

In the Matter Of:

NATERA v

NEOGENOMICS LABORATORIES, INC.

MICHAEL METZKER, PH.D.

September 26, 2023



IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC.,)
)
Plaintiff,)
)
vs.)
)
NEOGENOMICS LABORATORIES,)
INC.,)
)
Defendant.)
_____)

Case No. 1:23-cv-629

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VIDEOTAPED DEPOSITION OF
MICHAEL L. METZKER, PH.D.
TUESDAY, SEPTEMBER 26, 2023, 9:25 A.M.
LOS ANGELES, CALIFORNIA

STENOGRAPHICALLY REPORTED BY:
CHERYL HAAB SCOTT, RDR, CRR, CCRR
CA CSR No. 13600
WA CCR No. 3499
NV CCR No. 1003

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1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE MIDDLE DISTRICT OF NORTH CAROLINA 3 4 NATERA, INC.,) 5) 6 Plaintiff,) 7) 8 vs.) Case No. 1:23-cv-629 9) 10 NEOGENOMICS LABORATORIES,) 11 INC.,) 12) 13 Defendant.) 14) 15 16 17 18 19 20 21 22 23 24 25 VIDEOTAPED DEPOSITION OF MICHAEL L. METZKER, PH.D., taken at 865 South Figueroa Street, Los Angeles, California, on Tuesday, September 26, 2023, at 9:25 a.m., before Cheryl Haab Scott, RDR, CRR, CRR, Certified Shorthand Reporter No. 13600 in and for the State of California, Certified Court Reporter No. 3499 in and for the State of Washington, and Certified Court Reporter No. 1003 in and for the State of Nevada.	1 I N D E X 2 --o0o-- 3 WITNESS: Michael L. Metzker, Ph.D. 4 5 Examination By Dr. Walter 7 6 Examination By Dr. Srinivasan 114 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
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1 A P P E A R A N C E S 2 --o0o-- 3 For Plaintiff: 4 QUINN EMANUEL URQUHART & SULLIVAN, LLP 5 BY: TARA SRINIVASAN, PH.D., ESQ. 6 50 California Street, 22nd Floor 7 San Francisco, California 94111 8 415.875.6683 9 tarasrinivasan@quinnemanuel.com 10 QUINN EMANUEL URQUHART & SULLIVAN, LLP 11 BY: SANDRA L. HABERNY, PH.D., ESQ. 12 RAMZIG MESSERIAN, ESQ. 13 865 South Figueroa Street, 10th Floor 14 Los Angeles, California 90017 15 213.443.3438 16 sandrahuberny@quinnemanuel.com 17 razmesserian@quinnemanuel.com 18 For Defendants: 19 WEIL, GOTSHAL & MANGES LLP 20 BY: DEREK C. WALTER, PH.D., ESQ. 21 201 Redwood Shores Parkway 22 Redwood Shores, California 94065 23 650.802.3934 24 derek.walter@weil.com 25 Also Present: KEVIN JOHNSON, VIDEOGRAPHER SEAN BOYLE, PH.D., ESQ. (VIA ZOOM) MIGUEL CONCEPCION (VIA ZOOM)	1 INDEX TO EXHIBITS 2 --o0o-- 3 EXHIBIT NO. PAGE 4 Exhibit 1 "Declaration of Dr. Michael L. Metzker in Support of Plaintiff Natera, Inc.'s Motion for a Preliminary Injunction" 8 5 Exhibit 2 "Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA" 37 6 Exhibit 3 Notice from the United States Patent and Trademark Office; filing date, 05/06/2022, Application No. 17/738,354 64 7 Exhibit 4 Slideshow; first page entitled "Summary of Opinions" 71 8 Exhibit 5 Testimony excerpt, Metzker 72 9 Exhibit 6 Encyclopedia of Medical Devices and Instrumentation, Second Edition, Volume 5; "Nanoparticles - Radiotherapy Accessories" 84 10 Exhibit 7 Deposition of Michael L. Metzker, Ph.D., taken on April 29, 2020 86 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

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1 TUESDAY, SEPTEMBER 26, 2023, 9:25 A.M.
2 LOS ANGELES, CALIFORNIA
3 --oOo--
4 THE VIDEOGRAPHER: We're now on the record.
5 My name is Kevin Johnson. I'm a
6 videographer for Lexitas. This is a video
7 deposition for the United States District Court for
8 the Middle District of North Carolina. Today's
9 date, September 26, 2023, and the time is 9:25 a.m.,
10 Pacific time.
11 This deposition is being held at 865 South
12 Figueroa Street, 10th Floor, Los Angeles, California
13 90017, in the matter of Natera, Inc., versus
14 Neogenomics Laboratories, Inc.
15 Our deponent is Dr. Michael Metzker.
16 All counsel will be noted on the
17 stenographic record and our court reporter today is
18 Cheryl Scott.
19 You may now swear in the witness.
20 --oOo--
21 Whereupon,
22 MICHAEL L. METZKER, PH.D., Lexitas
23 having been called as a witness,
24 was duly sworn by the court reporter
25 and testified as follows:

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1 EXAMINATION
2 BY DR. WALTER:
3 Q Good morning. Please state your name and
4 address for the record.
5 A Good morning. My name is Michael Metzker,
6 M-e-t-z-k-e-r. My home address is 12015 Surrey
7 Lane, S-u-r-r-e-y, Houston, Texas, 77024.
8 Q One reminder before we get started is that
9 we have a court reporter taking everything down. So
10 I'd ask that you wait for me to finish my questions
11 before you start your answer.
12 Do you understand that?
13 A I do.
14 Q What did you do to prepare for your
15 deposition today?
16 A I reviewed my declaration.
17 Q Did you review any other materials to
18 prepare for your deposition besides your
19 declaration?
20 A I would have reviewed the patents in suit,
21 and I would have reviewed documents cited in my
22 declaration.
23 Q Did you meet with the counsel to prepare for
24 your deposition today?
25 A I did.

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1 Q When did you meet with counsel?
2 A That was yesterday.
3 Q How long did you meet with counsel for?
4 A Approximately seven to eight hours.
5 Q You said you reviewed your declaration.
6 That's been marked as Exhibit 1. You have that
7 before you; correct?
8 (Defendant's Exhibit 1 was marked.)
9 THE WITNESS: That's correct.
10 BY DR. WALTER:
11 Q Is there anything you wish to change in your
12 declaration?
13 A I do not.
14 Q Now, in your declaration, you present
15 opinions on whether the RaDaR product infringes two
16 patents; is that correct?
17 A That is correct.
18 Q And you also present opinions on whether the
19 Signatera product embodies those two patents?
20 A That is correct.
21 Q And presenting your opinions on
22 infringement, were you confident that you understood
23 how the RaDaR product worked?
24 A Based on the documents that were available
25 to me at the time I submitted my report.

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1 Q And since that time, have you come across
2 any information that changes your understanding of
3 how the RaDaR product works?
4 A I have not.
5 Q Is there any aspect of the RaDaR product
6 that you feel you didn't understand?
7 A No.
8 Q Your declaration does not include opinions
9 related to the doctrine of equivalents; correct?
10 A I believe that is correct.
11 Q Was there anything that prevented you from
12 offering opinions related to the doctrine of
13 equivalents?
14 DR. SRINIVASAN: Objection. Outside the
15 scope.
16 THE WITNESS: Not that I'm aware of.
17 BY DR. WALTER:
18 Q Does your declaration include any opinions
19 related to the topic of invalidity of the two
20 patents that are at issue in this case?
21 A It does not.
22 Q Have you formed any opinions related to the
23 topic of invalidity?
24 DR. SRINIVASAN: Objection. Outside the
25 scope.

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1 THE WITNESS: As I sit here today, I have 2 not, but that may change in the future. 3 BY DR. WALTER: 4 Q Our understanding is that you don't plan to 5 present opinions on invalidity in this case; is that 6 correct? 7 A I'll give you the same answer as I sit here 8 today, that -- that is true but that may change in 9 the future. 10 Q Why is it that, at this time, you don't plan 11 to present opinions on invalidity? 12 DR. SRINIVASAN: Objection. Outside the 13 scope. 14 THE WITNESS: I have not been asked to do so 15 yet. 16 BY DR. WALTER: 17 Q Are you prepared to testify on the subject 18 of invalidity here today? 19 DR. SRINIVASAN: Objection. Outside the 20 scope. 21 THE WITNESS: I am not. 22 BY DR. WALTER: www.LexitasLegal.com/Premier Lexitas 23 Q Okay. You understand that you need to 24 answer questions today I'm going to pose to you 25 unless you're instructed not to answer for reasons	1 Q What other documents have you reviewed? 2 A There were a bolus of documents produced 3 over the weekend that I have also briefly reviewed. 4 Q And what were those documents? 5 A Generally, there were some poster 6 presentations and then there were a number of work 7 instructions. 8 Q They were standard operating procedures? 9 A I believe one had a designation of an SOP. 10 Q And how many documents were you given to 11 review over the weekend? 12 A I don't know the exact number. 13 Q And for what purpose did you review those 14 documents? 15 DR. SRINIVASAN: Objection. Vague. 16 THE WITNESS: Well, as an expert, I was 17 reviewing documents that were presented in the case 18 to make a determination whether the additional 19 information would change my opinions or not, and in 20 this case, they did not. 21 BY DR. WALTER: 22 Q Was there any other purpose for which you 23 reviewed those documents? 24 DR. SRINIVASAN: Objection. Vague. 25 THE WITNESS: No. Not over the weekend.
Page 11	Page 13
1 related to privilege; correct? 2 A I do understand that. 3 Q Are you aware that on Friday of last week, 4 Neogenomics submitted an interrogatory response to 5 Natera related to the topic of invalidity? 6 A I'm aware of that. 7 Q Have you reviewed that? 8 A I have briefly reviewed that document. 9 Q For what purpose did you review that 10 document? 11 A Just so I had an understanding of what 12 Neogenomics's positions were. 13 Q And are you prepared to testify on that 14 today? 15 DR. SRINIVASAN: Objection. Vague. 16 THE WITNESS: Well, I did not include it in 17 my report, and if presented, I guess I would try to 18 answer questions as best I could with the knowledge 19 that I have currently. 20 BY DR. WALTER: 21 Q Since preparing your declaration, have you 22 reviewed any further documents that Neogenomics has 23 produced in this case besides the interrogatory 24 response? 25 A Yes.	1 No. 2 BY DR. WALTER: 3 Q Have you reviewed the file histories for the 4 patents that are at issue in this case? 5 A Yes. 6 Q Do you know how much time you spent 7 reviewing the file histories that are at issue in 8 this case? 9 A I do not. 10 Q Now, this declaration that's been marked as 11 Exhibit 1, do you know how much time you spent 12 preparing that declaration? 13 A I don't know the exact number. 14 Q Do you have an estimate? 15 A I may have spent anywhere from 75 to a 16 hundred hours. 17 Q Let's look at paragraph 88 of that 18 declaration -- actually, let's go to paragraph 100 19 of that declaration. 20 A Yes, I'm there. 21 Q You refer to a preamplification step that 22 you contend is used in RaDaR in paragraph 100. 23 Do you see that? 24 A I see that in the first sentence of 25 paragraph 100.

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1 Q And where is that preamplification step in 2 the diagram that you refer to in paragraph 100? 3 A So I'm looking at my declaration at page 57, 4 and there's a figure. And at the top of the figure, 5 to the left-hand side, there's a box that says 6 "preamp," and that would indicate the 7 preamplification step; and then there's also another 8 step called "access array IFC." 9 Q Do you know what "access array IFC" is? 10 A Yes. 11 Q What is that? 12 A It's a device produced by Fluidigm for doing 13 multiple reactions in a very small volume 14 instrument. 15 Q Now, you state in paragraph 100: 16 "Forsheiw illustrates in a first round of 17 PCR, amplifying the tagged products one or more 18 times to generate final amplification products." 19 Do you see that? 20 A I do. 21 Q And that first round of PCR is the process 22 that is referred to in the diagram as "preamp." Lexitas 23 Is that right? 24 A It is preamp, and it's also inclusive of the 25 access array IFC.	1 listen the whole time. 2 DR. HABERNY: Okay. I just want to make 3 sure. 4 (Discussion off the record.) 5 DR. HABERNY: This is all public 6 information. 7 THE WITNESS: Mr. Walter, can you repeat the 8 question, please. 9 BY DR. WALTER: 10 Q These tail adaptors that are referred to in 11 Claim 12, those are the tail adaptors that were 12 referred to in step 1A of the '035 patent; correct? 13 A Yes. 14 Q All right. And paragraph 108 of your 15 report, the last full sentence, you state: 16 "According to Defendant, Gale (2018) uses 17 the eTAm-Seq technology that employs barcoding PCR 18 using universal tailed adaptors." 19 Do you see that? 20 A If I can have a moment to review the 21 paragraphs. 22 I do see the last sentence that refers to 23 Gale using eTAm-Seq technology that employs barcode 24 PCR using universal tail adaptors, but those aren't 25 the only tail adaptors in the method.
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1 Q Now, at the end of that preamp and access 2 array IFC, the amplified products do not yet have 3 barcodes or sequencing tags; is that correct? 4 A That is correct. 5 Q Let's go to paragraph 108 of your 6 declaration. 7 A Yes, I'm there. 8 Q Here, you're opining on Claim 12; correct? 9 A Is your question to paragraph 108? 10 Q Yes. 11 A That is correct. 12 Q Claim 12 refers to the method of Claim 1, 13 where one or more universal tail adaptors comprised 14 of first universal tail adaptor and a second 15 universal tail adaptor; correct? 16 A That is correct. 17 Q And those tail adaptors that are referred to 18 in Claim 12, those are the tail adaptors that are 19 referred to in step 1A of Claim 1 of the '035 20 patent. 21 Is that correct? 22 DR. HABERNY: Counsel, is this designated 23 confidential or not? Just because all this is 24 public information. 25 DR. WALTER: I've been letting the fellow	1 Q You contend that Claim 12, the claim element 2 that refers to the use of tail adaptors, is 3 satisfied through the use of the universal tail 4 adaptor that you contend are included as part of the 5 barcoding PCR; correct? 6 A Well, as I just testified, those are one of 7 the tail adaptors. There are other tail adaptors in 8 the method. 9 Q That wasn't my question. 10 Do you contend that the universal tail 11 adaptor claim element of Claim 12 of the '035 patent 12 is satisfied by universal tail adaptors that you 13 contend are included as part of the barcoding PCR in 14 RaDaR? 15 A I will give you the same answer. It's 16 included, but it's not completely satisfied as there 17 are other tail adaptors in the method. 18 Q Okay. You contend that one way that the 19 universal tail adaptor of Claim 12 of the '035 20 patent is satisfied is through the use of the 21 universal tail adaptors that are included in the 22 barcoding PCR; correct? 23 A They can be included, but they're not 24 exclusive just to the barcoded tail adaptors. 25 Q That's not my question.

