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(End of in camera session.)

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(The following proceedings continued in public session.)

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JUDGE CHAPPELL: All right. Thank you, sir. You're excused. You may stand down.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: Anything further from the attorneys before we recess?

MS. MUSSER: Yes, Your Honor. From -- Complaint Counsel is hoping that you would be able to accommodate a witness who has a medical issue on Thursday and have a late start at 10:30, if that's doable for Your Honor.

JUDGE CHAPPELL: Let me look at the official calendar here. That would be 2 September?

MS. MUSSER: That would be this Thursday, which is the 2nd of September. Sorry, Your Honor. I was looking for a calendar.

JUDGE CHAPPELL: Start at 10:30? Yes, we can do that.

MS. MUSSER: Thank you.

JUDGE CHAPPELL: I'm assuming there is no objection, right, Mr. Marriott?

MR. MARRIOTT: There is no objection, Your Honor.

MS. MUSSER: Thank you, Mr. Marriott.

JUDGE CHAPPELL: Okay. Anything else?

MS. MUSSER: Not from Complaint Counsel.

MR. MARRIOTT: Nothing here, Your Honor. Thank you.

JUDGE CHAPPELL: Have you been able to plug in any witnesses for September 14 or 15?

MS. MUSSER: We're still working on that. We believe that if we're still going at that time, we will be able to present witnesses on that date. So Complaint Counsel should be able to, at least the 14-15, and we will coordinate with Respondents' counsel in the event we need to fill the time.

JUDGE CHAPPELL: You said something that got my attention. Did you say "if we're still going at that time"?

MS. MUSSER: If Complaint Counsel hasn't rested their case. We're just waiting to see how long we'll take. So I don't want to give anyone any false hope.

JUDGE CHAPPELL: Your case, okay.

MS. MUSSER: Just my case. I won't speak to --

JUDGE CHAPPELL: The rest of us would just go on without you. Is that what you're saying?

MS. MUSSER: You don't want to go on without me.

JUDGE CHAPPELL: Now, I told you I would let you know about the 29th or 30th, because those are two days I had blocked out. It's looking like right now it will be the 29th. I'm not 100 percent sure, but that will make the 30th available if we're still going.

MR. MARRIOTT: Very good.

JUDGE CHAPPELL: Okay. All right, so tomorrow, usual time. Thursday, 10:30. Friday --

MR. MARRIOTT: No, Your Honor. I understood we were off tomorrow, Your Honor.

JUDGE CHAPPELL: You are correct. This is Tuesday. You see, that mistake is understandable because this is a September calendar, so -- all right, so we will reconvene Thursday, 10:30 a.m. We're in recess.

MS. MUSSER: Thank you, Your Honor.

MR. MARRIOTT: Thank you.

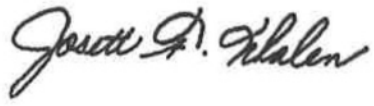
MS. SULLIVAN: Thank you, Your Honor.

MR. MARRIOTT: Good night, everybody.

(Whereupon, at 5:47 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

We, Susanne Bergling and Josett Whalen, do hereby certify that the foregoing proceedings were recorded by us via stenotype and reduced to typewriting under our supervision; that we are neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that we are not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.



JOSETT WHALEN, Court Reporter

SUSANNE BERGLING, Court Reporter

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:	)	
ILLUMINA, INC.,	)	
a corporation,	)	
and	)	Docket No. 9401
GRAIL, INC.,	)	
a corporation,	)	
Respondents.	)	

Virtual Proceeding Via Zoom
September 2, 2021
10:54 a.m.
TRIAL VOLUME 7
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

APPEARANCES:
ON BEHALF OF THE FEDERAL TRADE COMMISSION:

STEPHEN A. MOHR, ESQ.
SUSAN A. MUSSER, ESQ.
DANIEL ZACH, ESQ.
WADE LIPPARD, ESQ.
SARAH WOHL, ESQ.
DYLAN NAEGELE, ESQ.
CATHERINE SANCHEZ, ESQ.
JORDAN ANDREW, ESQ.
STEPHANIE BOVEE, ESQ.
NICOLAS STEBINGER, ESQ.
NICHOLAS WIDNELL, ESQ.
RICARDO WOOLERY, ESQ.
MARIBETH PETRIZZI, ESQ.
BEN LORIGO, ESQ.
WILLIAM COOKE, ESQ.
PETER COLWELL, ESQ.
ERIC D. EDMONDSON, ESQ.
MATTHEW E. JOSEPH, ESQ.
SAM FULLITON, ESQ.
BRIAN O'DEA, ESQ.
LAUREN GASKIN, ESQ.
DAVID GONEN, ESQ.
WELLS HARRELL, ESQ.
BETTY JEAN McNEIL, ESQ.
NANDU MACHIRAJU, ESQ.
JOSEPH NEELY, ESQ.
DAVID VON NIRSHCL, ESQ.
SUSAN HUBER, ESQ.

Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2859
smohr@ftc.gov

APPEARANCES: (continued)

ON BEHALF OF ILLUMINA, INC.:

CHRISTINE A. VARNEY, ESQ.
RICHARD J. STARK, ESQ.
DAVID R. MARRIOTT, ESQ.
J. WESLEY EARNHARDT, ESQ.
SHARONMOYEE GOSWAMI, ESQ.
MICHAEL ZAKEN, ESQ.
JESSE WEISS, ESQ.
MOLLY JAMISON, ESQ.
ALLISON KEMPF, ESQ.
KALANA KARIYAWASAM, ESQ.
BENJAMIN ATLAS, ESQ.
Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019-7475
(212) 474-1000
cvarney@cravath.com

-and-

KARL HUTH, ESQ.

Huth Reynolds LLP
41 Cannon Court
Huntington, New York 11743-2838
(212) 731-9333
huth@huthreynolds.com

APPEARANCES: (continued)
ON BEHALF OF GRAIL, INC.:
MICHAEL G. EGGE, ESQ.
MARGUERITE M. SULLIVAN, ESQ.
ANNA M. RATHBUN, ESQ.
DAVID L. JOHNSON, ESQ.
MARCUS CURTIS, ESQ.
MARILYN GUIRGUIS, ESQ.
SEAN MULLOY, ESQ.
SIMON TROCH, ESQ.
NATHANIEL AMANN, ESQ.
Latham & Watkins LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, D.C. 20004-1304
(202) 637-2200
michael.egge@lw.com

-and-

ALFRED C. PFEIFFER, ESQ.

Latham & Watkins LLP
505 Montgomery Street
Suite 2000
San Francisco, California 94111-6538
(415) 391-0600
al.pfeiffer@lw.com

ON BEHALF OF EXACT SCIENCES AND KEVIN CONROY:
ALLEN R. BACHMAN, ESQ.
DEREK KELLEY, ESQ.

K&L Gates
1601 K Street, N.W.
Washington, D.C. 20006
(202) 778-9117
allen.bachman@klgates.com

C O N T E N T S

P R O C E E D I N G S

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JUDGE CHAPPELL: We're on the record.

Anything before we start with the next witness?

MS. MUSSER: Nothing from complaint counsel.

JUDGE CHAPPELL: You're muted.

MR. MARRIOTT: Just my appreciation for the brief postponement. Thank you. And my apologies to everyone for the delays here.

JUDGE CHAPPELL: No problem. Hope everything is okay out there with the weather.

MR. MARRIOTT: I'm not sure we can quite go that far, but it's getting better, Your Honor.

JUDGE CHAPPELL: All right. Sounds good.

Go ahead and call your next witness.

MS. MUSSER: Good morning, Your Honor. Complaint counsel calls Kevin Conroy, chairman and CEO of Exact Sciences.

JUDGE CHAPPELL: Jada, is the public line on?

JADA: That is correct, the public line is on.

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Whereupon --

KEVIN CONROY

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. MUSSER:

Q. Good morning, Mr. Conroy.

A. Good morning, Susan.

Q. Can you please state and spell your name for the record.

A. Kevin Conroy, K-E-V-I-N C-O-N-R-O-Y.

Q. Mr. Conroy, I'd just like to remind you before we get started that we are in public session, which means the public has dialed in. And I'm going to ask you a series of questions. I will do my level best to stay away from anything that's confidential or sensitive and has been granted in camera status. But if at any point I ask you questions that you're uncomfortable asking [sic] in public session, please just let me know.

Does that work for you, Mr. Conroy?

A. Thank you.

Yes, it does.

