. JONES: Objection to form. 15 A. What's stated in Claim 1 is a system 16 for isolating a target human DNA from a human 17 stool sample, and then it lists a number of 18 things that are comprised within the system. 19 BY MS. FERNANDS: 20 Q. And that -- you would agree that 21 before target human DNA can be isolated from a 22 stool sample, the stool sample must be 23 collected, correct? 24 MR. JONES: Objection to form. Page 109

1 A. That the -- you're asking that the 2 stool sample would have to be collected? 3 BY MS. FERNANDS: 4 Q. Correct. 5 A. There has -- a stool sample must exist 6 in order to be able to extract DNA from it. 7 Q. If that stool sample were collected at 8 home, would you agree that there would need to 9 be a way to stabilize the stool sample before 10 it -- before it is processed to isolate DNA? 11 MR. JONES: Objection to form. 12 A. It depends what you're measuring. 13 BY MS. FERNANDS: 14 Q. Are there circumstances in which that 15 stool sample collected at home would not have 16 to be stabilized if the goal was to isolate 17 DNA from the stool sample? 18 A. Sorry. Could you repeat the first 19 part of that question. 20 Q. Are there circumstances in which a 21 stool sample collected at home would not have 22 to be stabilized if the goal was to isolate 23 DNA from that stool sample? 24 A. Sure. It depends -- I think there's a Page 110	1 Do you see that? 2 A. Yes, I see that. 3 Q. What are you referring to when you say 4 "applying this methodology"? 5 A. Let me review a little bit to set the 6 context here. 7 (Witness reviews document.) 8 So sorry. Your question is what do 9 I -- what am I referring to in terms of what 10 this methodology is? 11 Q. When you say "applying this 12 methodology" in Paragraph 125 of your 13 declaration, to what are you referring as the 14 methodology? 15 A. What I'm referring to is an automated 16 desktop immunochemical fecal occult blood test 17 that, as an example, as described in Vilkin, 18 is a way of being able to measure for blood in 19 stool. 20 Q. If you could, turn to Vilkin, the 21 Exhibit 1005, and look at Table 3 of Vilkin. 22 A. Yes. 23 Q. And the methodology of Vilkin included 24 taking three samples from each patient, Page 112
1 question of relative -- I think one could 2 always collect a stool sample at home without 3 preservation, could -- could isolate DNA from 4 the sample. I think one of the questions 5 which is also at hand here is how reproducibly 6 can one measure a particular analyte, and what 7 is the analyte, and understand the stability 8 of that analyte in order to more directly 9 answer that question. 10 Q. Can I ask you to go back to the Vilkin 11 reference, which is Exhibit 1005. It's the 12 one that's actually colored in red. 13 A. Yes. 14 Q. Could you also, in your declaration, 15 Exhibit 1002, turn to Paragraph 125. 16 Paragraph 125, the last sentence of 17 the paragraph, you state, "Applying this 18 methodology to a population of high-risk and 19 symptomatic patients, Vilkin found that 'All 20 cases of cancer and most advanced adenomas 21 would be detected, and a negative test would 22 provide a very high degree of certainty that 23 there was no clinically significant colorectal 24 neoplasia.'" Page 111	1 correct? 2 MR. JONES: Objection to form. 3 A. The methodology of Vilkin was one that 4 they had come up with to assess -- or 5 characterize, I should say, the performance of 6 their system, which is distinct, I would 7 suggest, from how FIT tests are used 8 clinically. 9 BY MS. FERNANDS: 10 Q. And it was, however, the methodology 11 of the Vilkin reference that resulted in all 12 cases of cancer and most advanced adenomas 13 being detected, correct? 14 MR. JONES: Objection to form. 15 A. I wouldn't characterize it that way, 16 no. 17 BY MS. FERNANDS: 18 Q. Well, you do say in your declaration 19 that "Vilkin found that all cases of cancer 20 and most advanced adenomas would be detected, 21 and a negative test would provide a very high 22 degree of certainty that there was no 23 clinically significant colorectal neoplasia," 24 right? Page 113