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1 Claim 12 refers to universal tail adaptors; 2 correct? 3 A It refers to one or more universal tail 4 adaptors, not just a tail adaptor. 5 Q You contend that that claim element of one 6 or more universal tail adaptors is satisfied by the 7 use of the barcoding PCR that you contend includes 8 universal tail adaptors in RaDaR; correct? 9 DR. SRINIVASAN: Objection. Asked and 10 answered. 11 THE WITNESS: My answer to your question is 12 it is one of the tail adaptors, but it's not 13 exclusively the only tail adaptor that satisfies -- 14 satisfies Claim 12. 15 BY DR. WALTER: 16 Q Okay. Now after the barcoding PCR that 17 takes place in RaDaR, are you aware of any further 18 amplification steps that are used in RaDaR? 19 DR. SRINIVASAN: Objection. Vague. 20 THE WITNESS: Yes. 21 BY DR. WALTER: 22 Q What amplification steps do you believe 23 there are following the barcoding PCR in RaDaR? 24 A So as I understand it, the sequencing 25 platform that's used is the Illumina platform. And	1 barcoding; correct? 2 A If I can have a moment to get to that 3 section on my declaration. 4 And your question is related to the '035 5 patent Claim 1B? 6 Q Yes. 7 A Can you repeat the question, please? 8 Q That refers to a barcode. 9 A Well, there's several limitations, one of 10 which is a wherein. One of the amplifying steps 11 introduces a barcode and one or more sequencing 12 tags. 13 Q What is a barcode? 14 A Can you be more specific? 15 Q Well, in Claim 1B of the '035 patent, we've 16 established that it refers to a barcode. What do 17 you understand that to be? 18 A Well, generally a barcode for sequencing 19 purposes would be a DNA sequence that has either 20 been selected or randomized that provides 21 information either related to a sample or a 22 particular fragment. 23 Q The barcode is used to either identify the 24 sample or the particular DNA fragment. 25 Is that right?
Page 19	Page 21
1 the Illumina platform requires a bridge 2 amplification to take place before sequencing takes 3 place. 4 Q Where, if at all, in your declaration do you 5 point to the Illumina bridge amplification? 6 A I don't think I actually describe it, but 7 it's something that Illumina tells all of its 8 customers to perform. 9 Q So the Illumina bridge amplification 10 process, you don't point to that anywhere in your 11 report as satisfying any of the claim elements of 12 any of the asserted patents; correct? 13 DR. SRINIVASAN: Objection. 14 Mischaracterizes testimony. 15 THE WITNESS: Well, I don't describe the 16 Illumina bridge amplification in my declaration at 17 all. 18 BY DR. WALTER: 19 Q You never refer to it once at all; correct? 20 A I don't. As I testified, Illumina would 21 instruct its users to use bridge amplification in 22 its sequencing process. 23 Q Now, Claim 1C of the '035 patent -- excuse 24 me. 25 Claim 1B of the '035 patent, that refers to	1 A Well, I'm talking generally. I'm not 2 talking about what's in the claim. In general, 3 barcodes can be used in either/or both ways. 4 Q In the claim, what do you understand the 5 word "barcode" to be referring to? 6 Do you know? 7 A Well, I really haven't spent a lot of time 8 analyzing the validity or the written description of 9 the claim. Just generally speaking, a barcode would 10 identify something in the sample. 11 Q When you say "something in the sample," what 12 is that something? 13 DR. SRINIVASAN: Objection. Vague. 14 THE WITNESS: Well, as I testified, a 15 barcode in general can be used to identify a 16 particular sample, or it can be used to identify a 17 particular fragment. 18 BY DR. WALTER: 19 Q Within the sample? 20 A Within the sample. 21 Q Now, one of the things you referred to at 22 various points, I think, in your declaration, and 23 probably at other points in your career is 24 "multiplex PCR." 25 What is multiplex PCR?

Page 22 1 A Generally -- again, I'm not trying to 2 provide any opinions on claim construction or 3 written description. But, generally, in the 4 scientific community, multiplex PCR is the 5 amplification of two or more targets in a single 6 reaction test tube. 7 Q And is multiplex PCR for those two or more 8 targets, would you have a separate primer pair for 9 each of those targets? 10 A Not necessarily. 11 Q Please describe why you wouldn't necessarily 12 need a separate primer pair for each of the targets 13 to have multiplex PCR. 14 A Well, again, I'm not trying to provide any 15 opinions on claim construction or written 16 description or even validity; but there are 17 different ways that investigators have reported in 18 the scientific community, one of which is where you 19 could use separate primers to amplify multiple 20 targets. You could also provide a multiplex 21 reaction where one end of the fragment has a common 22 primer, uses the same primer, and the other end uses 23 different primer sets. 24 Q Okay. So in that example you've given, the 25 two targets would each at least use one primer that	Page 24 1 call that a pair of primers. 2 Q Can you think of a way of doing multiplex 3 PCR wherein you would use the same forward and 4 reverse primer for each of the targets you were 5 trying to amplify? 6 DR. SRINIVASAN: Objection. Vague. 7 THE WITNESS: Well, I can imagine a scenario 8 where it's combined with another step. For example, 9 maybe in the first step, target-specific primers -- 10 primers pairs, and we'll just keep it simple -- are 11 amplifying two targets. And those primers have 12 common adaptors on the end of each primer that now 13 incorporates universal tags onto the amplified 14 products and then a second round of using a 15 universal PCR which would be the same primer pair 16 that's still amplifying the two targets in the 17 sample. So that could be an example of a multiplex 18 PCR using the same primer pairs. 19 BY DR. WALTER: 20 Q That universal PCR, you would call that a 21 multiplex PCR? 22 A Well, I would call it multiplex PCR in the 23 way I described it, which is part of a workflow 24 where the first steps involve target-specific 25 amplification. And then the second step using the
Page 23 1 was specific to the target. 2 Is that right? 3 A Yes. Based on the answer I just gave you, 4 that is correct. 5 Q Would you call it -- can you think of an 6 example of doing multiplex PCR where each target 7 would use the same pair of primers? 8 DR. SRINIVASAN: Objection. Vague. 9 THE WITNESS: I don't understand the 10 question. 11 BY DR. WALTER: 12 Q Can you think of a way of doing multiplex 13 PCR where each target you were trying to amplify 14 would use the same pair of primers? 15 DR. SRINIVASAN: Objection. Vague. 16 THE WITNESS: Again, I don't understand your 17 question. What do you mean by the "same pair of 18 primers"? 19 BY DR. WALTER: 20 Q Well, for PCR, you use a pair of primers for 21 each target; right? 22 A As I've testified, in general, not being 23 bound to any opinions on claim construction or 24 validity, the standard method for PCR would involve 25 a forward primer and a reverse primer. We would	Page 25 1 universal sequences to then amplify because they are 2 amplifying those multiple targets in the sample. 3 Q Okay. So a universal PCR, you contend, 4 could be a multiplex PCR. 5 Is that right? 6 DR. SRINIVASAN: Objection. Vague. Calls 7 for a legal conclusion. 8 THE WITNESS: I've explained it from a 9 scientific standpoint, from a technical standpoint 10 where it would be combined with a first 11 target-specific PCR step. 12 Q When you say "it would be combined with a 13 first target-specific PCR," what would be combined 14 with a first target-specific PCR? 15 THE WITNESS: The second round of PCR where 16 you're using the same primer set for the two targets 17 that I used just in the example, the general 18 example, in my previous question -- answer. 19 BY DR. WALTER: 20 Q Now, if you had a process whereby you had a 21 DNA sample and you ligated universal adaptors to all 22 the DNA fragments in your sample and then you did 23 PCR using those universal adaptors, would you call 24 that a multiplex PCR? 25 DR. SRINIVASAN: Objection. Lacks

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1 foundation. Calls for speculation. 2 THE WITNESS: Well, I haven't considered 3 that. 4 BY DR. WALTER: 5 Q Well, I'm asking you to consider it now. 6 A Yeah, I guess, again, I'm not providing any 7 opinions on claim construction or validity. I would 8 have to do some more research, for example, 9 reviewing the specification and the intrinsic 10 evidence in the case, to better understand the 11 example that you're -- just provided. 12 Q We'll walk through the example a little bit 13 more. Imagine you have a DNA sample with fragmented 14 DNA. 15 Do you understand that? 16 DR. SRINIVASAN: Objection. Vague. 17 THE WITNESS: I do understand the general 18 process of fragmenting DNA. 19 BY DR. WALTER: 20 Q And then imagine you ligate universal tail 21 adaptors to each end of the DNA fragments. 22 Do you understand that? 23 DR. SRINIVASAN: Objection. Incomplete 24 hypothetical. 25 THE WITNESS: I do understand that general	1 speculation. 2 THE WITNESS: Well, again, not being bound 3 to any opinions on claim construction or validity, 4 but in general, that method is not a targeted method 5 and therefore would not be a multiplex PCR method. 6 BY DR. WALTER: 7 Q Thank you. 8 Let's look at paragraph 88 of your 9 declaration. 10 Let me ask another question. You mentioned 11 the bridge amplification that takes place in the 12 Illumina sequencing system. 13 A Yes. 14 Q Is that a targeted amplification? 15 A No. 16 Q All right. Let's go to paragraph 88 of your 17 declaration. 18 A Yes, I'm there. 19 Q And here, you cite ForsheW (2012) as 20 disclosing a PCR scheme that you believe is used in 21 RaDaR. 22 A Well, I think I cite ForsheW because 23 Gale (2018) relies on ForsheW as part of the RaDaR 24 assay. 25 Q Is it your understanding that this PCR
Page 27	Page 29
1 premise of ligating adaptors onto the ends of DNA 2 fragments. 3 BY DR. WALTER: 4 Q And then you do a PCR wherein you use a 5 single forward and reverse primer that is directed 6 to the universal tail adaptors on the ends of the 7 DNA fragments. 8 Do you understand that? 9 DR. SRINIVASAN: Objection. Incomplete 10 hypothetical. 11 THE WITNESS: Can you repeat that question 12 again, please. 13 BY DR. WALTER: 14 Q And then you do a PCR in -- excuse me. And 15 then you do a PCR wherein you use a single forward 16 and reverse primer that is directed to universal 17 tail adaptors on the ends of the DNA fragments. 18 Do you understand that? 19 DR. SRINIVASAN: Same objection. 20 THE WITNESS: I understand the general 21 concept. 22 BY DR. WALTER: 23 Q Okay. Would you call that PCR a multiplex 24 PCR? 25 DR. SRINIVASAN: Objection. Calls for	1 scheme that you cite in paragraph 88 is what's used 2 in RaDaR? 3 A Well, I've only looked at public documents 4 to date, although I did see a couple of internal 5 documents over the weekend. But based on what 6 Gale (2018) says -- and I need to find that -- yeah, 7 so I'm actually -- sorry. I just want to go back to 8 paragraph 82 on page 42, and this is what Gale says. 9 "Library preparation using eTAm-Seq 10 technology. ETAm-Seq technology is based on methods 11 previously described" -- and gives three references. 12 Reference 22 is ForsheW (2012) -- "with an optimized 13 assay workflow utilizing multiplex PCR to enable 14 high-throughput library preparation without the use 15 of microfluidics." 16 Why I'm saying that is ForsheW (2012), the 17 access array IFC is the microfluidics that I 18 understand was removed in the Gale (2018) optimized 19 eTAm-Seq technology. 20 Q So is it your understanding that the diagram 21 that you relied upon in paragraph 88 is what's used 22 in RaDaR with the exception of the access array IFC 23 process being removed? 24 A At a high level, I generally think it 25 includes these steps.

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1 Q But not the access array items? When you 2 say "it," you mean RaDaR; right? 3 A I mean RaDaR; and based on what Gale (2018) 4 describes, the microfluidic part has been removed 5 from the assay. 6 Q So your understanding is that the access 7 array IFC that's described in Forshaw (2012) is not 8 part of RaDaR. 9 Is that your understanding? 10 A Based on the public documents that I have 11 reviewed in this case so far, that's my 12 understanding. 13 Q It's accurate, then, that you do rely upon 14 Forshaw (2012) for information regarding how the 15 RaDaR products work; correct? 16 A That's correct. 17 Q Now, you mentioned this -- you understand 18 that the Forshaw paper describes a method known as 19 TAM-Seq? 20 A That's correct. 21 Q And you contend that RaDaR uses the eTAM-Seq 22 core TAM-Seq method; correct? 23 A That's based on the public documents that I 24 -- that have been made available to me or that I 25 have reviewed since I provided my declaration.	1 labeled as the access array IFC, and your 2 understanding is enhanced TAM-Seq uses some 3 additional statistical methods for error correction; 4 is that right? 5 A Right. And that knowledge is based on the 6 Gale (2018) paper that cites three papers. And 7 again, I'm looking at page 42 at paragraph 82 that 8 cites reference 22, 25, and 26. And I think those 9 references better capture all the differences 10 between TAM-Seq and eTAM-Seq. 11 Q And you reviewed those references? 12 A I have. 13 Q And the differences you're able to identify 14 sitting here today are the two that we've discussed, 15 the lack of a microfluidic device and the 16 statistical methods; is that right? 17 A Right. And I think eTAM-Seq also -- and 18 again, it -- as I understand, this is not a memory 19 test, but I believe eTAM-Seq also uses -- you know, 20 just looking through my declaration -- different 21 inputs or copy numbers that are also part of the 22 eTAM-Seq methodology. And give me a moment, and I 23 will find that for you. 24 Here it is. Great. So I'm looking at page 25 17 in paragraph 44, and this the same Gale
Page 31	Page 33
1 Q Do you have any understanding of how 2 eTAM-Seq differs from TAM-Seq? 3 A Yes. 4 Q Okay. What is your understanding of how 5 eTAM-Seq or enhanced TAM-Seq differs from TAM-Seq? 6 A Well, one difference I've already testified 7 is it does not require the microfluidic portion of 8 the TAM-Seq technology. 9 Q Anything else? 10 A I believe there are also some statistical 11 methods for reducing errors. 12 Q Anything else? 13 A There could be, but not off the top of my 14 head as I sit here right now. 15 Q Other than those two differences, you're not 16 able to identify any other differences between the 17 enhanced TAM-Seq method that's used in RaDaR and the 18 TAM-Seq method that's described in Forshaw (2012); 19 is that right? 20 A Well, without reviewing the actual documents 21 that I cite in my report, I'm giving you my best 22 estimation of what I understand based on the public 23 documents produced today, are the differences. 24 Q And those two differences are the enhanced 25 TAM-Seq does not use a microfluidic system that's	1 reference; but in this block code, I add additional 2 information where Gale uses different input amounts 3 of DNA, either 2000AC, which are amplifiable copies 4 as they refer to them as low, 8,000 AC medium and 5 16,000 AC high. I think they also use that as part 6 of their error-reduction method. 7 Q Anything else you're aware of that reflects 8 a difference between enhanced TAM-Seq and TAM-Seq? 9 A Again, there may be others, not as I sit 10 here right now. 11 Q And you understand the Forshaw (2012) 12 describes TAM-Seq; is that right? 13 A Forshaw (2012) does describe TAM-Seq. 14 Q Okay. Now, you understand that part of the 15 RaDaR process involves the analysis of cell-free 16 DNA? 17 A Yes. 18 Q And you contend that the RaDaR process 19 involves the amplification of cell-free DNA; right? 20 A It does involve the amplification of 21 cell-free DNA. 22 Q Let's go to paragraph 89 of your 23 declaration. 24 And here you're referring to Forshaw (2012)? 25 A Yes.