Q. And Mr. Conroy, where do you work?

A. I work at Exact Sciences.

Q. And how long have you worked at Exact Sciences?

A. Over twelve years.

Q. And what is your current title?

A. Chairman and CEO.

Q. And at a very high level, can you describe your responsibilities as chairman and CEO.

A. Yes. As chairman I'm responsible for setting the agenda of the board of directors, and as CEO I'm responsible for the operations of the company.

Q. And as part of your responsibilities as CEO over the operations of the company, do you have any responsibility related to strategic planning of Exact Sciences?

A. Yes. That falls under me.

Q. And can you at a high level describe your responsibilities related to strategic planning.

A. Yes.

Strategic planning is all about planning for the future, way out into the future, kind of a five-year plan, a three-year plan, and then that folds into an annual planning process.

So you try to create a vision, for at a company like ours that's focused on patients, planning for how you can screen more people to detect cancer early and all of the investments and people that you need to make that happen.

Q. And as part of that forward-looking planning, do you also conduct risk assessments for -- looking for potential risks that could affect those plans?

A. That's an important part of strategic planning, is to assess internal and external threats, for example, whether you have the people to get the job done or the external development, what's going on in the outside world that could affect your ability to make that long-term plan become real.

Q. And as CEO and chairman, do you have any responsibilities relating to the merger and acquisition strategy of Exact Sciences?

A. Yes. Ultimately I'm responsible for that.

Q. And as chairman and CEO, what responsibilities, if any, do you have for negotiating supply contracts?

A. I normally am not involved in negotiating supply contracts.

Q. Do you ever get involved --

A. The people who do negotiate supply contracts roll up and report to me, but normally I don't negotiate them.

There are exceptions to that, but for the most part I'm not involved directly.

Q. And when do you get involved directly?

A. I have been involved in a very limited number of cases, including involved to a certain extent in negotiating or having conversations with Illumina because of the critical nature of next-generation

sequencing as part of our long-term plan.

And I got involved in that not at the outset but as things became more difficult. And -- but normally -- I'm trying to think. I can't think of very many other cases where I've been involved in negotiating a supply agreement, even with critical suppliers.

Q. And what are your current responsibilities relating to commercialization of Exact's products?

A. My responsibilities ultimately are to make sure that we get our tests, which we think are advanced tests that can have a positive impact on human health, to physicians, to healthcare providers, and ultimately to patients.

And so all of those responsibilities roll up directly to me, and we have individuals who are responsible for different parts of the tests that we offer. And those people execute the long, medium and near-term plans to make those tests available optimally to patients.

Q. But is it fair to say, as chairman and CEO, you're generally familiar with the commercialization planning for Exact's cancer tests?

A. Yes, I am.

Q. Mr. Conroy, do you have any advanced degrees?

A. I -- I have a J.D. I have a J.D. that I earned in 1991.

Q. Where did you earn your J.D.?

A. University of Michigan.

Q. And did you practice law, Mr. Conroy?

A. I did. I practiced intellectual property law for I think about nine years in private practice and then in-house counsel for a handful of years before moving to becoming a general manager.

Q. Were you a member of the patent bar?

A. I was, yes.

Q. And Mr. Conroy, why are you here today?

A. Because I was subpoenaed to attend.

Q. And is there any reason you can't testify truthfully and accurately here today?

A. No.

Q. And Mr. Conroy, I know you touched on this briefly, but at a very high level, can you describe what type of work Exact Sciences does.

A. Well, our mission at Exact Sciences is to eradicate cancer through earlier detection and tests that help guide the right treatment to the right patient. That's our overarching North Star, and all of the tests that we develop in some way, shape or form help lead to helping people avoid cancer, detect cancer

earlier, or for people who are diagnosed with cancer, make sure that they get the right treatment -- the best treatment possible.

And this is all made possible by the powerful information that you can get from the human genome, the genetics, the inherent genetics that we're born with, and also the cancer genome or what is going on inside the tumor cells that somebody may have.

Q. What type of products does Exact work on as part of that mission you just described?

A. A range of tests, starting with hereditary cancer testing, which is your germline, what you're born with, to screening tests and then all the way to tests that help a patient who has been diagnosed with cancer get the right treatment and to detect, for example, whether their cancer has recurred.

And another important part of what we do is to provide the software that helps physicians and patients better interact with those tests, manage that data, and make the best possible decision that they can for that patient in terms of treatment.