1 A. Where are you reading from? 2 Q. This is in your Paragraph 125, the 3 last sentence where you quote Vilkin. 4 A. That's a quote from Vilkin. But as I 5 look at the data and as I think an expert at 6 the time would look at the data, anybody would 7 recognize that FOBT does not detect all cases 8 of cancer. 9 All cases of cancer do not bleed, and 10 if that were the case, there would have been 11 zero impetus to develop any other type of 12 test, like DNA -- fecal DNA test. 13 Q. The Vilkin reference reports 100 14 percent detection for cancer in Table 3, 15 correct? 16 A. No, I wouldn't interpret it that way. 17 What they show is that for Sample 1, it 18 detected 83 percent of cancers. In Sample 2, 19 it detected 66.7 percent of cancers. And in 20 Sample 3, it detected 100 percent of cancers. 21 So I don't think that one can say 22 that, across the board, it detects 100 percent 23 of cancers. 24 Q. And -- Page 114	1 they confirmed six subjects with cancer. 2 Q. So turning back to Table 3 of Vilkin 3 on page 7 of Exhibit 1005, you pointed to the 4 results for Samples 1, 2, and 3 separately, 5 correct? 6 A. Yes. 7 Q. If you look up in the discussion, the 8 first paragraph of the discussion, the second 9 sentence "The reference states that clinical 10 evaluation demonstrated a high sensitivity of 11 76.5 percent for all significant colorectal 12 with neoplasia and acceptable specificity of 13 95.3 percent." 14 Do you see that? 15 A. Yes. 16 Q. And that 76.5 percent is the combined 17 results of Samples 1, 2, and 3 in Table 3, 18 correct? 19 A. I would have to review to see what 20 they are referring to as significant 21 colorectal neoplasia. So I don't know that 22 that's the case, what you're suggesting. 23 Q. In Table 3, they refer to six 24 colorectal cancers and 28 advanced adenomatous Page 116
1 A. I'll also -- sorry. I'll also note 2 that this was an extremely small sample 3 number. This was six cancers, I believe. So 4 that it's certainly not representative of a 5 population. 6 Q. How many would you need to be 7 representative of a population? 8 MR. JONES: Objection to form. 9 A. You would need more than six. 10 BY MS. FERNANDS: 11 Q. Those six cancers were detected in 500 12 examinees, correct? 13 A. My understanding of the design of the 14 study, which I think is what you're asking 15 about, is that they had recruited patients -- 16 let me review first. Sorry. 17 (Witness reviews document.) 18 So in the "Results" section, they talk 19 about 521 patients in total, but there was 21 20 that did not have incomplete colonoscopies, so 21 they excluded those. They had a remaining set 22 of 500 subjects where the data was analyzed 23 and that I believe in that population is where 24 they found -- yes, in that population is where Page 115	1 polyps, correct, in the footnote? 2 A. They -- yeah, they have an asterisk 3 next to sensitivity for significant colorectal 4 cancer neoplasia, 34 samples. The asterisk 5 indicating -- yes, the six cancers and 28 6 advanced adenomatous polyps. 7 Q. The 76.5 percent in the discussion 8 refers to the same combined results as 9 Samples 1, 2, and 3 in Table 3, correct? 10 A. It would include that, I would assume. 11 Q. Well, Table 3 says sensitivity for 12 significant colorectal neoplasia, correct? 13 A. Yes. 14 Q. And then the cancer plus AAP percent 15 for the Samples 1, 2, and 3 is 76.5 percent, 16 correct? 17 A. That's what they are indicating. 18 Q. And in their discussion, they say the 19 clinical evaluation demonstrated a high 20 sensitivity of 76.5 percent, correct? 21 A. What they are saying is that they 22 are -- they are performing a calculation which 23 combines cancer and the advanced polyps, 24 adenomas, but it's -- I believe it's also Page 117