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1 Q And you refer to the preamplification step 2 and a singleplex PCR step; correct? 3 A This is a block quote from ForsheW (2012). 4 Q And it refers there to a preamplification 5 and a singleplex PCR stage; right? 6 A Yes. 7 Q Now, I want to talk about the 8 preamplification step which we've already discussed 9 some today. 10 You contend that in connection with that 11 preamplification step, the universal tail adaptor is 12 added; correct? 13 A Correct. And ForsheW (2012) explains that 14 as CS1 and CS2 being the universal tail adaptors. 15 Q To your knowledge, does the specification of 16 either of the patents in suit ever refer to a 17 universal tail adaptor? 18 A Gee, they're quite large patents. I would 19 have to review that to know one way or the other. 20 Q Did you ever look? 21 A I have reviewed those patents. 22 Q And did you ever look to see if they refer 23 to a universal tail adaptor? 24 A I don't think -- I don't remember whether I 25 did or did not, but they do talk about tail	1 person of ordinary skill in the art would have 2 looked at ForsheW (2012) and understood CS1 and CS2, 3 meeting that claim limitation, and so I think they 4 would just understand it from that perspective. 5 BY DR. WALTER: 6 Q Can you be any more specific than that as to 7 what an ordinary skilled artisan would understand a 8 "universal tail adaptor" to mean as referred to in 9 Claim 1 of the '035 patent? 10 DR. SRINIVASAN: Objection. Vague. 11 THE WITNESS: I cannot. I've given you my 12 best answer. 13 BY DR. WALTER: 14 Q And your best answer is that you don't know 15 what it is except you think that the CS1 adaptor 16 satisfies the claim? 17 DR. SRINIVASAN: Objection. 18 Mischaracterizes testimony. 19 THE WITNESS: What I said is I've taken the 20 approach -- first, I'm not offering an opinion on 21 claim construction. I am offering that there are no 22 terms in dispute; that a person of ordinary skill 23 would have just used plain and ordinary meaning and 24 just looking at the claim language and looking at 25 ForsheW (2012) would understand that CS1 and CS2
Page 35	Page 37
1 adaptors. 2 Q What is a universal tail adaptor as referred 3 to in Claim 1 of the '035 patent? 4 A Well, I'm not providing any opinions on 5 claim construction of what a universal tail adaptor 6 means in the context of the claim. I haven't 7 provided that in my declaration. 8 Q What did you understand universal tail 9 adaptor to mean as referred to in Claim 1 of the 10 '035 patent as you prepared your opinions on 11 infringement? 12 DR. SRINIVASAN: Objection. Calls for a 13 legal conclusion. 14 THE WITNESS: Well, I think I've taken the 15 approach that I don't think there are any terms in 16 dispute in this case, and that any term would be 17 reviewed by a person of ordinary skill in the art to 18 have its plain and ordinary meaning. 19 BY DR. WALTER: 20 Q And in that case, what is the plain and 21 ordinary meaning of "universal tail adaptor" to a 22 person of ordinary skill in the art? 23 DR. SRINIVASAN: Objection. Calls for a 24 legal conclusion. 25 THE WITNESS: Well, in my opinion, I think a	1 meets that claim limitation. 2 BY DR. WALTER: 3 Q You understand what a universal tail adaptor 4 is as a skilled artisan; correct? 5 A In the general scientific community, I would 6 have an understanding of what that is. 7 Q Give me your understanding of what a 8 universal tail adaptor is in the general scientific 9 community as you would understand it. 10 A Again, I'm not offering an opinion on claim 11 construction. But just generally, it would be what 12 we call a common sequence that is attached to the 13 ends of a DNA fragment. 14 Q And what do you mean by "common sequence"? 15 A Well, again, not being bound to any opinions 16 on claim construction, a common sequence could be -- 17 and there probably other ways of characterizing 18 common sequence -- but the one I'm thinking about 19 right now would be a sequence that would be the same 20 attached to different fragments. 21 (Defendant's Exhibit 2 was marked.) 22 BY DR. WALTER: 23 Q All right. I've marked as Exhibit 2 a 24 document that is Exhibit 7 to your declaration which 25 is the ForsheW (2012) publication.

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1 You recognize this; correct? 2 A Yes. 3 Q All right. I'm going to continue to ask 4 about that preamplification step, and I want you to 5 look at page 3, the left-hand column. 6 A I'm on page 3. 7 Q At the top of the left-hand column, there's 8 a sentence that begins "We therefore applied." 9 Do you see that? 10 A I do see the sentence. 11 Q It says: 12 "We therefore applied a two-step 13 amplification process: A limited-cycle 14 preamplification step for all primer sets were used 15 together to capture the starting molecules present 16 in the template." 17 Do you see that? 18 A I do see that. 19 Q And let's go to page 2 of "Supplementary 20 Methods." 21 A Yes, I'm on page 2. 22 Q And you can see at the bottom there is a 23 reference to the preamplification step that we've 24 been discussing. 25 Do you see that?	1 Q This is listing the target-specific primers 2 that were used in that preamplification reaction? 3 A That's correct. 4 Q And there's more than 20 targets that are 5 listed there? 6 A Well, I haven't counted them. Looks like 7 20. 8 Q There's more than 20; right? Because the 9 table continues on the next page; right? 10 A You are correct. 11 Q And it's this preamplification step that you 12 contend satisfies Claim Element 1A of the '035 13 patent; correct? 14 A The preamplification step does satisfy the 15 claim element tagging isolated cell-free DNA with 16 one or more universal tail adaptors. 17 Q Now, let's go to page 9 of the Forshew 18 publication. And you can see in the top left-hand 19 column. 20 A My copy has been marked as -- 21 Q Yes. 22 A -- it should be. Okay. 23 Q In highlighted text, it says: 24 "Whole-genome sequencing of tumor material 25 was used to identify tumor mutations and a
Page 39	Page 41
1 A I do see that section. 2 Q And it states: 3 "Preamplification reactions were carried out 4 in 10-microliter reaction volumes containing 5 50 nanometers [sic] of each forward and reverse 6 target-specific primer." 7 Do you see that? 8 (Reporter clarification.) 9 THE WITNESS: I think you misquoted that 10 sentence. 11 BY DR. WALTER: 12 Q Right. It states: 13 "Preamplification reactions were carried out 14 in 10-microliter reaction volumes containing 50 15 nanomolar of each forward and reverse 16 target-specific primer." 17 Correct? 18 A That is correct. 19 Q So you understand that the preamplification 20 step that's described in Forshew (2012) is a 21 reaction where all the targets are amplified 22 together in the same tube? 23 A That's my understanding. 24 Q Now, let's go to Table S1. 25 A Yes, I'm there.	1 mutation" -- excuse me -- "in a patient with 2 metastatic breast cancer undergoing two phases of 3 chemotherapy. Ten mutations were selected, and 4 short amplicons (less than 120 base pairs) were 5 designed to cover the mutation loci." 6 Do you see that? 7 A I do see that sentence on page 9. 8 Q And it talks about plasma samples being 9 collected over the course of 497 days. 10 Do you see that? 11 DR. SRINIVASAN: Objection. Outside the 12 scope. 13 THE WITNESS: I do see that sentence on 14 page 9 of Forshew as well. 15 BY DR. WALTER: 16 Q You understand that this experiment in 17 Forshew (2012) was to monitor for cancer over time? 18 DR. SRINIVASAN: Objection. Outside the 19 scope. 20 THE WITNESS: It's been a while since I've 21 read this paper. I would have to read it again to 22 understand what this experiment is. 23 BY DR. WALTER: 24 Q If you want to take a few minutes to review 25 this experiment, that's fine. Go ahead and do so.

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1 Let me know when you're done.

2 A I will. And I'm actually starting on page 8

3 in the section titled "Monitoring Levels of ctDNA."

4 Okay. I've read that section.

5 Q All right. Having reviewed that section,

6 you understand this is describing experiments that

7 used TAm-Seq?

8 DR. SRINIVASAN: Objection. Calls for

9 speculation. Outside the scope.

10 THE WITNESS: Well, the paper does use

11 TAm-Seq.

12 BY DR. WALTER:

13 Q And the experiments described in the section

14 beginning on page 8 entitled "Monitoring Levels of

15 ctDNA" and continuing on to page 9, that uses

16 TAm-Seq; correct?

17 A Well, the document does cite TAm-Seq in this

18 section.

19 Q It says "We performed TAm-Seq in duplicate"

20 on page 9; correct?

21 A Sorry, I'm not finding -- oh, yes. It does

22 state that in the paper. www.LexitasLegal.com/Premier Lexitas

23 Q And these experiments were done to monitor

24 cancer over time in blood plasma; correct?

25 DR. SRINIVASAN: Objection. Outside the

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1 scope. Calls for speculation and vague.

2 THE WITNESS: Well, I mean, I just read this

3 section. I still would have to further consider

4 what they're actually trying to do. I will agree

5 they are using TAm-Seq in this article.

6 BY DR. WALTER:

7 Q And they're using it to monitor -- to look

8 for cancer -- the presence of cancer mutations in

9 blood plasma over time.

10 You agree with that; right?

11 DR. SRINIVASAN: Objection. Calls for

12 speculation.

13 THE WITNESS: I would have to think about

14 this further to be able to answer that question.

15 BY DR. WALTER:

16 Q You've reviewed this paper carefully for

17 your declaration; right?

18 A I have.

19 Q And you cite it throughout your declaration;

20 right?

21 A I have, but not for the purposes of

22 validity.

23 Q And -- and in order to answer this question

24 about whether this passage regarding monitoring

25 levels of circulating tumor DNA is for the purpose

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1 of monitoring cancer in blood plasma over time, you

2 would need to review the whole paper more carefully.

3 You wouldn't be able to answer that without further

4 review; is that right?

5 A That's correct. I haven't -- sitting here

6 right now, I haven't formed an opinion on validity

7 nor was I asked to. That may change in the future.

8 DR. SRINIVASAN: Counsel, we've been going

9 for about an hour now. I'd like to request that we

10 take a break when you feel it's appropriate.

11 DR. WALTER: All right.

12 BY DR. WALTER:

13 Q The experiments that are listed -- that are

14 described on pages 8 and 9, that involved ten

15 targets; correct?

16 A I'm not sure. I mean, it looks like there's

17 several targets being discussed, but I don't know

18 the exact number.

19 Q It states:

20 "Ten mutations were selected, and short

21 amplicons were designed to cover the mutation loci."

22 Do you see that?

23 A Sorry, are we on page 8 or page 9?

24 Q Page 9, the highlighted text.

25 A I can agree that's what the paper states,

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1 but I'm not offering an opinion of what that means.

2 Q Okay. Do you understand what --

3 DR. SRINIVASAN: Would you like to take a

4 break?

5 THE WITNESS: Yeah, if --

6 DR. WALTER: Let me finish this line of

7 questioning.

8 BY DR. WALTER:

9 Q Having reviewed the paper for your

10 declaration, having relied upon your declaration,

11 are you able to say what that passage means when it

12 states "Ten mutations were selected" --

13 (Reporter clarification.)

14 BY DR. WALTER:

15 Q "Ten mutations were selected, and short

16 amplicons less than 120 base pairs were designed to

17 cover the mutation loci."

18 Can you say what that means?

19 DR. SRINIVASAN: Objection. Outside the

20 scope. Calls for speculation.

21 THE WITNESS: I haven't -- I have not formed

22 an opinion of what that means. I may do that in the

23 future; but for my purposes of infringement, I'm

24 focused primarily on the assay and not how it was

25 applied in this paper.

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1 BY DR. WALTER:
2 Q Okay. So as someone who's an expert in the
3 field and who has reviewed the Forshaw paper
4 thoroughly and has relied upon it in his
5 declaration, you're not able to tell me sitting here
6 today what that sentence I've just referred to
7 means; is that right?
8 A That's right. I have not formed an opinion
9 because this would be an opinion based on validity;
10 and I have not spent any time or research doing that
11 as of today, but that may change in the future.
12 DR. HABERNY: Counsel, both counsel and the
13 witness have requested a break now several times.
14 Can we take one?
15 DR. WALTER: We can take a break now.
16 DR. HABERNY: It's been more than an hour.
17 DR. WALTER: Actually, I don't think it's
18 been an hour. It's only been -- it's been exactly
19 one hour. But I wanted to finish my line of
20 questioning. We can take a break now.
21 THE VIDEOGRAPHER: We're going off the
22 record. The time is 10:25 a.m. www.LexitasLegal.com/Premier Lexitas
23 (Recess.)
24 THE VIDEOGRAPHER: We're back on the record.
25 It's 10:38 a.m.