Q. Do you consider Exact a clinical testing business?

A. Yes.

Q. Can you explain what that means to you.

A. Clinical testing is testing a real person or a patient sample -- I say "real person." A lot of times we test people who aren't patients because they're perfectly healthy. If you're screening somebody for cancer, that is by definition somebody who isn't a patient. They are somebody who is generally healthy -- and patients who actually have cancer.

Q. And I want to take you back a little bit. I believe you testified that you've been working at Exact a while.

When did you start at Exact again?

A. I started on April 2, 2009.

Q. And on April 2, 2009, when you started, can you describe Exact's business at that time.

A. Well, there were three of us, and we -- you couldn't really describe it much as a business. It was an idea. And the idea was to develop two things, a colon cancer screening test that allows you to accurately detect colon cancer through a sample collected in the privacy of your own home. And then secondly, long-term was to develop what then we called a pan-cancer screening test or a universal cancer screening test from a simple blood draw.

Q. And has Exact changed since you had that idea in 2009?

A. Yeah. We now have almost 6,000 people, and we have a range of different tests that we have brought to physicians and patients. And we are a fully, what we would call a commercial company in that we have teams of people who educate healthcare providers about the tests that we offer, and we provide clinical testing services.

Q. And how many products is Exact currently offering for sale?

A. It's approximately seven or eight different products, two main tests, Cologuard, which is a screening test for colon cancer, and Oncotype DX, two different tests there, a breast cancer test and a prostate cancer test.

Q. And does Exact have any labs as part of its business today?

A. Yes. We have a host of labs. We have labs in Madison, Wisconsin; Redwood City, California; Phoenix, Arizona; and Baltimore, Maryland.

Q. And does Exact have manufacturing capabilities today?

A. We do. We manufacture and ensure the quality of the components that go into our tests. And the principal manufacturing location is Madison, Wisconsin.

Q. And does Exact have a clinical sales force today?

A. We do. Altogether, we have over a thousand people that call upon healthcare providers, educating them about the various tests that we offer.

Q. And why does the clinical sales force target healthcare providers?

A. All of this technology is really new technology, and the only way to get healthcare providers to understand the performance characteristics of new technology, how that new technology can and should be used, what the guidelines say about that technology, and how it performs relative to other types of tests is to engage with them on a very regular basis.

The average technology, new medical technology, takes about 17 years to be fully implemented, and that is if you're constantly out engaging with the physicians who use new technology. It's virtually impossible to bring new technologies to healthcare providers and to patients without doing so.

Q. And just a few follow-ups on some of those areas of growth that you just testified about.

When you mentioned lab capability, how did Exact grow its lab capabilities from those four people

on April 2, 2009 to its current capabilities today?

A. Well, we have this amazing team of clinical laboratorians who built our first lab here in Madison, secured all of the regulatory and quality approvals necessary to turn that lab on and start offering tests to the public. And we built that capacity from a very small lab to now the ability to offer millions of Cologuard tests and hundreds of thousands of Oncotype DX tests and other tests, and we constantly invest in those clinical laboratory capabilities.

Q. And Exact Sciences was able to grow that capability in-house; is that fair?

A. Yes.

Q. And you talked about this thousand-person clinical sales force.

How did Exact expand its sales force so much?

A. Well, I remember that when we first decided to hire a sales force that we hired 80 people to offer Cologuard to a target market of 350,000 primary care physicians. And the original plan was 50. We bumped it to 80. And today we have more than 500 just calling on primary care physicians, plus we have a partnership with Pfizer where they add to that ability.

And still we don't have the ability to call on all primary care physicians, nurses, et cetera.

So that has just grown over time. As Cologuard has grown, we've been able to invest more of our time, energy and money into building that sales force.

Q. And where did you recruit your sales force from, what type of companies?

A. All over the country from people primarily who had experience calling on healthcare providers and in particular primary care healthcare providers.

Q. And as part of this growth that you've just described, has Exact collaborated with any other organizations as part of its research and development efforts?

A. Our principal collaboration was with the Mayo Clinic, so that's how this whole thing started way back in March of 2009. Before I even joined the company, I met with Dave Ahlquist at the Mayo Clinic. And that turned into a partnership in June of 2009, and that partnership we're very fortunate has continued for twelve years.

We now also have a partnership with City of Hope and a -- a development partnership and also with Johns Hopkins University.

So we have -- those are critically important to take an idea of what you can do with technology and

translate it into a test that is safe and effective for patients who need those tests.