1 likely that they are interpreting the data 2 using all three of the samples, which again, I 3 would not submit is a normal way that people 4 would run a FIT test. 5 Q. But it is -- at the bottom, Table 3, 6 it does say Samples 1, 2, and 3, correct? 7 A. At the bottom of the table, the last 8 line is "Samples 1, 2, and 3." 9 Q. And the number reported for cancer 10 plus AAP is 76.5 percent? 11 A. What I'm -- what I'm saying is that 12 one -- 13 Q. It's a simple question. The number 14 that they reported for Samples 1, 2, and 3 for 15 cancer plus AAP is 76.5 percent, correct? 16 A. I don't think you should be cutting me 17 off, but what I'm saying is that this is a 18 study which is run in a certain way. This 19 should not be interpreted as being 20 representative of what a FIT testing would 21 provide necessarily and that, in this 22 particular case, they are using three 23 different samples to get to a cancer 24 sensitivity of 100 percent, which no expert at Page 118	1 BY MS. FERNANDS: 2 Q. What clear benefit, in your opinion, 3 does Vilkin show? 4 A. What they show is that it indeed has 5 high sensitivity and specificity, that it can 6 be run using an automated system. Its samples 7 can be shipped using preservative, which is 8 characteristic of FIT tests in general. And 9 furthermore, despite what they have done here, 10 most of the time in clinical practice, there 11 is a single sample which is taken from a 12 patient, which is then sent in to a lab for 13 reading. 14 Q. Do you consider yourself an expert in 15 FIT testing? 16 A. I consider myself an expert in reading 17 the literature and understanding what's being 18 described. 19 Q. On what do you base your statement 20 that, most of the time in practice, only a 21 single FIT test is taken? 22 A. Because I've read a lot of literature 23 about FIT testing. 24 Q. Have you cited anything in your Page 120
1 the time or even now would expect is true and 2 that they're using that to calculate the high 3 sensitivity of 76 percent. 4 Q. When you say they're using that to 5 calculate the high sensitivity of 76 percent, 6 what are you referring to as "that"? 7 A. I'm referring to the 100 percent 8 sensitivity for cancer combined with whatever 9 sensitivity there was for the AAPs. 10 Q. Why did you rely on Vilkin as an 11 example of an iFOBT? 12 MR. JONES: Objection to form. 13 A. Vilkin describes a study of where they 14 were trying to characterize a performance of a 15 given FIT test system, and they were looking 16 to characterize what the performance of this 17 test was. They did it in a way to be able to 18 control for a number of elements, which may or 19 may not be representative of clinical 20 practice. 21 But the reason I selected this to be 22 used in the declaration is because it shows a 23 clear benefit of using FIT testing for 24 measuring hemoglobin in stool samples. Page 119	1 declaration that says that, most of the time 2 in FIT testing, only a single sample is taken? 3 A. In those specific words, no, I doubt 4 it. 5 Q. In Vilkin on page 8, the numbering at 6 the bottom, do you see that in the last full 7 paragraph in the -- in the left-hand column 8 begins "at present"? 9 Do you see that? 10 A. Yes. 11 Q. The second sentence there says, "This 12 is in contrast to the annual two-day average 13 risk population iFOBT collection as routinely 14 used in Japan, United States, and Australia 15 and one-day biannual testing as performed in 16 Italy." 17 Do you see that? 18 A. I see that. 19 Q. So as of the Vilkin reference, there 20 was an annual two-day average risk population 21 iFOBT collection routinely used in Japan, 22 United States, and Australia, correct? 23 A. Are you asking me to interpret that 24 sentence? Page 121

1 Q. Do you have any reason to -- do you 2 have any basis to contradict that there was an 3 annual two-day average risk population iFOBT 4 collection routinely used in Japan, 5 United States, and Australia as of the time of 6 Vilkin? 7 A. My reading of this is that what 8 they're saying is that the test should be run 9 twice in a year. That doesn't need -- that 10 doesn't mean that you need to collect two 11 samples on a given day. One of the samples 12 could be in January, and the next sample could 13 be in August. 14 Q. Wouldn't that more logically be two 15 annual samples? 16 A. I'm not the one that wrote this paper 17 nor worded it this way, but that's the way I'm 18 interpreting it certainly relative to other 19 references. 20 Q. So I've just handed you what is 21 Geneoscopy Exhibit No. 1004, a reference 22 called Lenhard. 23 Do you recognize this? 24 A. Yes. Page 122	1 number and the percent is the percent 2 detected? 3 A. That's my understanding. 4 Q. So under HIC1 for all cancers, 11 5 of 26 cancers were detected, correct? 6 A. That's what it appears to be showing, 7 yes. 8 Q. That's a 42 percent? 9 A. Correct. 10 Q. And under FOBT, 9 of 26 cancers were 11 detected by FOBT, correct? 12 A. Yes. 13 Q. And that's 35 percent? 14 A. Yes. 15 Q. And then the combined, it's 17 of 26 16 cancers detected, correct? 17 A. Yes. 18 Q. And that's 65 percent? 19 A. Yes. 20 Q. So the combined detected six more 21 cancers than the HIC1 alone; is that right? 22 A. It would appear so. 23 Q. And then there's also, next to the N 24 percent in that row, 95 percent CI. Page 124
1 Q. This is a reference on which you rely 2 in your declaration; is that correct? 3 A. Yes. 4 Q. Could you turn to Table 4 of Lenhard 5 on page 5, as marked at the bottom. 6 What is your understanding of what 7 Table 4 of Lenhard is showing? 8 A. My understanding is that it's showing 9 the positivity rates of a DNA assay, which 10 happens to be a HIC1 methylation marker in one 11 set of data; a second set of data, which shows 12 results for a FOBT, which happens to be a 13 guaiac FOBT; and then a third set of data 14 which looks at the combination of those two 15 tests. 16 Q. And if we look at the -- we call it 17 the second row. At the very top row, it says, 18 "HIC1, FOBT, and combined," right? 19 A. Yes. 20 Q. Then the next row down, there is an N 21 and then a parenthetical with a percent sign 22 in it, right? 23 A. Yes. 24 Q. Does that mean that the N is the Page 123	1 Do you see that? 2 A. Yes. 3 Q. And is that 95 percent confidence 4 interval? 5 A. That's my understanding. 6 Q. And then for the HIC1, there's a range 7 of percentages there, 23 percent to 63 8 percent. 9 Do you see that? 10 A. Yes. 11 Q. And for the FOBT, there's a range of 12 percentages under the 95 percent CI, 17 13 percent to 56 percent, correct? 14 A. Yes. 15 Q. And then under the combined, under 95 16 percent CI, it's 44 percent to 83 percent. 17 Do you see that? 18 A. Yes. 19 Q. Did you do any analysis to determine 20 whether there was a statistically significant 21 difference between the HIC1 and the combined 22 test here? 23 A. I don't recall. I may have. 24 Q. But you don't recall, as you're Page 125