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1 BY DR. WALTER:
2 Q Dr. Metzker, during the break, did you
3 discuss the substance of your testimony with
4 counsel?
5 A I did not. I just asked a general question
6 of how long the deposition would be.
7 Q Now, apologies if I asked that already. The
8 preamplification process that we've been talking
9 about in Forshaw 2012, is that a multiplex PCR?
10 A Can I refer back to the figure?
11 Q Yes.
12 A Okay. I'm on page 57. In the
13 preamplification, where two or more primer pairs are
14 in the same reaction tube, is a multiplex PCR.
15 Q And that would have been a targeted
16 multiplex PCR. Is that fair?
17 A They are doing targeted multiplex PCR.
18 Q And for what steps of Claim 1 of the '035
19 patent do you rely upon that preamplification
20 process?
21 A I would rely on the preamplification process
22 of Forshaw (2012) for Claim 1A of the '035 patent
23 and also Claim 1B of the '035 patent.
24 Q You rely on the preamplification for both
25 steps; is that right?

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1 A That is correct.
2 Q And for what steps of Claim 1 of the '454
3 patent do you rely upon that preamplification
4 process?
5 A I do not believe that I actually cite
6 Forshaw (2012) -- let me just go back and make sure
7 that's right.
8 DR. SRINIVASAN: Objection.
9 (Reporter clarification.)
10 DR. SRINIVASAN: I'd like to interpose an
11 objection of lacks foundation for the last question.
12 THE WITNESS: I don't believe I used
13 Forshaw (2012) as part of the infringement analysis
14 of the '454 patent.
15 BY DR. WALTER:
16 Q And you do rely upon the preamplification
17 process that's in RaDaR; right?
18 DR. SRINIVASAN: Objection. Vague.
19 THE WITNESS: Can you point me to which
20 preamplification process you mean in RaDaR?
21 BY DR. WALTER:
22 Q Is there a preamplification process that you
23 understand is used in RaDaR?
24 A And are we referring to the '454 or the '035
25 patent?

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1 Q I wasn't referring to either one -- does
2 the -- does the RaDaR process -- does that use a
3 preamplification process?
4 DR. SRINIVASAN: Objection. Vague.
5 BY DR. WALTER:
6 Q Let's do it this way. Let's look at
7 paragraph 88.
8 In paragraph 88, you have the diagram from
9 Forshaw (2012)?
10 A That is correct.
11 Q And the diagram refers to a preamplification
12 process; correct?
13 A That is correct.
14 Q Do you contend that that preamplification
15 process is used in RaDaR today?
16 A Well, to the best of my knowledge, based on
17 publicly available documents, which I've relied
18 on -- for example, Gale (2018), and I'm looking at
19 the previous page, 47 -- in paragraph 87, they
20 describe using the eTAm-Seq, not the TAm-Seq, and
21 they describe the eTAm-Seq technology as based on
22 methods previously described, and they do list
23 Forshaw. So I did testify there are differences, as
24 I understand them, between TAm-Seq and eTAm-Seq.
25 Q Okay. That wasn't my question.

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1 My question was different. 2 Do you contend that the preamplification 3 process is used in RaDaR today? 4 DR. SRINIVASAN: Objection. Vague. 5 THE WITNESS: Well, what I can contend is 6 what is stated in Gale; and Gale says "next 7 generation sequencing libraries were prepared using 8 a two-step multiplex PCR amplification process." 9 Because there are changes between 10 Forshaw (2012) and Gale (2018), I can just state 11 what's -- Gale describes as a two-step PCR -- 12 multiplex PCR process. 13 BY DR. WALTER: 14 Q And do you have any understanding of how 15 that two-step multiplex PCR that's set forth in Gale 16 works? 17 A Yes, I have a general idea of how it works. 18 Q And what's your understanding of how that 19 works? 20 A There's a first target-specific multiplex 21 PCR step that involves both tagging fragments and 22 amplifying tag fragments, and then there's a second 23 PCR step involving using common primers that 24 incorporate barcodes and sequencing tags into the 25 amplified products.	1 microfluidic part of the TAm-Seq assay. 2 BY DR. WALTER: 3 Q Now, that microfluidic part, that was used 4 for a singleplex PCR; is that correct? Is that your 5 understanding? 6 A That is my understanding. 7 Q And so the way Forshaw (2012) operated is 8 that there was a targeted multiplex PCR reaction, 9 and that was followed by a singleplex PCR reaction 10 on the microfluidic device; correct? 11 A Right. My understanding, the 12 preamplification PCR step involved 15 cycles, the 13 sample was then dispersed into individual reaction 14 wells and singleplex PCR was then performed. 15 Q Now, how, if at all, was that 15-cycle 16 preamplification step that's used in Forshaw 2012 17 different from the targeted multiplex PCR that's 18 described in Gale (2018) and that you understand is 19 used in RaDaR today? 20 DR. SRINIVASAN: Objection. Vague. 21 THE WITNESS: I have not seen any documents 22 to date that provides any more information than what 23 I've provided in my report or my declaration. 24 BY DR. WALTER: 25 Q Are you aware of any differences whatsoever
Page 51	Page 53
1 Q All right. Now, that first target-specific 2 multiplex PCR, do you have any understanding how 3 that differs from the preamplification process 4 that's set forth in Forshaw (2012), if at all? 5 DR. SRINIVASAN: Objection. Vague. 6 THE WITNESS: My understanding is based on 7 Gale's description that the multiplex PCR is 8 performed without the use of the microfluidics. 9 BY DR. WALTER: 10 Q Are there any other differences you're aware 11 of? 12 DR. SRINIVASAN: Objection. Asked and 13 answered. 14 THE WITNESS: Differences of what? 15 BY DR. WALTER: 16 Q Differences between the target-specific 17 multiplex PCR that you understand is used in RaDaR 18 today that's described in Gale (2018) and the 19 preamplification process that's set forth in 20 Forshaw (2012)? 21 DR. SRINIVASAN: Objection. 22 Mischaracterizes testimony. 23 THE WITNESS: My understanding is based on 24 publicly available documents as stated by 25 Gale (2018), that the eTAm-Seq removed the	1 between the 15-cycle preamplification step that's 2 used in Forshaw (2012) relative to the targeted 3 multiplex PCR that's described in Gale (2018) and 4 that you contend is used in RaDaR today? 5 DR. SRINIVASAN: Objection. Vague. 6 THE WITNESS: I'm sorry. Mr. Walter, can 7 you repeat that question? It's quite long. 8 BY DR. WALTER: 9 Q Are you aware of any differences whatsoever 10 between the 15-cycle preamplification step that's 11 used in Forshaw (2012) relative to the targeted 12 multiplex PCR that's described in Gale (2018) and 13 that you contend is used in RaDaR today? 14 A Well, I can only tell you what has been 15 described in the public documents. They both 16 involve multiplex -- targeted multiplex PCR. The 17 eTAm system removed the microfluidic portion of the 18 eTAm technology. 19 Q For what elements of the '035 patent, if 20 any, do you rely on the singleplex amplification 21 process that was performed in the microfluidic 22 device? 23 DR. SRINIVASAN: Objection. Vague. 24 THE WITNESS: I'm not sure I need to rely on 25 the singleplex step because in the preamplification

Page 54 1 step involving 15 cycles, both Claim 1A, the 2 limitation tagging isolated cell-free DNA, and the 3 limitation in Claim 1B of amplifying the tagged 4 products, are satisfied just in the preamplification 5 step. 6 BY DR. WALTER: 7 Q Let's go to paragraph 89 of your 8 declaration. 9 A Yes, I'm there. 10 Q Now, following the multiplex PCR and RaDaR, 11 you understand there's an additional PCR process? 12 (Reporter clarification.) 13 BY DR. WALTER: 14 Q Let me start again. 15 Following the multiplex PCR in RaDaR, you 16 contend that there's an additional PCR process to 17 introduce sample barcodes and sequencing adaptors; 18 correct? 19 A That's correct. 20 Q And that barcoding process that happens 21 after the targeted multiplex PCR and before the 22 sequencing; correct? www.LexitasLegal.com/Premier Lexitas 23 DR. SRINIVASAN: Objection. Vague. 24 THE WITNESS: Well, in Forshaw (2012), I 25 believe that is correct.	Page 56 1 paragraph 99 -- when Gale refers to eTAm-Seq 2 technology is based on methods previously described, 3 giving references 22, 25, and 26, I believe 4 reference 26 is the reference that I'm relying on. 5 Q And that reaction barcode, do you rely upon 6 that in your report for any of your infringement 7 opinions? 8 A I don't believe I've included that in my 9 report or declaration. 10 Q So you think it's possible that in reference 11 26, there's a suggestion of a reaction barcode 12 that's introduced in connection with the targeted 13 multiplex PCR? Assuming that there's a reaction 14 barcode that's introduced in the targeted multiplex 15 PCR, whatever that might be, you do understand that 16 there's a sample barcoding PCR that takes place 17 after the targeted multiplex PCR and before the 18 sequencing; correct? 19 DR. SRINIVASAN: Objection. Vague. 20 Incomplete hypothetical. 21 THE WITNESS: I believe that's correct. The 22 sample barcode is added in the second round. 23 BY DR. WALTER: 24 Q And a sequencing adaptor is also added in 25 the second round after the targeted multiplex PCR;
Page 55 1 BY DR. WALTER: 2 Q And is that true in RaDaR as well? 3 A That may not be correct. 4 Q Do you know? 5 A I've seen other documents that -- that 6 illustrate the barcode being added in the first PCR 7 step. 8 Q You believe that in RaDaR, as it's used 9 today, the barcode is added in the first PCR step? 10 DR. SRINIVASAN: Objection. Vague. 11 THE WITNESS: Based on the publicly 12 available documents that I've seen to date, at least 13 one barcode is added in the first PCR step. 14 BY DR. WALTER: 15 Q And what barcode do you contend that is? 16 A I believe it's referred to as the "reaction 17 barcode." 18 Q And what is the reaction barcode? 19 A That's the best I can give without actually 20 looking at the document that I'm relying on to get 21 that answer. 22 Q And what document do you think you're 23 talking about? 24 A It's also cited -- so when Gale cites to 25 references -- for example, I'm looking at page 56,	Page 57 1 correct? 2 DR. SRINIVASAN: Objection. Vague. 3 THE WITNESS: Correct. You'd have to do 4 that if you were going to do Illumina sequencing. 5 BY DR. WALTER: 6 Q And that targeted multiplex PCR that you 7 believe takes place in RaDaR, for what claim element 8 do you rely upon that in the '454 patent? 9 A You said for the '454 patent? 10 Q Yes. 11 A So I'm looking at paragraph 50 of my 12 declaration on page 21 in the very last sentence has 13 a depending claim performing barcoding PCR prior to 14 sequencing, and I'm citing to Claim 11. 15 Q I was asking about the targeted multiplex 16 PCR, not the barcoding PCR. 17 A Oh, I apologize. I thought I heard 18 "barcoding" in your question. 19 Q No. I asked about the targeted multiplex 20 PCR. 21 A Apologize. Please -- could you repeat the 22 question, please. 23 Q That targeted multiplex PCR that you believe 24 takes place in RaDaR, for what claim elements do you 25 rely upon that in the '454 patent?

Page 58 1 A So Claim 1B of the '454 patent has the 2 limitation performing targeted multiplex 3 amplification to amplify 10 to 500 target loci. So 4 it would be that claim code. 5 Q Now, after the barcoding PCR you 6 contend that's in RaDaR, the barcoded products are 7 subject to sequencing? 8 A Yes. I state that in my report at 9 paragraph 69. 10 Q And in paragraph 69, you also refer to a 11 process of confirming variance. 12 Do you see that? 13 A Well, what I state in my declaration is in 14 reference to a figure that Neogenomics uses in one 15 of their public documents. 16 Q Now, actually, the last sentence of 17 paragraph 69, you state: 18 "Defendant uses the figure below to 19 demonstrate that the RaDaR assay uses high-depth 20 sequencing to confirm variants in tumor DNA obtained 21 from the plasma cell-free DNA." 22 Do you see that? www.LexitasLegal.com/Premier 23 A I do. 24 Q Do you understand the computational process 25 by which the RaDaR process confirms variance?	Page 60 1 BY DR. WALTER: 2 Q Is that also used for detecting the 3 mutations that cause cancer in the ctDNA? 4 DR. SRINIVASAN: Objection. Vague. Calls 5 for speculation. 6 THE WITNESS: Can you repeat that question? 7 BY DR. WALTER: 8 Q Is that bioinformatics also used 9 to detect -- how is the circulated tumor DNA 10 detected in the -- in the blood sample? 11 A Well, as I understand it based on the public 12 documents, RaDaR develops up to 48 individual 13 variant assays that it can then test for ctDNA in a 14 patient's blood sample. 15 Q And you mentioned the bioinformatics that 16 are used for detecting ctDNA. Do you know anything 17 about how the bioinformatics is used to detect 18 ctDNA? 19 DR. SRINIVASAN: Objection. Vague. 20 THE WITNESS: In the RaDaR assay? 21 BY DR. WALTER: 22 Q Yes. 23 A In the assay where they're looking at the 24 plasma for the -- up to the 48 variant markers that 25 have been identified?
Page 59 1 A I have not seen any internal documents that 2 provides detailed information of how variants are 3 confirmed. The sentence is based on the figure and 4 the bottom portion of the figure, second to the 5 right, says "high-depth sequencing, variant 6 confirmation in tumor DNA, CHIP filtering and ctDNA 7 detection." 8 That's the information that I use to support 9 the sentence in paragraph 69. 10 Q And what is -- and did you rely upon that 11 for step 1C of Claim 1 of the '454 patent? 12 A Correct. 13 Q And what is that shown above the box in the 14 diagram that says "high-depth sequencing, variant 15 confirmation in tumor DNA, CHIP filtering and ctDNA 16 detection"? 17 A It looks like a depiction of a computer 18 screen. 19 Q Okay. And what do you understand that is 20 intended to convey? 21 DR. SRINIVASAN: Objection. Vague. Calls 22 for speculation. 23 THE WITNESS: Well, I think it's trying to 24 convey part of the bioinformatics that RaDaR uses in 25 its detection of ctDNA.	Page 61 1 Q Yes. 2 A I understand it generally based on the 3 public documents that have been provided to date. 4 Q And what do you understand about how that's 5 done? 6 A Well, it's right here in the figure. It 7 describes it as high-depth sequencing, variant 8 confirmation in tumor DNA CHIP filtering, which is a 9 way of removing variants that are not associated 10 with ctDNA, and then the actual ctDNA detection, 11 which is -- as I understand it, is either it's 12 present or it's absent. 13 Q And do you know how that ctDNA detection is 14 done, that present or absent call is made? 15 A I've not seen any internal documents that 16 provide that much detail yet. And if they're 17 provided, then I would review them, and I could 18 probably tell you that all I have currently are 19 publicly available documents and I'm relying on the 20 way they describe their bioinformatic process. 21 Q Do you know if the cell-circulating tumor 22 DNA is detected by looking for mutations? 23 DR. SRINIVASAN: Objection. Vague. 24 THE WITNESS: Well, as I understand the 25 RaDaR assay, they select up to 48 variants; and they