JUDGE CHAPPELL: We seem to have lost the witness' counsel. Was that at his choice?

MR. BACHMAN: I'm here, Your Honor. Can you hear me?

JUDGE CHAPPELL: I'm sorry. I misspoke. I'm trying to read the boxes here. I believe it -- we lost an attorney, just -- I think it was -- maybe it was the attorney for Mr. Conroy.

There he is. If you dropped on your own, that's fine, Mr. Kelley.

MR. KELLEY: Apologies, Your Honor. I was having issues with my webcam.

JUDGE CHAPPELL: All right. Go ahead.

BY MS. MUSSER:

Q. I believe you mentioned someone named David Ahlquist.

Is that Dr. Ahlquist?

A. "Ahlquist." Yes.

JUDGE CHAPPELL: Hold on a second.

I just want to make sure the record is clear.

So, Mr. Bachman, you're not the counsel for Mr. Conroy, the witness; you're the counsel for the company Exact Sciences?

MR. BACHMAN: I apologize, Your Honor. One and the same.

I understood I should list my client first, Exact Sciences, and then my counsel afterwards. That's what I attempted to do. I am counsel for Kevin Conroy and I also represent Exact Sciences.

JUDGE CHAPPELL: Okay. Good. We need to get that on the record.

And Mr. Kelley, who are you representing?

MR. KELLEY: I also represent Exact Sciences. Allen is my boss.

JUDGE CHAPPELL: All right. Now we're clear.

Go ahead, Ms. Musser.

MS. MUSSER: And Your Honor, just for clarity of the record, I believe Scott Coward is in attendance today. He is also in-house counsel for Exact Sciences.

JUDGE CHAPPELL: All right.

BY MS. MUSSER:

Q. And my apologies, Mr. Conroy. I believe we were talking about Dr. Ahlquist -- Ahlquist. My apologies again.

Who is Dr. Ahlquist?

A. So Dr. Ahlquist was a gastroenterologist at the Mayo Clinic who for years conducted research on colon

cancer screening, looking for biomarkers that could identify colon cancer early, identify them in stool, in blood, other patient samples. Then -- and he was a leader at the Mayo Clinic and a highly regarded both researcher and clinician.

Q. And can you explain how that collaboration with Dr. Ahlquist impacted the development and commercialization of Exact's products?

A. Sure.

We wouldn't be here without his work. I met with him in March of 2009, after initially declining to join Exact Sciences. And the board at Exact Sciences suggested that I go visit with Dr. Ahlquist and look at the research that he was doing, and the research included data demonstrating the ability to detect colon cancer and even precancerous polyps accurately from a stool sample.

So that was kind of the first part of the meeting. The second part of the meeting, Dave had this vision, which I honestly thought was a little far out there at the time, which was the idea of detecting many or most cancers from a simple blood draw, something that he called a pan-cancer test.

So the vision, which was pretty unique at the time, was to be able to look for tiny fragments of

cancer DNA in a patient's blood. And in that meeting was the genesis for a partnership and a long-term collaboration where we worked daily, weekly, monthly to bring these tests to physicians and patients, so Mayo Clinic and Dave Ahlquist was a critical part of that. Dave, unfortunately, passed away.

Q. And how did Dr. Ahlquist's idea of looking for these tiny fragments of cancer in DNA -- how did that impact Exact Sciences' mission statement? Did that relate at all?

A. It was -- it was the genesis of our mission, was to detect cancer earlier, because -- and I'll never forget in that first meeting Dave -- Dave just explained it simply. And I didn't know a lot about colon cancer.

He showed nine out of ten people diagnosed with Stage I or II colon cancer survive five or more years, whereas only one out of ten people diagnosed with late-stage cancer survive five or more years, so the whole goal is to shift detection from late stage, which is largely where colon cancer is detected today, to early stage where it's frequently surgery alone has cured it with no chemotherapy. If diagnosed Stage I, that's the typical treatment.

So that was the vision, and that has -- we've

stayed true to that vision over the last twelve years.

Q. Mr. Conroy, what does that vision and that mission statement mean to you personally as CEO and chairman of Exact Sciences?

A. It's -- it is a joy to be able to come into work every day to invest and work on new technologies and new tests that can change outcomes and being able to see that through over the last twelve years of working on technologies that you actually bring to patients.