1 sitting here, whether you tried to determine 2 if there was a statistically significant 3 difference here? 4 A. I -- I'm pretty sure I did. I don't 5 recall what I -- what I saw when I was doing 6 that. 7 Q. If you did that, you did not include 8 it in your declaration; is that right? 9 A. I don't believe we discussed 10 statistical significance. 11 Q. Would you agree that the range of 23 12 percent to 63 percent with a 95 percent 13 confidence interval for HIC1 is a broad range? 14 MR. JONES: Objection to form. 15 A. I would -- I would -- what I would say 16 is that the range of the 95 percent confidence 17 interval, in general -- well, no, I'll stick 18 with this case. 19 So that range, which is a 40 20 percentage point difference, is perhaps larger 21 than one might like to see in a study. And 22 one could even convince themselves that there 23 is a significant overlap with the same range 24 in another test like the FOBT in this case. Page 126	1 cancers, do you see that? 2 A. Yes. 3 Q. And the range for localized cancers is 4 22 percent to 96 percent for HIC1, right? 5 A. Yes. 6 Q. And it's 12 percent to 188 percent for 7 combined; is that correct? 8 A. Yes. 9 Q. And there's a footnote there that says 10 an estimated by normal approximation of -- I 11 can never say that -- "poisson" distribution. 12 It's French. My French is always abysmal. If 13 you look down to the sixth row down the 14 asymptomatic cases, do you see that? 15 A. Yes. 16 Q. And for asymptomatic cases, HIC1 17 identified four of ten, correct? 18 A. Four of ten, yes. 19 Q. FOBT identified three of ten? 20 A. Yes. 21 Q. The combined identified six of ten, 22 correct? 23 A. Yes. 24 Q. And the range of confidence interval Page 128
1 But that does not mean that those two 2 are not statistically significantly different. 3 BY MS. FERNANDS: 4 Q. Is it possible to calculate the 5 statistical significance here? 6 A. Sure. 7 Q. And you don't recall whether you did 8 or didn't actually do that? 9 A. I'm pretty sure I did, but I don't -- 10 I can't remember what I -- what the result of 11 that analysis was. 12 Q. Do you know, as you sit here today, 13 whether there is any statistically significant 14 difference between the results of the HIC1 15 test and combined test for all cancers? 16 A. I would guess that there is a 17 statistically significant difference. 18 Q. Why would you guess that? 19 A. It's more of a hunch than anything 20 else. I'm not trying to do the calculations 21 in my head, but if we go from a 42 percent to 22 a 65 percent sensitivity range, it would be a 23 guess off the top of my head. 24 Q. Then if you look at the localized Page 127	1 for the asymptomatic cases for HIC1 is 12 2 percent to 74 percent, correct? 3 A. Correct. 4 Q. And the range of the confidence 5 interval for asymptomatic cases combined is 26 6 percent to 88 percent, correct? 7 A. Yes. 8 Q. Do you know if that is a statistically 9 significant difference? 10 A. As we sit here right now, I do not 11 know. I would say that these are very small 12 numbers, so I would be skeptical of that 13 difference is statistically different. 14 Q. You referred earlier today to 15 p-values. 16 Do you recall that? 17 A. Yes, I think you mentioned it. 18 Q. Do you -- does Lenhard report a 19 p-value anywhere with respect to the 20 confidence interval -- the probability of the 21 results for the HIC1, FOBT and combined 22 tests? 23 A. Does he report that anywhere is what 24 you're asking me? Page 129