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1 associate that tumor-specific variants. Whether
2 those are mutations or not, I wouldn't know unless I
3 actually could evaluate those variants.
4 DR. SRINIVASAN: I'd like to just note for
5 the record that our in-house counsel person that was
6 listening has dropped off at 11:05 a.m.
7 BY DR. WALTER:
8 Q Go ahead.
9 A Oh, I finished my answer.
10 Q And do you have any understanding in RaDaR
11 as to how those tumor-specific mutations are
12 identified in the sequencing data?
13 DR. SRINIVASAN: Objection. Vague.
14 THE WITNESS: As I understand, they select
15 up to 48 variants. They compare it to normal DNA,
16 so they also -- as I understand it based on public
17 information, they will sequence the buffy coat,
18 which provides basically a normal background to
19 subtract out germline variants, CHIP variants to
20 then prioritize the 48 that will go into the RaDaR
21 assay.
22 BY DR. WALTER: www.LexitasLegal.com/Premier Lexitas
23 Q I think I was asking about something
24 different.
25 I -- I was asking about how the variants

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1 that are in the sequencing data from the cell-free
2 DNA are identified. Do you know how that's done?
3 A Well, my understanding, based on the public
4 documents, is they used high throughput sequencing
5 to generate sequence reads, and then there's a
6 bioinformatic pipeline to identify whether the
7 variants that are in the assays are detected or not.
8 Q And that's the pipeline that's being
9 referred to by the image of the computer above the
10 box that says "high-depth sequencing, variant
11 confirmation in tumor DNA CHIP filtering, and
12 circulating DNA tumor detection"?
13 DR. SRINIVASAN: Objection. Calls for
14 speculation.
15 THE WITNESS: Well, in this particular
16 figure, that's what it's trying to illustrate, are
17 the bioinformatic steps. The one right before it is
18 the InVision platform that involves the library in
19 creating the sample that goes into the sequencing
20 process.
21 BY DR. WALTER:
22 Q Now, you mentioned you reviewed the
23 prosecution history for the '454 patent?
24 A Yes.
25 Q Do you recall what rejections the examiner

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1 issued?
2 DR. SRINIVASAN: Objection. Outside the
3 scope.
4 THE WITNESS: I did not memorize the file
5 history, so I could not answer that without
6 reviewing the file history again.
7 (Defendant's Exhibit 3 was marked.)
8 BY DR. WALTER:
9 Q All right. I've handed you a document
10 that's been marked as Exhibit 3. They are some
11 excerpts from the file history for the '454 patent.
12 And if you take a look at page 4, just a few
13 pages into the document, you can see in paragraph
14 11, there's a rejection based on the Forshaw (2012)
15 publication.
16 Do you see that?
17 A Can I have a moment to read through this
18 section?
19 Q Yes.
20 A Thank you. Okay. I read that section on
21 Forshaw.
22 Q So you understand that during prosecution,
23 the examiner based a rejection based on
24 Forshaw (2012)?
25 DR. SRINIVASAN: Objection. Outside the

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1 scope. Calls for a legal conclusion.
2 THE WITNESS: I do see that sentence stated
3 in paragraph 11 of the prosecution history on
4 page 4.
5 BY DR. WALTER:
6 Q And if you go to page 5.
7 A Yes, I'm there.
8 Q It states "Forshaw, et al., shows in the
9 abstract and throughout analysis of cell-free DNA of
10 individuals with tumors for mutation analysis by
11 multiplex amplification using a pool of primer pairs
12 followed by sequencing of amplicons."
13 Do you see that?
14 A I do see that sentence.
15 Q And you do agree that the Forshaw (2012)
16 paper that does disclose the use of a multiplex
17 amplification; correct?
18 A Forshaw (2012) does describe multiplex PCR.
19 Q Now, I want you to flip ahead. There's a
20 response from Natera entitled "Amendment and Reply
21 Under 37 CFR 1.111."
22 A Yes, I believe I'm on that page.
23 Q And you can see beginning on page 7, Natera
24 responds there to the objection based on Forshaw;
25 correct?

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1 A At the very bottom paragraph, I do see
2 "Claim Rejections."
3 Q Now, take a look at page 9 of 11.
4 A Can I have a moment to read through this
5 section?
6 Q Yes.
7 A Thank you. Okay. I read through this
8 section.
9 Q All right. On page 9, there's a paragraph
10 in about the middle of the page that reads:
11 "Furthermore, Forshew's TAM-Seq process was
12 rationally and deliberately designed to rely on
13 singleplex, 'individual amplification to purify and
14 select for intended targets' (page 3). In fact,
15 Forshew had considered but dismissed multiplex
16 targeted amplification."
17 Do you see that?
18 A I see those sentences.
19 Q You do agree, though, that the
20 Forshew (2012) publication we've been looking at,
21 that it does use multiplex targeted application;
22 correct? www.LexitasLegal.com/Premier Lexitas
23 A In the preamplification step, it does use
24 multiplex PCR.
25 Q So as far as Natera was suggesting in this

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1 office action response that Forshew was not using
2 multiplex targeted amplification, that would be
3 incorrect; right?
4 DR. SRINIVASAN: Objection. Calls for a
5 legal conclusion.
6 This is entirely outside the scope of his
7 declaration.
8 THE WITNESS: I guess I'm not reading that
9 at all.
10 BY DR. WALTER:
11 Q But you agree that insofar as Natera was
12 suggesting -- and maybe you don't agree that that's
13 what they're suggesting; but to the extent they were
14 suggesting that Forshew doesn't use targeted
15 multiplex amplification, that would be incorrect
16 because Forshew does use multiplex targeted
17 amplification; right?
18 DR. SRINIVASAN: Objection. Lacks
19 foundation. Mischaracterizes testimony. Outside
20 the scope. Calls for a legal conclusion.
21 THE WITNESS: Again, I'm just not reading it
22 that way.
23 BY DR. WALTER:
24 Q Okay. You read it how?
25 A Well, I mean, I'm just reading it from a

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1 technical standpoint; and it looks like Natera is
2 pointing out that Forshew relied on a singleplex
3 step to reduce nonspecific amplification in its
4 product. I mean, that's what it appears to me to be
5 saying.
6 Q Okay. And you understand that to the extent
7 the RaDaR process uses a singleplex amplification
8 step, it would no longer infringe; correct?
9 A I'm sorry. Can you repeat that question?
10 Q You understand that to the extent the RaDaR
11 process utilizes a singleplex amplification, it
12 would no longer infringe; correct?
13 DR. SRINIVASAN: Objection. Lacks
14 foundation. Calls for speculation.
15 THE WITNESS: Well, I don't know about that.
16 It is a comprising claim. The eTAM-Seq uses
17 targeted multiplex PCR. It therefore meets the
18 claim limitation. And if an additional step is
19 added, yet the claims can be mapped to the product,
20 the product still infringes, as I understand.
21 BY DR. WALTER:
22 Q And you understand that the same thing
23 applies with regard to prior art. If the prior art
24 discloses a targeted multiplex PCR and includes an
25 additional step, it would still satisfy the claims;

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1 right?
2 DR. SRINIVASAN: Objection. Outside the
3 scope. Lacks foundation. Calls for a legal
4 conclusion.
5 THE WITNESS: I haven't formed any opinions
6 on validity.
7 BY DR. WALTER:
8 Q How many patent cases have you been an
9 expert in?
10 A Quite a few.
11 Q More than a dozen?
12 A That's probably a true statement.
13 Q More than two dozen?
14 A Probably a true statement.
15 Q More than three dozen?
16 A That, I don't know. I don't know the exact
17 number.
18 Q Okay. And so this is a comprising claim;
19 right?
20 A It is.
21 Q We're talking about Claim 1 of the '454
22 patent. That's a comprising claim; right?
23 A I believe it is. Let me just review that
24 quickly, but I believe that is correct. Yes.
25 Q And so do you understand what comprising

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1 means in the context of patent law, as someone who's
2 testified as an expert in more than two-dozen patent
3 cases?

4 DR. SRINIVASAN: Objection. Outside the
5 scope. Calls for a legal conclusion.

6 THE WITNESS: Well, I'm not a legal expert.
7 I've testified in many depositions. I'm a technical
8 expert. I rely on standards that are provided by
9 counsel. I have not provided any opinions on
10 validity. They're not set forth in my declaration,
11 so I'm not prepared to offer any opinions with
12 respect to validity.

13 BY DR. WALTER:

14 Q Okay. I was asking about comprising. You
15 understand what "comprising" means in the context of
16 patent law as someone who's testified as an expert
17 in more than two-dozen patent cases; right?

18 DR. SRINIVASAN: Objection. Outside the
19 scope. Calls for a legal conclusion.

20 THE WITNESS: Well, I've only analyzed
21 comprising with respect to infringement.

22 DR. HABERNY: ~~Derek, you're asking him about~~
23 validity. He's not offering opinions about
24 validity. This judge has stated in her orders and
25 at the status conference that discovery is going to

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1 be limited for this proceeding. We will call the
2 Court and have this resolved if you don't stop
3 asking him questions outside the scope of the
4 opinions that he came here to offer.

5 DR. WALTER: Okay, I think --

6 DR. HABERNY: You're asking him about
7 invalidity.

8 DR. WALTER: I think this is a fair question
9 here.

10 DR. HABERNY: No, it's not. Do not ask him
11 about invalidity anymore.

12 DR. WALTER: All right. Your position's
13 clear.

14 (Defendant's Exhibit 4 was marked.)

15 BY DR. WALTER:

16 Q All right. I've handed you a document
17 that's been marked as Exhibit 4. It's entitled
18 "Summary of Opinions."

19 What is Exhibit 4, Dr. Metzker?

20 A Well, Exhibit 4 appears to be a trial
21 presentation involving QIAGEN.

22 Q And these are demonstratives that you used
23 in testifying at trial; correct?

24 A I have not seen these in a while. I'm not
25 sure whether I relied on this presentation or a

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1 subset of this presentation. This trial was several
2 years ago.

3 Q Take a moment and review and see if you can
4 confirm whether these are actual slides you relied
5 upon.

6 And I'll remind you that you're under oath
7 here today.

8 A Well understood.

9 Can you repeat the question, Mr. Walter?

10 Q Please confirm that these are the
11 demonstrative slides you relied upon when testifying
12 at trial on behalf of QIAGEN.

13 A I cannot confirm that I relied on each and
14 every slide in the QIAGEN case.

15 Q When you testified at that QIAGEN trial on
16 behalf of QIAGEN, you were under oath?

17 A Yes, I was.

18 Q You were truthful?

19 A Yes, I was.

20 (Defendant's Exhibit 5 was marked.)

21 BY DR. WALTER:

22 Q I've handed you now a portion of your trial
23 testimony from that QIAGEN trial, and you can see
24 there at the beginning there's actually your oath.
25 Do you see that on page 887 on Exhibit 5?

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1 A I do.

2 Q And take a look at the text that appears on
3 page 906, line 25, to page 907, line 21.

4 A I'm sorry. How far on page 907?

5 Q Line 21.

6 A Okay. I read through that.

7 Q All right. Based on that testimony, you can
8 confirm that you're using slide 21 in Exhibit 4 to
9 contrast target-specific PCR with universal PCR;
10 correct?

11 A That's correct.

12 Q And the barcoding PCR that's done in RaDaR,
13 you understand that to be a universal PCR?

14 DR. SRINIVASAN: Objection. Vague.

15 THE WITNESS: Well, I think I've testified
16 there are two barcoding steps: One involving
17 target-specific amplification, and then there's the
18 second step involving universal amplification.

19 BY DR. WALTER:

20 Q Okay. That second step that involves the
21 sample-specific barcodes that you cite in your
22 report, that is a universal PCR; correct?