Now we have screened over six million people with Cologuard. Most of them, the majority, would never have been screened. And the result of that, if you model that out, is about 200,000 people with precancerous polyps had those polyps removed, and about 30,000 people diagnosed with early stage, treatable stage, colon cancer versus later stage, so it's -- it's a joy to be able to come into work every day.

Q. And are you familiar with Exact Sciences' five core values?

A. Yes, I am.

Q. Is innovation one of those values?

A. It is.

Q. What does innovation mean to Exact Sciences?

A. Innovation means looking at a complex problem

and thinking about it in different ways, ways that maybe others have never thought about solving those problems, and then investing in a collaborative effort to solve them, bringing together people of all different perspectives and backgrounds and experiences and skill sets to do so.

Cologuard is an example of that. Oncotype DX is an example of that. These were far-out-there ideas when first thought of, and so it is a core value to constantly innovate and work with others internally and externally so that you can make a difference in people's lives.

Q. And you mentioned Oncotype and Cologuard.

Are you familiar with a product called CancerSEEK?

A. Yes.

Q. What is CancerSEEK?

A. So CancerSEEK is a test that was developed by Bert Vogelstein at Johns Hopkins. Bert -- Dr. Vogelstein is probably the preeminent researcher in cancer, certainly in colon cancer and other cancers, and he has devoted his life to this concept, like Dr. Ahlquist, of earlier detection.

So he developed CancerSEEK within his own lab and then ran clinical studies to demonstrate the

ability from a single blood draw to detect cancer earlier across many different types of cancer. And that eventually became part of a company called Thrive, a company which we invested in and later acquired.

Q. And what impact does this acquisition of Thrive have on Exact's core value of innovation?

A. In terms of CancerSEEK?

Q. Yes.

A. So CancerSEEK is an example of amazing innovation. The way that the Vogelstein lab and team thought about detecting cancer earlier was different than the way that others had approached that.

We combined -- we are in the process of combining the CancerSEEK approach with an approach that we worked on at the Ahlquist lab and within Exact Sciences to bring the best of both of those technologies together so that we will, as we plan to, bring the very best, most accurate test for multicancer screening to physicians and patients.

Q. And you mentioned that CancerSEEK's approach to early cancer detection was different.

Can you explain how it was different?

A. What --

Q. And I'll remind you we're in public session, so

just if you're uncomfortable, I can ask that later.

A. No. Not at all.

In essence, what the CancerSEEK test does is it looks for driver mutations, mutations in a patient's DNA, in a particular organ, that would turn that cell or cells into cancer cells. And there was a curated approach to identifying the specific DNA mutations -- and there was a lot of work that went into that -- and a panel or a series of those mutations coupled with proteins -- and there was a lot of work in identifying which mutations and which proteins -- and then building a test on next-generation sequencing technology, the Illumina technology, and protein detection technology that allowed you to accurately find cancers with a high level of specificity, meaning that -- a low false positive rate.

Q. And will this new --

JUDGE CHAPPELL: Hold on a second.

I'm noticing a lot of boxes on the Zoom screen. And based on what I heard earlier, there is more than one attorney on video for this witness. Only the attorney who will be lodging any objections should be on video. Otherwise, your video should be off.

Thank you.

MS. MUSSER: May I proceed, Your Honor?
JUDGE CHAPPELL: Go ahead.
MS. MUSSER: Thank you.
BY MS. MUSSER:
Q. You just testified about differences in CancerSEEK's approach to detecting early stage cancer. Did I get that right, Mr. Conroy?
A. Yes.
Q. Will this -- do you -- will CancerSEEK's approach to detecting early cancer in patients be beneficial for those patients?
A. It has the ability to do so. It may not be beneficial to all patients, but to some patients with cancer it has the ability to be very beneficial.
Q. And going back to innovation, that core value that you described, how will the ability to bring CancerSEEK to patients advance Exact's commitment to innovation?
A. Our commitment to innovation is very fundamental to who we are, this constant investment in advancing whole new ideas for detecting cancer earlier. And CancerSEEK was -- is a proven approach in the sense that it ran a 10,000-patient clinical trial prospectively, like in the normal way that you would see a physician, and you got a sense for the

performance of that test in its rudimentary form because that -- the original version of CancerSEEK is not the test that it is today.