1 Q. Does Lenhard report a p-value anywhere 2 in his article, yes. 3 A. Let me read it carefully and see. 4 (Witness reviews document.) 5 He mentioned a p-value near the top of 6 page 147, where he's comparing sensitivity of 7 localized cancers compared to advanced 8 cancers, and he indicates a p-value of .084. 9 Q. And that p-value is higher than 10 the .05 that you indicated earlier is typical; 11 is that correct? 12 A. Correct. But in this case, it's also 13 noteworthy that for that particular analysis, 14 he's looking at a total set of localized 15 cancers, which is only 6, compared to advanced 16 cancers, which is 20. 17 So that makes it more difficult to 18 establish a clinical -- a statistical 19 significant difference when you're comparing 20 very small numbers. 21 He does have a number of other 22 p-values on this page. I'll keep reading. 23 (Witness reviews document.) 24 Q. Before you move on -- and I'll let you Page 130	1 Q. Turn to Table 1 of Lenhard. 2 And Table 1 of Lenhard -- well, what 3 is your understanding of what Table 1 is? 4 A. My understanding is that Table 1 is 5 showing the clinical features of the samples 6 that were used for analyzing by HIC1 -- sorry. 7 This is restricted to patients with colorectal 8 cancer. 9 Q. And in the sixth -- the sixth column 10 indicates the symptoms these patients 11 presented with, correct? 12 A. It -- the column is labeled 13 "Symptoms," correct. And it has a footnote -- 14 well, the symptoms listed here are 15 numerical -- numerically indexed, and then the 16 footnote seems to provide the written 17 descriptions for those indices. 18 Q. And so the No. 2, based on the 19 footnote, is blood mixed with stool, yes? 20 A. That's what they seem to be 21 indicating. 22 Q. And so, for example, Patient No. 7 is 23 identified as having Symptom No. 2, blood 24 mixed with stool, correct? Page 132
1 continue to look -- the p-value that you just 2 identified is not a comparison of the HIC1 to 3 the combined, is it? 4 A. No. I believe what he's doing is he's 5 comparing the -- I'm sorry. Let me back up. 6 What he's comparing is the HIC1 7 sensitivity for local versus advanced cancer, 8 so he's not comparing HIC1 to combined. He 9 does offer a number of other comparisons where 10 he calculates p-values. At the end of the 11 "Results" section, right before the 12 "Discussion" section, the last sentence 13 reads -- sorry -- the second to the last 14 sentence reads, "The combination of both 15 assays resulted in increased detection rates 16 for CRCs, 65 percent with a 95 percent 17 confidence interval of 44 to 83." 18 He does not include a p-value in that 19 calculation for some reason. 20 Q. He had included p-values for other 21 calculations in that paragraph but not for 22 that one, correct? 23 A. He included p-values for some 24 calculations, and in some cases, he did not. Page 131	1 A. That's what they would indicate here, 2 yes. 3 Q. But that patient was negative with the 4 FOBT test; is that right? 5 A. That's what they are showing. 6 Q. And a FOBT test is intended to 7 identify blood protein in stool, correct? 8 MR. JONES: Objection to form. 9 A. FOBT tests, in general, are certainly 10 intended to pick up hemoglobin in stool as an 11 indication of cancer. The symptoms that are 12 listed here, I'm not sure what that's meant to 13 indicate, the blood mixed with stool. 14 Obviously, I can read the words and understand 15 them, but I don't know, you know, in what 16 state has the blood been observed in this 17 case. So I couldn't necessarily explain why 18 the FOBT did not pick that up. 19 But I would note that in addition to 20 FOB tests -- FOBT tests being imperfect for 21 detecting blood -- mostly because blood may 22 not exist -- it's also possible that the 23 hemoglobin could be degraded sufficiently that 24 it doesn't get detected. Page 133