23 A Can we go to that figure?

24 Q You can look at whatever you want in your
25 report.

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1 A Well, I'm trying to understand your 2 question. What's the basis of your question? 3 Q The question was clear. And there's -- the 4 barcoding PCR that you contend is done in RaDaR in 5 order to produce sample barcodes, that's what you 6 would characterize as a universal PCR; correct? 7 DR. SRINIVASAN: Objection. Vague. 8 THE WITNESS: Well, I think I've 9 characterized it today, in today's deposition, 10 because it's in combination with the t multiplex 11 PCR. That second PCR is also a multiplex PCR step. 12 But it is using common primers to amplify everything 13 that has common adaptors based on the first PCR. 14 BY DR. WALTER: 15 Q Okay. And based on that, you would call 16 that a universal PCR; right? 17 A Well, I've characterized it here today as a 18 multiplex PCR using common primers in amplification. 19 Q I know you've characterized it here today as 20 a multiplex PCR using common primers in 21 amplification. But that process, that PCR 22 process -- let's try to do it this way. 23 Let's take a look at paragraph 97. There's 24 a step there that refers to barcoding PCR. 25 A Yes, this is a figure from Gale	1 DR. SRINIVASAN: Objection. Calls for a 2 legal conclusion. Outside the scope. 3 THE WITNESS: No, I'd characterize it the 4 way I just characterized it in my last sentence. 5 BY DR. WALTER: 6 Q When you testified at the QIAGEN trial, you 7 were under oath? 8 A I was. 9 Q And your testimony was truthful? 10 A It absolutely was. 11 Q Now, you characterized that barcoding PCR as 12 a multiplex PCR. Would you characterize that 13 barcoding PCR as a targeted multiplex PCR? 14 DR. SRINIVASAN: Objection. Calls for a 15 legal conclusion. Outside the scope. 16 THE WITNESS: The first step in -- the first 17 PCR step is a targeted multiplex PCR. I would say 18 the second step is a multiplex PCR. 19 BY DR. WALTER: 20 Q Okay. And the first step that you were 21 referring to in paragraph 97, that's the amplicon 22 PCR; correct? 23 A That is correct. 24 Q That's what you would call the "targeted 25 multiplex PCR"; correct?
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1 (2016) [sic]. 2 Q That barcoding PCR, that uses -- that uses a 3 common tail sequence that's attached to all the 4 fragments? 5 DR. SRINIVASAN: Objection. Vague. 6 THE WITNESS: That is my understanding. But 7 this figure is actually illustrating my point that 8 even the barcoding PCR is multiplex PCR amplifying 9 multiple targets within the same sample. 10 BY DR. WALTER: 11 Q Okay. And that process that you contend 12 amplifies multiple targets in the same sample, would 13 you characterize that as a universal PCR? 14 DR. SRINIVASAN: Objection. Calls for a 15 legal conclusion. 16 THE WITNESS: Well, I think I've answered 17 the best way I can, that based on the way I 18 understand RaDaR to operate, that second PCR is 19 using common sequences adapted to the fragments but 20 is performing a multiplex PCR reaction amplifying 21 multiple targets. 22 BY DR. WALTER: 23 Q Okay. That's nonresponsive. 24 That barcoding PCR, would you characterize 25 that as a universal PCR? Yes or no?	1 DR. SRINIVASAN: Objection. Calls for a 2 legal conclusion. Outside the scope. 3 THE WITNESS: Well, this is part of the 4 eTam-Sequence -- seq assay; this is where they're 5 using target-specific primers that have adaptors 6 attached to the ends that are both tagging and 7 amplifying tagged products. That's what I -- how 8 I've described what's going on in eTam-Seq. 9 BY DR. WALTER: 10 Q The circled figure that's labeled as 11 "amplicon PCR," that you refer to as a "targeted 12 multiplex PCR"; correct? 13 A They're using target-specific primers, and 14 they're amplifying multiple loci. So you would 15 refer to this as "targeted multiplex PCR." 16 Q And the barcoding PCR, you would only refer 17 to that as "multiplex PCR"; correct? 18 A That is the way I've characterized it. 19 Q And why would you characterize it 20 differently? 21 A Because the second step is using common 22 primers, not target-specific primers. 23 DR. SRINIVASAN: Counsel, we've been going 24 for about an hour. I do request a break. 25 DR. WALTER: Okay.

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1 DR. SRINIVASAN: Before we break, I'd like 2 to put on the record that Natera reserves the right 3 to strike all testimony about invalidity and prior 4 art. 5 THE VIDEOGRAPHER: We're going off the 6 record. The time is 11:35 a.m. 7 (Recess.) 8 THE VIDEOGRAPHER: We're back on the record. 9 It's 11:48 a.m. 10 BY DR. WALTER: 11 Q All right. Now, we talked earlier about how 12 for Claim 1A of the '035 patent, you rely upon the 13 barcoding PCR process. 14 Do you recall that? Did you do that in 15 paragraph 87? 16 A I do state that Gale (2018) uses the 17 TAm-Seq -- eTAm-Seq technology that employs 18 barcoding PCR. 19 Q And you rely upon that barcoding PCR for the 20 universal tail adaptor element. We discussed that 21 at the beginning of your deposition. 22 Do you recall that? 23 A I don't understand the question. 24 Q You rely upon the barcoding PCR as 25 introducing the universal tail adaptors that are	1 DR. SRINIVASAN: Objection. Vague. 2 THE WITNESS: Well, I think it meets the 3 limitation of one or more universal tail adaptors. 4 BY DR. WALTER: 5 Q All right. Now, you understand that claim 6 element 1C requires that following the generation of 7 the tagged products, that there be one or more 8 amplification processes, at least one of which is 9 targeted? 10 A We're referring to the '454 patent now? 11 Q The '035 patent. 12 A The '035 patent. Claim 1C? 13 Q Yes. No, 1B. Sorry, 1B. 14 You understand that Claim 1B of the '035 15 patent requires that there be one or more 16 amplifications following generation of the tagged 17 products, and at least one of those amplifications 18 has to be targeted; correct? 19 A There is a wherein clause, one of the 20 amplification steps comprises targeted amplification 21 of a plurality of single nucleotide polymorphism, 22 (SNP loci) in a single reaction volume. 23 Q In the RaDaR process, what targeted 24 amplifications are there, if any, following the 25 barcoding PCR step?
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1 recited in Claim Element 1A; correct? 2 DR. SRINIVASAN: Objection. Vague. 3 THE WITNESS: I think that is not correct. 4 BY DR. WALTER: 5 Q Okay. Let's go look at Claim 12. 6 If you look at the bottom of page -- 7 paragraph 108, you state: 8 "According to Defendant, Gale (2018) uses 9 the eTAm-Seq technology that employs barcoding PCR 10 using universal tailed adaptors." 11 Do you see that? 12 A I do see that as the last sentence. 13 Q Based on that, you would agree that you are 14 relying upon the barcoding PCR in RaDaR for the 15 universal tail adaptors element claim; correct? 16 A Well, I think, as I testified, it's one of 17 the adaptors that I'm relying on. The CS1 and CS2 18 adaptors are also incorporated, and they also -- 19 person of ordinary skill in the art would have 20 understood that would meet the limitation of the 21 universal tail adaptor. I testified to that. 22 Q All right. So you rely upon what you 23 contend is a universal tail adaptor in connection 24 with the barcoding PCR's one feature that satisfies 25 the universal tail adaptor element; is that correct?	1 A I don't think there are any targeted after 2 the barcoding, but the tagged products in 1C comes 3 from the first target multiplex PCR step. 4 Q So you don't rely upon the barcoding PCR for 5 Claim Element 1A; is that correct? 6 A Claim Element 1A -- of the -- again, the 7 '035? 8 Q Yes. 9 A The barcoding step was the question? 10 Q Yes. 11 A That is correct. The tagging comes in 12 through the targeted multiplex PCR step. 13 Q Why, at the bottom of paragraph 108, do you 14 point out that the barcoding PCR uses universal tail 15 adaptors? What's the point of that? 16 A The point of that is because of the claim 17 limitation 1B for the other wherein step, wherein 18 one or more amplification steps introduces a barcode 19 in one or more sequence tags; and because Claim 12 20 depends on Claim 1, that's why I'm citing that. 21 Q Okay. But you don't cite -- you don't 22 actually refer to the sequence tag or the barcode in 23 connection with this claim. You only refer to the 24 universal tail adaptor; right? 25 A I'm sorry. I don't understand the question.

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1 Q In paragraph 108, where you refer to the 2 barcoding PCR, you don't actually refer to the 3 barcode or the sequencing tag. You, in fact, only 4 refer to the universal tail adaptor that you think 5 is there; right? 6 A Well, Claim 12 is a depending claim; and 7 it's a wherein one or more of the universal tail 8 adaptors comprises a first universal tail adaptor or 9 a second universal tail adaptor. That's the 10 limitation. And in my opinion, a person of 11 ordinary skill in the art would have understood the 12 adaptors that come in through barcoding are -- can 13 meet that limitation. 14 DR. SRINIVASAN: Counsel, I'd like to ask 15 when you ask the witness questions, please don't 16 laugh or demean him. 17 DR. WALTER: Okay. 18 BY DR. WALTER: 19 Q Paragraph 1A -- Claim Element 1A is the one 20 that refers to the universal tail adaptor; right? 21 A Claim 1A is tagging isolated cell-free DNA 22 with one or more universal tail adaptors to generate 23 a tail product. 24 Q And by virtue of your opinions in Claim 12, 25 you rely upon the barcoding PCR process for that	1 DR. SRINIVASAN: Objection. Vague. 2 THE WITNESS: Well, I would disagree with 3 that. 4 BY DR. WALTER: 5 Q Which other step besides 1A actually refers 6 to a universal tail adaptor? 7 A Well, Claim 1B which is amplifying the 8 tagged products; so, therefore, they've already 9 included the universal tail adaptors. 10 Also has a wherein clause: 11 "One of the amplifying steps introduces 12 barcodes or one or more sequence tags, and those are 13 introduced by universal tail adaptors." So I think 14 it completely depends on Claim 1B as well. 15 Q Claim Step 1B does not include the language 16 "universal tail adaptor"; right? 17 A It does not. It includes the tagged 18 products which incorporated the universal tail 19 adaptor in step 1A. 20 (Discussion off the record.) 21 (Defendant's Exhibit 6 was marked.) 22 BY DR. WALTER: 23 Q All right. I've handed you a document 24 that's been marked as Exhibit 6, but it's entitled 25 "Encyclopedia of Medical Devices Instrumentation."
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1 claim element; correct? 2 A Not necessarily, no. 3 Q Your opinion states: 4 "According to defendant, Gale (2018) uses 5 the eTAm-Seq technology that employs barcoding PCR 6 using universal tail adaptors." That's what your 7 report says; right? 8 A Well, it does say that; but you're not 9 focused on the sentence before that that says 10 "Gale (2018) described the InVision liquid biopsy 11 platform technology (used in the RaDaR assay), which 12 includes tagging isolated cell-free DNA with one or 13 more universal tail adaptors to generate tagged 14 products." I also rely on that sentence. 15 Q And then the very next sentence refers to 16 the barcoding PCR; right? 17 A Well, it does. As I testified, I do believe 18 that one -- one of ordinary skill in the art would 19 have understood that the one or more universal tail 20 adaptors would include the barcoded adaptors used in 21 the barcoding PCR step. 22 Q And it's only step 1A of the claims that 23 refers to the universal tail adaptor. There's no 24 other step that refers to the universal tail adaptor 25 other than step 1; right?	1 Do you recognize this? 2 A I do. 3 Q What is this? 4 A Well, it's a chapter that I wrote for the 5 Encyclopedia of Medical Devices and Instrumentation, 6 17, 18 years ago. 7 Q It was in 2006, it was published? 8 A Correct. 9 Q Now, you state on page 384, you have a 10 paragraph refers to multiplex PCR. 11 Do you see that? 12 A 384, I do not see multiplex PCR. 13 Q All right. About halfway down on the 14 left-hand column, there's a paragraph that begins 15 with "multiplex PCR." 16 A I do see that paragraph. 17 Q And the last sentence reads: 18 "Moreover, up to 46 primer pairs have been 19 simultaneously amplified by multiplex PCR with 20 excellent success (90%) for the large-scale 21 identification of human single nucleotide 22 polymorphisms by hybridization to high-density DNA 23 CHIP arrays." 24 Do you see that? 25 A I do see that sentence.

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1 Q And it was true, in fact, that as of 2009, 2 it had been reported to do over 9,000 targets in a 3 single multiplex reaction for sequencing; correct? 4 DR. SRINIVASAN: Objection. Lacks 5 foundation. Outside the scope. 6 THE WITNESS: I think you're referring to a 7 Fluidigm patent that I've previously relied on, and 8 I believe they reported up to 9,200 targets in a 9 multiplex PCR. 10 BY DR. WALTER: 11 Q For sequencing; correct? 12 A For sequencing. But it's a Fluidigm, and so 13 I don't remember -- I don't think it was actually 14 multiplex PCR. It would have been the Singleton 15 approach that we've seen in Forshaw. 16 Q And what was the Singleton approach? 17 A Where a sample would be allocated into 18 individual compartment wells, and then individual 19 primer pairs would be used to amplify specific 20 target regions. 21 DR. WALTER: All right. I've marked as 22 Exhibit 7, Michael Metzker in the matter of Illumina 23 versus Natera in a deposition transcript from 24 May 29th, 2020. 25 (Defendant's Exhibit 7 was marked.)	1 single-tube multiplex PCR of over 9,000 targets for 2 sequencing; correct? 3 A It does have a preamplification step that 4 does target at multiplex PCR. 5 Q Of over 9,000 targets; correct? 6 A That's what they report. 7 DR. WALTER: All right. Do you want to take 8 a break for the lunch? 9 DR. HABERNY: Sure. 10 THE VIDEOGRAPHER: We're going off the 11 record. The time is 12:06 p.m. 12 (Recess.) 13 THE VIDEOGRAPHER: We're back on the record. 14 The time is 12:16 p.m. 15 BY DR. WALTER: 16 Q Okay. Is it accurate that for the '035 17 patent you rely on both -- strike that. 18 Is it accurate that for the '035 patent, you 19 rely upon the preamplification step of 20 Forshaw (2012) for both Claim Element 1A and Claim 21 Element 1B? 22 A Yes. 23 Q You rely upon the same amplification process 24 for both elements; correct? 25 A No.
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1 BY DR. WALTER: 2 Q You were truthful during this deposition? 3 A I absolutely was, but the date on the front 4 page isn't correct. 5 Q What is the actual date? 6 A It should be April 29th, 2020. 7 Q Okay. 8 A And that's set forth in the testimony. 9 Q Let's take a look at page 188, lines 12 to 10 15. 11 It states: "It is the -- are 9,216 12 different target nucleic acid all amplified in the 13 same reaction." 14 Your testimony was: "Correct." 15 "In the preamplification" -- excuse me -- 16 "in the pre-preamplification, that is a single tube 17 of multiplex PCR reaction." 18 Do you see that? 19 A I do see that. 20 Q Okay. That was your testimony at the time? 21 A It was. And the step I was referring to is 22 the next step where they are allocated into 23 individual wells and amplified separately. 24 Q Okay. So in the PCR -- in the Fluidigm 25 reference that you opined upon, that is teaching a	1 Q All right. Please explain. 2 A Well, I am relying on the preamplification 3 step for the element in Claim 1A of tagging isolated 4 cell-free DNA with one or more universal tail 5 adaptors to generate tagged products. I am also 6 relying on the preamplification step. In 1B, where 7 the amplifying the tagged products one or more times 8 to generate final amplification products, depend on 9 the wherein, one of the amplification steps 10 comprises target amplification of a plurality of 11 single nucleotide polymorphisms. But I'm also 12 relying on the second step where the -- and I'm 13 looking at Forshaw figure -- Forshaw (2012), the 14 figure in paragraph 109 where it says "sequence 15 adaptor and barcode attachment." I'm relying on 16 that PCR step meeting the claim element wherein one 17 or more of the amplification steps introduce as a 18 barcode in one or more sequencing tags. 19 Q You understand that it's the -- your 20 contention is it's the preamplification step that 21 generates the tagged products that are referred to 22 in Claim Element 1A of the '035 patent; correct? 23 A The preamplification step is creating the 24 tagged products in Claim 1A of the '035 patent. 25 Q And then you rely upon the preamplification