1 BY MS. FERNANDS: 2 Q. And so if you look at Patient Nos. 15, 3 20, and 22, all also have the symptom of blood 4 mixed with stool but a negative FOBT, correct? 5 A. 15 -- 15, 19? 6 Q. 15, 20 -- is it 20 or 19? 7 A. 15, 19, and 20 is what I see. Oh, 8 sorry -- oh, they are negative. Sorry. 15, 9 20 -- 10 Q. And 22. 11 A. -- and 22. 12 Yes, it would appear that those are 13 similar with those designations, but again, I 14 don't -- I don't personally know what blood 15 and mixed with stool actually means. And if 16 you read the blood, you would think it would 17 get picked up by a FOBT, but I don't know any 18 more details about how they ran the test or 19 how they collected it. 20 Q. Lenhard does not describe the home 21 collection of fecal samples, does it? 22 A. What they describe is "The stool 23 samples that were collected before cathartic 24 preparation for a colonoscopy or a surgery, a Page 134	1 Was that intentional? 2 A. Oh, did I? No, that wasn't 3 intentional. "Samples were received within 4 ten hours after defecation at the lab, 5 aliquoted, and stored at minus 80 degrees." 6 So I read that to say that samples 7 were -- oh, I see what you're suggesting. 8 I don't read that to suggest that 9 people were defecating at the lab. I read 10 that to say that samples were received at the 11 lab and that -- I mean, I suppose it's 12 possible that these people were defecating in 13 the lab, but I don't think that was the case. 14 Q. In any event, the samples -- there is 15 no description there of any home collection? 16 A. There is no specific description of 17 at-home collection, but it's also not -- it's 18 certainly possible that samples were collected 19 at home and then brought to the lab within ten 20 hours. It's well within protocol of many 21 studies I've read. 22 Q. At the very least, the sample in 23 Lenhard was separated at the lab? You would 24 agree with that? Page 136
1 period of at least 12 days was respected 2 between previous biopsy examinations of 3 colorectal tumors before stool sampling. 4 Samples were received within ten hours [sic] 5 after defecation, aliquoted, and stored at 6 minus 80..." 7 So they don't -- you know, as we were 8 talking about before, they don't specifically 9 mention collecting at home, but it's certainly 10 possible that samples may have been collected 11 at home and brought into the lab within ten 12 hours. 13 Q. And when you were reading that last 14 sentence, you were in the "Materials and 15 Methods" section, right? 16 A. Yes. 17 Q. And the last sentence of the "Patient 18 and Stool Samples" subsection there -- 19 A. Uh-huh. 20 Q. -- you were reading from that for a 21 bit, correct? 22 A. Yes. 23 Q. And you skipped the words at "the 24 laboratory." Page 135	1 A. What do you mean by "separated"? 2 Q. Aliquoted. 3 A. Aliquoted, yes. 4 Q. So I've just handed you Exhibit No. 5 1011, a reference with first author Nishikawa. 6 Do you recognize this? 7 A. Yes. 8 Q. And this is a document on which you've 9 relied in your declaration as well, correct? 10 A. Yes. 11 Q. Nishikawa does not describe home 12 collection of fecal samples, correct? 13 A. In the "Methods" section, under 14 "Patient and Specimens," it does not 15 specifically mention collecting samples at 16 home, but again, it doesn't preclude that 17 either. 18 Q. And in that "Methods" section, that 19 first paragraph states, "Stool specimens are 20 immediately frozen at negative 80 degrees 21 Celsius until use," correct? 22 A. It says that they were immediately 23 frozen, but I don't know what that actually 24 refers to. It -- if, in fact, samples were Page 137

1 collected at home and then brought into the 2 laboratory, it's possible that they were 3 immediately frozen once they were brought into 4 the laboratory, or it could have been 5 something else entirely. 6 Q. Well, the paragraph, as it reads, 7 says, "Stool and tissue specimens that were 8 collected from 31 patients with colorectal 9 cancer," correct? 10 A. It does. 11 Q. Then it goes on, "Under normal 12 controls, stool specimens were obtained from 13 five patients who had no evidence of malignant 14 tumors on colonoscopy, gastroduodenoscopy and 15 upper abdominal ultrasonography," correct? 16 A. Yes, it says that. 17 Q. Continues, "All of these patients gave 18 informed consent for our study," correct? 19 A. Yes. 20 Q. And then it finishes, "The stool 21 specimens were immediately frozen at negative 22 80 degrees Celsius until use," correct? 23 A. But there's no point in there that 24 says anything about when the stool samples Page 138	1 (Recess taken from 2:36 p.m. 2 to 2:47 p.m.) 3 4 BY MS. FERNANDS: 5 Q. I'm handing you what is Exhibit 1020, 6 an article titled "New Stool Screening Test 7 for Colorectal Cancer." First author, Young. 8 Do you recognize this? 9 A. Yes. 10 Q. And this is one of the references on 11 which you've relied in forming your 12 opinions? 13 A. Yes. 14 Q. On the first page of Young in the 15 second column under the "Rule of stool base 16 screening test and screening algorithm" -- are 17 you with me? 18 A. Yes. 19 Q. -- you see the statement that "As the 20 goal of screening for colorectal cancer is to 21 reduce population mortality from and/or 22 morbidity to colorectal cancer, potential 23 screening tests require rigorous evaluation 24 that goes beyond what is required for Page 140
1 were collected relative to those procedures 2 that they underwent. You're implying that 3 they collected the stool samples at the same 4 time that these procedures were run, and 5 there's no indication that that's the case. 6 Q. What is your understanding of "Stool 7 specimens were immediately frozen"? 8 A. I think we've just talked about that. 9 It's possible that the samples were frozen as 10 soon as the people in the laboratory were -- 11 obtained them, but it's not clear when the 12 samples -- or where the samples were actually 13 collected. 14 Q. There's no mention of home 15 collection? 16 A. There is no mention of home 17 collection. What I'm suggesting, it does not 18 preclude home collection either. 19 MR. JONES: Do you want to take 20 a break soon? We've been going an hour and a 21 half. 22 MS. FERNANDS: Sure. Off the 23 record. 24 Page 139	1 diagnostic tests being used in situations 2 where disease prevalence is high." 3 Do you see that statement? 4 A. Yes. 5 Q. And that is a statement in this Young 6 reference on which you've relied, right? 7 A. Yes. 8 Q. And then it goes on to state, 9 "Screening tests are applied to healthy people 10 where the risk of disease is relatively low," 11 correct? 12 A. That's what it says. 13 Q. And that's an accurate statement about 14 what screening tests are, correct? 15 MR. JONES: Objection to form. 16 A. No, not necessarily. 17 BY MS. FERNANDS: 18 Q. You disagree with the Young reference 19 statement that "Screening tests are applied to 20 healthy people where the risk of disease is 21 relatively low"? 22 A. I would characterize it more as 23 screening tests are applied to perhaps 24 asymptomatic, average risk population. But Page 141

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1 depending on what you're testing for, the risk 2 of disease could certainly vary. 3 Q. If you turn to the third page of this 4 Young reference, the second column, do you see 5 the -- in the paragraph that begins "to 6 summarize"? 7 A. Yes, yes. Sorry. Yes. 8 Q. So on page 3 of Exhibit 1020, 9 paragraph beginning "To summarize" reads, "To 10 summarize, we need new tests because there is 11 much room to improve participation rates of 12 those being invited to screen to improve 13 sensitivity for cancer, to improve sensitivity 14 for adenomas, and to achieve the improved 15 sensitivity without unacceptable deterioration 16 and specificity." 17 Do you see that? 18 A. I see that. 19 Q. And that's Young's summary in this 20 article, which is Exhibit 1020, correct? 21 MR. JONES: Objection to for. 22 A. I think it's a summary of a particular 23 section, certainly not at the end of the 24 paper, so I don't think it's a summary of the Page 142	1 you've relied, correct? 2 A. Yes. 3 Q. If you turn to the second page of 4 Hoepffner, in the first column, do you see the 5 paragraph beginning the "metastatic CRC"? 6 A. Yes. 7 Q. And the last sentence of that 8 paragraph reads, "An ideal screening test must 9 be noninvasive, acceptable to patients, 10 simple, have high sensitivity and specificity, 11 inexpensive, cost effective, easy to implement 12 across a large population, and should be 13 effective in reducing morbidity and mortality 14 from CRC in the screening population." 15 Do you see that? 16 A. I see that. 17 Q. And that's a statement here in this 18 Hoepffner reference, correct? 19 A. It's a sentence included in his paper. 20 MS. FERNANDS: Can we go off the 21 record for just a quick moment. 22 23 (Recess taken from 2:53 p.m. 24 to 2:54 p.m.) Page 144
1 whole paper. 2 BY MS. FERNANDS: 3 Q. It is Young's -- Young begins that 4 paragraph with "to summarize," correct, for 5 that section? 6 A. Yes. The section seems to be headed 7 "Justification of New Test Development." The 8 first part talks about evaluation of test 9 performance. The next part talks about 10 performance of the gFOBT. And then the part 11 that you were referring to appears to be a 12 summary of that section. 13 Q. A summary of the "Justification of New 14 Test Development," correct? 15 A. I would agree with that, that that's 16 what he's written. 17 Q. I've just handed you what's been 18 marked as Exhibit 1023. It's an article, 19 "Comparative evaluation of new bedside fecal 20 occult blood test in a prospective multicenter 21 study." First author, Hoepffner. 22 Do you recognize this? 23 A. Yes. 24 Q. This is another article on which Page 143	1 2 MS. FERNANDS: Dr. Whitney, I 3 have no further questions for you today. 4 THE WITNESS: Thank you. 5 MR. JONES: No questions for me. 6 7 (Deposition concluded at 2:54 p.m.) 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 Page 145