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1 process for subsequent step 1B that refers to 2 amplifying the tagged products wherein one of the 3 amplification steps comprises a targeted 4 amplification; correct? 5 A That is correct. 6 Q Okay. Is it accurate, then, that you're 7 taking the preamplification step and breaking it 8 into two parts: One part that you allocate to step 9 1A, and then another part that you allocate to step 10 1B? 11 DR. SRINIVASAN: Objection. Vague. 12 THE WITNESS: I am not breaking apart the 13 preamplification step. 14 BY DR. WALTER: 15 Q You are relying upon the entirety of the 16 preamplification step for both step 1A to generate 17 the tagged products and also Claim Step 1B that 18 refers to amplifying the tagged products one or more 19 times wherein one of the amplification steps 20 comprises targeted amplification; is that right? 21 DR. SRINIVASAN: Objection. Vague. 22 THE WITNESS: I'm relying on the 23 preamplification step, which includes 15 cycles. I 24 explained that, actually, in my review article that 25 you've presented as figure -- or Exhibit 7, where	1 report, do you explain that the -- well -- let's do 2 it this way. 3 For Claim Element 1A of the process of 4 generating the tagged products, you are relying upon 5 the first cycle of the PCR preamplification; 6 correct? 7 A Yes, that would be the first time the 8 target-specific primers will hybridize to the 9 cell-free DNA. 10 Q And then for step 1B, you're relying upon 11 the subsequent 14 cycles; correct? 12 A Well, I'm only relying on those cycles that 13 amplify the tagged products. 14 Q Where, if anywhere in your report, do you 15 state that you're only relying upon the first cycle 16 for step 1A and then the subsequent 14 cycles that 17 only amplify the tagged products for step 1B? 18 A Well, I generally explain it in -- first, I 19 can have a chance to look at paragraph 87. 20 So on page 47, the first sentence says: 21 "Gale (2018) describes the InVision liquid 22 biopsy platform technology (used in the RaDaR assay) 23 which includes tagging isolated cell-free DNA with 24 one or more universal tail adaptors to generate 25 tagged products."
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1 the initial PCR amplifies the genomic targets, but 2 subsequent rounds of PCR begin to amplify the 3 product from the last cycle; and it's that product 4 from the last cycle that now constitutes the tagged 5 products that are being amplified. So that's all 6 happening within that preamplification step. 7 BY DR. WALTER: 8 Q So you allocate a portion of that 9 preamplification step to the tag and process 10 generation, and then another portion of it to the 11 amplifying the tagged products; is that right? 12 A No. I'm not allocating anything. I'm just 13 describing the PCR cycle. And it is illustrated in 14 figure 1 of Exhibit 7, where the first cycle of PCR 15 amplifies from the target sequence. But subsequent 16 cycles of primer extension, template denaturation, 17 and then hybridization -- all of the products now 18 that are being amplified are from the previous 19 cycle. And, in this case, it's the tagged products. 20 Q Now, figure 1 of Exhibit 7, that's not in 21 your report anywhere? 22 A It is not. It's one of the references that 23 is cited in my CV, and I do rely on my knowledge in 24 providing opinions in this declaration. 25 Q Okay. Now where, if anywhere in your	1 A person of ordinary skill in the art would 2 understand how PCR works; and in subsequent rounds, 3 the products of the previous round become the 4 template for the next cycle. 5 Q Okay. Where do you say anywhere in your 6 report that you're relying upon the first cycle of 7 the PCR to generate the tagged products, and where 8 do you point out that first cycle? 9 A Well, I don't explicitly point out the first 10 cycle. It's well known how the PCR cycle works. 11 Q Okay. Now, where, if anywhere, do you state 12 in your report that you're relying upon the 13 subsequent 14 cycles that only amplify the tagged 14 products? Where do you say that? Where do you 15 point out those 14 cycles? 16 A Well, I'm looking at paragraph 94, and I 17 say: 18 "The accused assay satisfies this claim 19 limitation. For example, the RaDaR assay includes 20 amplifying the tagged products one or more times to 21 generate final amplification products wherein one of 22 the amplification steps comprises target -- targeted 23 amplification of a plurality of single nucleotide 24 polymorphism (SNP loci) in a single reaction 25 volume."

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1 Q That's your best disclosure of that?

2 A Yes.

3 Q Okay. Now, where, if anywhere, do you refer

4 to the preamplification step involving 15 cycles in

5 your report?

6 A It is in the -- so I'm relying on

7 Forshew (2012). You provided that as one of the

8 exhibits. And it states that -- I think in the

9 method section.

10 Q Okay. Where is that in your report? Where

11 is the 15 cycles referred to in your report?

12 A So I'll first take you to paragraph 56.

13 "In forming the opinions set forth in this

14 declaration, I considered '454 patent, the '035

15 patent, their file histories, and other documents

16 cited in this declaration, including the following

17 documents"...

18 So I relied on Forshew for how the assay

19 worked; and in that document, it states that it does

20 15 cycles in the preamplification step.

21 Q Where in your declaration do you refer to

22 the 15 cycles? www.LexitasLegal.com/Premier Lexitas

23 DR. SRINIVASAN: Objection. Asked and

24 answered.

25 THE WITNESS: I will look again to see if I

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1 have a specific notation for that.

2 Well, I would say it's associated with the

3 figure, for example, in paragraph 88. The

4 preamplification and access array. I illustrate the

5 figure there as text associated with this figure

6 that's not explicitly cited in this report; but this

7 figure relies on that information, and that's

8 exactly what Forshew did.

9 BY DR. WALTER:

10 Q Okay. Now, nowhere in paragraph 88 does it

11 refer to 15 cycles of PCR; correct?

12 A No, it refers to the figure. And through

13 testimony today, I've addressed your requests where

14 I've explained the 15 cycles and where the 15 cycles

15 come from.

16 Q You understand that needed to be in your

17 report; right?

18 A Well, I've tried to provide a very detailed

19 report but to make it concise enough so that it hits

20 the main points. That's a detail in Forshew, and

21 I'm happy to explain that further which I've done

22 through testimony today.

23 Q All right. Now, in Claim 1A -- so you're

24 taking the preamplification and you're breaking it

25 into two parts conceptually: The first part, which

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1 is the first cycle; and then the remaining 14

2 cycles; correct?

3 A I'm just explaining how the PCR process

4 works.

5 Q Okay. For the purpose of your infringement

6 theory, you rely upon the first cycle of the

7 preamplification step for Claim Element 1A; correct?

8 A The first cycle is how the tagged -- how

9 the -- how tagging isolated cell-free DNA is

10 performed with one or more universal tail adaptors

11 based on what is disclosed in Forshew (2012).

12 Q And nowhere in your report with respect to

13 Claim 1A do you specifically call out that first

14 cycle, do you?

15 DR. SRINIVASAN: Objection. Asked and

16 answered.

17 THE WITNESS: Well, I didn't think I needed

18 to. I did call out, for example, that the RaDaR

19 assay includes tagging isolated cell-free DNA with

20 one or more universal tail adaptors to generate

21 tagged products.

22 Anybody who understands the PCR cycle would

23 understand that would happen in the first cycle.

24 BY DR. WALTER:

25 Q All right. Now, in the subsequent 14 cycles

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1 of the preamplification, there will be DNA fragments

2 that include the universal tail sequence; correct?

3 A Can you repeat that question, please?

4 Q In the subsequent 14 cycles of the

5 preamplification, there will be DNA fragments that

6 include the universal tail sequence; correct?

7 A They will be the product of the previous

8 amplification cycle.

9 Q And those DNA fragments that include the

10 universal tail sequence, they can be subject to

11 amplification by one of the primers in the pool;

12 correct?

13 A One of the target-specific primers in the

14 pool that's specific to that target.

15 Q And that will yield an additional tagged

16 product; correct?

17 A That is correct.

18 Q And you rely upon that process for step 1B

19 of the claim; correct?

20 A Which process are you referring to?

21 Q The process I just described, wherein a DNA

22 fragment which includes a universal tail sequence is

23 subject to amplification by one of the primers in

24 the pool that's specific to the target.

25 A I rely on the product that contain- -- that

Page 98	Page 100
1 is now tagged with a universal tail adaptor is now 2 subject to the wherein clause of one of the 3 amplification steps comprising target amplification. 4 So there are target-specific primers. They target 5 the tagged product, and they create a new tagged 6 product. 7 Q And that happens only in the last 14 cycles 8 of the PCR preamplification step in Forshaw (2012); 9 correct? 10 A That's correct. Every time a primer 11 hybridizes, it is tagging the product with a new 12 tag. 13 Q All right. Now, where do you call out those 14 last 14 cycles in connection with step 1B 15 specifically? Where do you point out that you're 16 relying upon those last 14 cycles and not the first 17 cycle? 18 A Well, I'll point you to paragraph 94, where 19 I've already testified that the RaDaR assay includes 20 amplifying the tagged products one or more times to 21 generate final amplification products wherein one of 22 the amplification steps comprises targeted 23 amplification of a plurality of single nucleotide 24 polymorphism (SNP loci) in a single reaction volume. 25 I mean, I state that in my declaration.	1 is still present if -- and when it gets copied, it 2 doesn't change. It's still present. So it 3 separates in the denaturation step. So if a 4 target-specific primer hybridizes to another 5 cell-free DNA molecule, it is still tagging 6 according to Claim 1A, so a little bit of it is 7 still happening in cycle 2 and cycle 3 because that 8 doesn't go away. 9 What happens is you're now multiplying the 10 amount of tagged product in the reaction, so by 11 probabilities in the subsequent cycles, most of the 12 tagged product now becomes a template for the primer 13 extension reaction. 14 Q All right. So if I understand correctly, 15 you rely upon processes that take place wherein a 16 primer hybridizes to an original cell-free DNA 17 molecule and generates a complementary strand in the 18 first cycle of PCR for step 1A; correct? 19 DR. SRINIVASAN: Objection. Vague. 20 THE WITNESS: If that process happens. Not 21 every cell-free DNA molecule will actually hybridize 22 to a target-specific primer; but in the instance 23 where that does happen, I do believe it meets the 24 claim limitation of tagging isolated cell-free DNA 25 with one or more universal tail adaptors to generate
Page 99	Page 101
1 Q And in that passage, you don't refer to 2 either the first cycle or any of the separate 14 3 cycles, do you? 4 A I do not, because one of ordinary skill 5 would have understood how the PCR cycle works. For 6 example, I've written about it. It's in Exhibit 7. 7 And it's and well under- -- this cycle would be 8 understood by a person of ordinary skill. 9 Q And those subsequent 14 cycles that generate 10 the "new tagged product," as you refer to it, do you 11 rely upon those 14 cycles for Claim Element 1A? 12 DR. SRINIVASAN: Objection. Asked and 13 answered. 14 THE WITNESS: No. 15 BY DR. WALTER: 16 Q You rely upon the first cycle for Claim 17 Element 1A and the 14 subsequent cycles for Claim 18 Element 1B; correct? 19 A No. 20 Q Okay. You don't rely upon the 14 cycles 21 after the first cycle for Claim Element 1A; correct? 22 A I don't -- I'm not trying to break it down 23 into cycle 1 is -- reads on the limitation in Claim 24 1A, and then the remaining cycles only read on the 25 limitation in Claim 1B. The original cell-free DNA	1 tagged products. 2 BY DR. WALTER: 3 Q And that is the process you rely upon for 4 step 1A; correct? 5 A Well, that's the process that's used in 6 Forshaw (2012). 7 Q Is there any other process that you rely 8 upon for step 1A other than that process? 9 A Again, are you asking with respect to 10 Forshaw (2012)? 11 Q For your infringement case. 12 A Yes. So I cite to Gale (2018), and I 13 explain how Gale (2018) also meets the limitation of 14 Claim 1A, and that's in paragraph 87. I also rely 15 on Lipsyc-Sharf (2022) in paragraph 90 -- 16 Q Okay. Let me stop you. I'm not asking 17 different publications. I'm asking different 18 processes. Do you understand the difference? 19 A Well, I do now. 20 Q Okay. That was my question. Processes, not 21 publications. 22 Okay. So what you contend infringes in the 23 RaDaR product -- that means step 1A of Claim 1 of 24 the '035 patent -- is a process wherein a 25 target-specific primer hybridizes to a cell-free DNA