1 CERTIFICATION 2 I, DARLENE M. COPPOLA, a Notary Public, do hereby 3 certify that DUNCAN H. WHITNEY, PH.D., after having 4 satisfactorily identifying himself, came before me on 5 the 16th day of October, 2025, in Boston, 6 Massachusetts, and was by me duly sworn to testify to 7 the truth and nothing but the truth as to his 8 knowledge touching and concerning the matters in 9 controversy in this cause; that he was thereupon 10 examined upon his oath and said examination reduced to 11 writing by me; and that the statement is a true record 12 of the testimony given by the witness, to the best of 13 my knowledge and ability. 14 I further certify that I am not a relative or 15 employee of counsel/attorney for any of the parties, 16 nor a relative or employee of such parties, nor am I 17 financially interested in the outcome of the action. 18 WITNESS MY HAND THIS 21st day of May, 2025. 19 20 <i>Darlene M. Coppola</i> 21 DARLENE M. COPPOLA My commission expires: 22 NOTARY PUBLIC November 2, 2029 23 REGISTERED MERIT REPORTER 24 CERTIFIED REALTIME REPORTER Page 146	1 BRENDAN JONES 2 bjones@foleyhoag.com 3 MAY 21, 2025 4 RE: Geneoscopy, Inc. v. Exact Sciences Corporation 5 5/16/2025, DUNCAN H. WHITNEY, PH.D., (#7349335). 6 The above-referenced transcript has been 7 completed by Veritext Legal Solutions and 8 review of the transcript is being handled as follows: 9 __ Per CA State Code (CCP 2025.520 (a)-(e)) – Contact Veritext 10 to schedule a time to review the original transcript at 11 a Veritext office. 12 __ Per CA State Code (CCP 2025.520 (a)-(e)) – Locked .PDF 13 Transcript - The witness should review the transcript and 14 make any necessary corrections on the errata pages included 15 below, notating the page and line number of the corrections. 16 The witness should then sign and date the errata and penalty 17 of perjury pages and return the completed pages to all 18 appearing counsel within the period of time determined at 19 the deposition or provided by the Code of Civil Procedure. 20 Contact Veritext when the sealed original is required. 21 __ Waiving the CA Code of Civil Procedure per Stipulation of 22 Counsel - Original transcript to be released for signature 23 as determined at the deposition. 24 __ Signature Waived – Reading & Signature was waived at the 25 time of the deposition. Page 148
1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 CASE NO. IPR2024-01330 4 U.S. PATENT 11,970,746 5 6 ***** 7 8 GENEOSCOPY, INC., 9 10 Petitioner 11 12 vs. 13 14 EXACT SCIENCES CORPORATION, 15 16 Patent Owner 17 18 ***** 19 20 I, DUNCAN H. WHITNEY, PH.D., say that I have 21 read the foregoing deposition and hereby declare under 22 penalty of perjury the foregoing is true and correct: 23 (as prepared) (as corrected on errata.) 24 Executed this _____ day of _____, 25 2025, at _____, _____. _____ DUNCAN H. WHITNEY, PH.D. Page 147	1 __X_ Federal R&S Requested (FRCP 30(e)(1)(B)) – Locked .PDF 2 Transcript - The witness should review the transcript and 3 make any necessary corrections on the errata pages included 4 below, notating the page and line number of the corrections. 5 The witness should then sign and date the errata and penalty 6 of perjury pages and return the completed pages to all 7 appearing counsel within the period of time determined at 8 the deposition or provided by the Federal Rules. 9 __ Federal R&S Not Requested - Reading & Signature was not 10 requested before the completion of the deposition. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 Page 149

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1 Geneoscopy, Inc. v. Exact Sciences Corporation 2 DUNCAN H. WHITNEY, PH.D. (#7349335) 3 E R R A T A S H E E T 4 PAGE____ LINE____ CHANGE_____ 5 _____ 6 REASON_____ 7 PAGE____ LINE____ CHANGE_____ 8 _____ 9 REASON_____ 10 PAGE____ LINE____ CHANGE_____ 11 _____ 12 REASON_____ 13 PAGE____ LINE____ CHANGE_____ 14 _____ 15 REASON_____ 16 PAGE____ LINE____ CHANGE_____ 17 _____ 18 REASON_____ 19 PAGE____ LINE____ CHANGE_____ 20 _____ 21 REASON_____ 22 _____ 23 _____ 24 (DUNCAN H. WHITNEY, PH.D.) Date 25 _____ Page 150	

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

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

(A) to review the transcript or recording; and

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

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

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