Page 102 1 molecule and generates a complementary strand so as 2 to create a new DNA molecule that has a universal 3 tail adaptor; correct? 4 DR. SRINIVASAN: Objection. Vague. 5 THE WITNESS: I wouldn't characterize it 6 that way. So ForsheW (2012) does use 7 target-specific primers; but on the 5 prime end of 8 the primer sequence is either the CS1 or the CS2, 9 the common sequence. That is the tag. So it 10 requires the primer to actually be a composition of 11 both target-specific region and the tailed to meet 12 the claim limitation of 1A of the '035 patent. 13 BY DR. WALTER: 14 Q All right. And that process, you contend 15 that's what infringes in RaDaR; correct? That's 16 what meets Claim Element 1A in RaDaR; correct? 17 DR. SRINIVASAN: Objection. Asked and 18 answered. Mischaracterizes testimony. 19 THE WITNESS: Well, what I'm saying that 20 meets that claim limitation is the preamplification 21 step where a target-specific primer with a universal 22 tail adaptor hybridizes to isolate its cell-free DNA 23 and extends it to create the tagged product. 24 BY DR. WALTER: 25 Q Are there any other processes in RaDaR that	Page 104 1 Mischaracterizes testimony. Vague. 2 THE WITNESS: Well, it generates a tagged 3 product. It does -- it does do that. But it's all 4 based -- all of my information is based on publicly 5 available documents; and if there's more documents 6 out there, I would reserve the right to review those 7 as well. 8 BY DR. WALTER: 9 Q And that process that we've just discussed, 10 that happens if the first cycle of the 11 preamplification PCR; correct? 12 A Well, I think as I've testified, it does 13 happen in the first cycle; but it can also happen in 14 subsequent cycles. 15 Q Are there any other processes, other than 16 the one we've just discussed, that you believe 17 satisfies that tagging claim element in Element 1A 18 of the claim? 19 DR. SRINIVASAN: Objection. Asked and 20 answered. 21 THE WITNESS: Well, based on the public 22 documents I have right now, that appears to be the 23 only information that I have; but that information 24 seems sufficient to render my opinion that it meets 25 the claim limitation.
Page 103 1 you believe meets Claim Element 1A other than that 2 process? 3 A Yes. 4 Q Okay. Which process? 5 A Well, there is a wherein clause: 6 "The isolated cell-free DNA is isolated from 7 a blood sample collected from a subject who is not a 8 pregnant woman." 9 Q Okay. I think -- I'm not asking about that. 10 Let's try to isolate it down. Let's just focus on 11 the claim limitation that refers to tagging isolated 12 cell-free DNA with one or more universal tail 13 adaptors to generate tagged products. I want to 14 focus on that claim element only. 15 Do you understand that? 16 A I do now. 17 Q Now, the process that you contend satisfies 18 that claim element in RaDaR is the process wherein a 19 primer that's specific to a target and that has a 20 5 prime universal tail adaptor hybridizes to a 21 cell-free DNA molecule and extends it to generate a 22 new DNA molecule that is complementary to the 23 cell-free DNA molecule and has the 5 prime tail; is 24 that right? 25 DR. SRINIVASAN: Objection.	Page 105 1 BY DR. WALTER: 2 Q Now, for Claim Element 1B, there are 3 processes wherein the cell-free DNA -- the copied -- 4 let me try to ask this a different way. 5 Now, in Claim Element 1B, what you rely upon 6 is the portions of the preamplification process 7 wherein a primer hybridizes to a copy of a cell-free 8 DNA molecule that was generated in a previous cycle 9 of the PCR process and generates a new tagged 10 product; correct? 11 DR. SRINIVASAN: Objection. 12 Mischaracterizes testimony. Vague. 13 THE WITNESS: Sorry. I'm not following your 14 question. 15 BY DR. WALTER: 16 Q In Claim Element 1B, which you rely upon, 17 are the courses of the preamplification process 18 wherein a high primer hybridizes to a copy of a 19 cell-free DNA molecule that was generated in a 20 previous cycle of the PCR process; correct? 21 A I guess it's easier just to stay to the 22 claim language in what you're referring to as the 23 "copied cDNA -- cfDNA molecule with a tag on it." 24 It's just the tagged product; right? And I am 25 relying on those products that have been generated

Page 106 1 in step 1A are now subject to one or more 2 amplifications where one is a target amplification 3 or wherein one is subject to introducing barcodes or 4 one or more sequencing tags. 5 Q Now, that process, that can only happen in 6 the 14 cycles of the preamplification step that 7 happened after the first PCR step; correct? 8 A That is correct. So step 1B can start as 9 early as cycle 2, but it doesn't necessarily -- is 10 limited to cycle 2. 11 Q And you don't say that in your report 12 anywhere, do you? 13 DR. SRINIVASAN: Objection. 14 Mischaracterizes testimony. 15 THE WITNESS: Again, I think I do 16 characterize that in my report. I pointed you to 17 several paragraphs where I've said that the RaDaR 18 assay meets this claim limitation with respect to 19 either the target amplification or introducing 20 barcodes in one or more sequencing tags. 21 BY DR. WALTER: 22 Q Where in your report do you state that step 23 1B can begin as early as the second step of the 24 preamplification process in RaDaR? Please point me 25 to a paragraph where you state that.	Page 108 1 not meet the limitation of Claim 1A. 2 (Discussion off the record.) 3 THE VIDEOGRAPHER: We're going off the 4 record. The time is 12:48 p.m. 5 --oOo-- 6 (LUNCHEON RECESS.) 7 --oOo-- 8 THE VIDEOGRAPHER: The time is 1:18 p.m. 9 BY DR. WALTER: 10 Q Dr. Metzker, have you ever heard of the term 11 "amplification" used in the context of PCR 12 amplification? 13 A In general, yes. 14 Q What do you understand amplification to 15 refer to in that setting? 16 A Well, in the setting of PCR, it's where a 17 template molecule is copied and that is repeated 18 multiple times to make multiple copies. 19 Q And how many cycles of repetition can there 20 be in that amplification process? 21 A I'm sorry. Which process are we talking 22 about? 23 Q The amplification process. 24 A There can be numerous cycles. People have 25 used all kinds of cycle numbers.
Page 107 1 A Oh, I cannot state it with that much 2 specificity; but I am pointing to you the general 3 statement that is in paragraph 94, and I'm now just 4 answering questions that you've asked about these 5 different elements. 6 Q Okay. Now, those processes wherein the 7 primers hybridize to tagged products that are 8 generated as early as the first step of the 9 preamplification process, that will generate new 10 tagged products; correct? 11 DR. SRINIVASAN: Objection. Vague and 12 incomplete hypothetical. 13 THE WITNESS: A target-specific primer with 14 a universal adaptor -- 15 (Reporter clarification.) 16 THE WITNESS: -- that hybridizes to a tagged 17 product will create a new tagged product. 18 BY DR. WALTER: 19 Q Do you rely upon those, quote, "new tagged 20 products" that we just referred to for step 1A of 21 the claim? 22 A Oh, that doesn't meet step 1A because step 23 1A requires that tagged -- tagging isolated 24 cell-free DNA. So -- so a tagged product that acts 25 as a template to create a new tagged product does	Page 109 1 Q Is there any limit? 2 A I'm sure there is. I mean, I don't think 3 you would cycle for infinity. 4 Q What's the largest number of cycles you've 5 ever heard of for amplification? 6 A For a single reaction, as many as 60. 7 Q And how about in the context of a multiplex 8 PCR? What's the largest numbers of cycles you've 9 heard of for amplification? 10 A I don't know off the top of my head. I 11 think multiplex, you tend to use fewer cycles; but I 12 don't remember what's the highest number. 13 Q One example we're aware of is 15 in the 14 Forshew reference; right? 15 A Yes. 16 Q Now, you understand that when you're talking 17 about those copies in the context of amplification, 18 the only molecules that people understand to be the 19 copies are the molecules that result when the primer 20 hybridizes to an original sample molecule and the 21 point where this generates a complementary strand. 22 That's the only thing that people refer to as copies 23 in the context of PCR amplification; right? 24 A I'm sorry. I'm not understanding the 25 question.

Page 110	Page 112
1 Q Now, in the context of amplification, you 2 talked about how that refers to making copies of a 3 molecule? 4 A Well, I said just making copies, yes. 5 Q Now, the only thing that people understand 6 to be a copy in the context of PCR amplification is 7 the product that results when the primer hybridizes 8 to one of the original sample molecules and a 9 complementary strand is generated. But that's -- 10 that's the only thing people call a copy; correct? 11 A I'm not sure I agree with that. 12 Q Okay. Well, what else would be a copy? 13 A Well, first, I'm not sure what people would 14 agree with. I mean, I'm not -- I can tell you what 15 I think, but I don't know what people would agree 16 with. 17 Q What do you think? 18 A Well, I think you can make a copy from an 19 original stand. You can make a copy from a copy. I 20 don't think -- at the end of the day, they think of 21 it as a product. 22 Q When you say "you can make a copy from a 23 copy," what did you mean by that? 24 A Well, we talked about this in step 1B where 25 the amplification can occur from a tagged product	1 "isolated cell-free DNA molecule." The 2 hybridization of the target-specific primer with the 3 universal tail adapter tags -- creates the tagged 4 product. 5 BY DR. WALTER: 6 Q And how is that tagged product created? 7 A The tagged product is created by hybridizing 8 to the target-specific region of the cell-free DNA 9 and performing primer extension to now include the 10 sequence of the cell-free DNA plus now the universal 11 tail adaptor. 12 Q Now, that product that you said now includes 13 a sequence of the cell-free DNA, that's actually the 14 complementary sequence; correct? 15 A In that cycle, that's correct. 16 Q And the universal tail adaptor that is not 17 ever covalently attached to the original cell-free 18 DNA; correct? 19 DR. SRINIVASAN: Objection. Vague. 20 THE WITNESS: Not in the method that uses 21 PCR to tag the cell-free DNA molecule. 22 BY DR. WALTER: 23 Q And that's what you contend is infringing 24 here as a method that uses PCR to tag the cell-free 25 DNA molecule; correct?
Page 111	Page 113
1 using a target-specific primer. So in that case, 2 the tagged product would represent a copy because 3 it's now tagged, and that can serve as a template in 4 the next primer extension reaction. 5 Q And will that lead to a new copy? 6 A Well, I don't know about a new copy, but 7 it's another copy. 8 Q It's another copy, okay. 9 Why do you distinguish between "a new copy" 10 and "another copy"? 11 A Well, I guess I don't think of copies in 12 time -- old copy, new copy. They're just copies. 13 Q Now, we talked earlier about how in step 1A 14 of Claim 1 of the '035 patent, you rely upon the 15 hybridization of the primer with the universal tail 16 adaptor to one of the original cell-free DNA 17 molecules; correct? 18 A Can you repeat the question, please. 19 Q We talked earlier about how for step 1A of 20 Claim 1 of the '035 patent, you rely upon the 21 hybridization of the primer with universal tail 22 adaptor to one of the original cell-free DNA 23 molecules; correct? 24 DR. SRINIVASAN: Objection. Vague. 25 THE WITNESS: Well, I refer to it as the	1 A Well, the claim limitation is tagging 2 isolated cell-free DNA. It's not the molecule. 3 Q And do you contend that that is infringed by 4 PCR; correct? 5 A Yes. That is one way of tagging cell-free 6 DNA. 7 Q And in that process, the universal tail 8 adaptor is never directly attached to the original 9 cell-free DNA molecule; correct? 10 A It does not attach to the original cell-free 11 DNA molecule. It is made into a copy that is now 12 the tagged product. And that's what creates the 13 tagged product. 14 Q And then additional copies can be made from 15 that tagged product; correct? 16 A Correct. 17 DR. WALTER: All right. I don't have any 18 further questions. 19 DR. SRINIVASAN: Any questions? 20 DR. HABERNY: Why don't we take a minute to 21 regroup. 22 THE VIDEOGRAPHER: We're going off the 23 record. The time is 1:26 p.m. 24 (Recess.) 25 THE VIDEOGRAPHER: We're back on the record.

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1 It's 1:42 p.m.
2 --oOo--
3 DR. SRINIVASAN: I just have a few redirect
4 questions for you, Dr. Metzker.
5 --oOo--
6 EXAMINATION
7 BY DR. SRINIVASAN:
8 Q Is there more than one way to tag cell-free
9 DNA isolated from a sample?
10 A Yes.
11 Q And what are they?
12 A Well, one way which we've been talking about
13 is taking the isolated cell-free DNA, hybridizing
14 primer that has a 5 prime tag attached to it and
15 extending that product to create a double-stranded
16 DNA molecule. That is one way of tagging the
17 cell-free DNA.
18 Q Are there any others?
19 A Yes. You can also use a process called
20 "ligation," where you can attach -- and you can do
21 that enzymatically or chemically to attach the
22 universal tailed adaptors to the cell-free DNA. Lexitas
23 Q Are there any others that you can think of?
24 A Not off the top of my head. Ligation would
25 be -- or PCR -- the two most common ways of doing

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1 that.
2 Q Okay. And so these two methods that you've
3 just described, do you think they achieve
4 substantially the same result?
5 DR. WALTER: Objection. Beyond the scope of
6 his report.
7 THE WITNESS: Yes.
8 BY DR. SRINIVASAN:
9 Q And do these tagging methods accomplish
10 substantially the same thing?
11 DR. WALTER: Same objection.
12 THE WITNESS: Yes.
13 DR. SRINIVASAN: Okay. No further
14 questions.
15 DR. WALTER: All right. And we'll state for
16 the record that especially with regard to those last
17 questions, he doesn't have opinions of doctrine of
18 equivalents, so trying to lob it in now is improper.
19 And I should note that I think it's been clear that
20 there's some aspects of his infringement case that
21 are not present in his report, so we're reserving
22 our rights on a motion to strike.
23 DR. HABERNY: Well, Counsel, you spent a
24 good bit of this deposition asking him about
25 invalidity opinions that were not in his report as

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1 well. So what's good for the goose is good for the
2 gander. And if you're going to ask him questions
3 about things that are not in his report, then it's
4 perfectly fair game for him to give opinions
5 especially since his report was done before
6 Neogenomics even served its contentions in this
7 case, and so, you know, he's responding to
8 contentions; and I think that it's perfectly
9 acceptable for him to do so during a deposition only
10 after the fact that he was able to review them.
11 DR. WALTER: Okay. Thank you.
12 THE VIDEOGRAPHER: We're going off the
13 record?
14 MR. MESSERIAN: Yes.
15 THE VIDEOGRAPHER: This concludes today's
16 deposition. We're going off the record at 1:44 p.m.
17 (Time noted: 1:44 p.m.)
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1 DECLARATION UNDER PENALTY OF PERJURY
2
3 I, Michael L. Metzker, Ph.D., do hereby certify
4 under penalty of perjury that I have read the
5 foregoing transcript of my deposition taken on
6 Tuesday, September 26, 2023; that I have made such
7 corrections as appear noted herein; that my testimony
8 as contained herein, as corrected, is true and
9 correct.
10
11
12 DATED this ____ day of _____ ,
13 2023, at _____ , _____ .
14 City State
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20 Michael L. Metzker, Ph.D.
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1 ERRATA SHEET

2 Printed Name _____ Date _____

3 Signature _____

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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

2 The undersigned Certified Shorthand Reporter and

3 Deposition Notary Public of the States of California,

4 Washington and Nevada does hereby certify:

5 That the foregoing deposition was taken before me

6 at the time and place therein set forth, at which time the

7 witness was duly sworn by me;

8 That the testimony of the witness and all

9 objections made at the time of the deposition were

10 recorded stenographically by me and were thereafter

11 transcribed, said transcript being a true and correct copy

12 of the proceedings thereof.

13 I further certify that I am neither counsel for

14 nor related to any party to said action, nor in any way

15 interested in the outcome thereof.

16 Further, that if the foregoing pertains to the

17 original transcript of a deposition in a federal case,

18 before completion of the proceedings, review of the

19 transcript was not requested/offered on the record.

20 In witness whereof, I have subscribed my name,

21 this date: September 27, 2023

22

23

24 Cheryl Haab Scott, RDR, CRR, CCRR

25 CSR No. 13600/WA CSR No. 3499/NV CCR No. 1003

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