So we have continued to innovate that original version of CancerSEEK. It was first studied about three, maybe even four years ago. And there have been constant improvements made with the use of next-generation sequencing technologies and other technologies.

Q. And have those innovations improved the CancerSEEK product?

A. Yes.

Q. Will those improvements benefit patients?

A. Yes.

Q. And does Exact plan on continuing to innovate to continue to develop the CancerSEEK product?

A. Absolutely. Every day.

Q. And you also mentioned Cologuard.

Can you describe at a high level how Cologuard works?

A. So Cologuard is relatively straightforward in concept. It's a package that comes to your home with a collection kit, and a patient collects a stool sample and pours a preservative over that sample, and it is sent back to our labs, where we test it for ten

different biomarkers and we -- eleven, including a protein biomarker, so ten DNA markers and one protein marker. And that generates a score, and that score translates into either a positive result or a negative result.

A positive result is bad. You may -- you need to get a colonoscopy. And a negative result is good in that you can go back into the screening population and get tested three years later.

Q. And is Cologuard FDA-approved?

A. Yes, it is.

Q. Was Cologuard the first product that Exact obtained FDA approval for?

A. Yes, it was.

Q. Can you walk me through at a high level the process of getting FDA approval for Cologuard?

A. We ran a 10,000-patient study where every patient got a colonoscopy, got a Cologuard test, and also got a fecal immunochemical test, what's called an FIT test.

So the two tests that were used prior to Cologuard mainly were colonoscopy and the FIT test. And we were comparing against colonoscopy as a gold standard, so that was considered truth, and the -- and we were also comparing against the FIT test as a

comparator test.

With that 10,000-patient study we were able to demonstrate the accuracy of Cologuard and the relative accuracy of the FIT test.

We submit all of that data to the FDA -- so the study took over two years. There was about a year submission process leading up to approval, so altogether -- we started the process in 2009 of developing a test, and in 2014 we received FDA approval.

Q. And as part of that process, did Exact have to provide the FDA information on Cologuard?

A. Extensive information.

So if you took all the binders of data that we supplied to the FDA, you could stack them from the floor to the ceiling twice. And then we had to provide multiple sets, so there was actually a very large semi truck which sent documents to the FDA, so it was extensive documentation.

Q. And did Cologuard -- or did Exact need to provide any information about Cologuard's suppliers?

A. Yes.

Our suppliers are critical to the process and are -- the key suppliers are inspected by the FDA to help ensure that the quality measures are put into

place and being followed prior to FDA approval and since FDA approval.

So the people at the FDA are tasked with a really important goal of safety and efficacy, and the quality of a product is part of that and the suppliers are an absolutely critical part of that quality assurance.

Q. And why did Exact decide to obtain FDA approval for Cologuard?

A. As a screening test, it's -- it's -- it's essential.

First of all, the FDA requires it.

Second of all, the -- Medicare will not pay for a test that is not FDA-approved.

Physicians want to know that a test has been proven to be safe and effective in the population that they're going to use it, and they want to understand the data, the performance data, of a test, so we never seriously thought about bringing the test to market through what's called a lab-developed test process without FDA approval. It was all about FDA approval, Medicare coverage, private insurance coverage. Those were the goals.

Q. And during this process, did Exact work with any consultants to facilitate the FDA approval?

A. Yes. Many consultants. Biostatisticians, regulatory consultants, so people who know that FDA process extremely well, people who helped us set up the quality systems, et cetera.

Q. And why did Exact decide to use consultants in order to help with the FDA process?

A. There are people who are expert in working with the FDA, in helping to design studies. It's very hard to do that just internally. There -- so you want to rely on the expertise of people.

For example, our biostatistician was somebody who had been in front of 50 FDA panel meetings. And we have never been in front of a panel meeting, so getting that type of input and support and help is just critical to having a smooth working relationship with FDA.

Q. And did use of these consultants accelerate the Cologuard FDA approval process?

A. They not only accelerated it, they helped enable it.

Q. And I believe you earlier mentioned that Exact has purchased a company called Thrive. Did I get that right?

A. Yes.

Q. When did Exact purchase Thrive?

A. We purchased Thrive -- I think the deal was announced in -- I should know this -- October of 2020. Late last year. And then it actually closed -- it would have closed at the beginning of 2021 after regulatory approvals.

Q. And prior to Exact's acquisition of Thrive, did Exact invest in Thrive?

A. So we invested in Thrive a year, year and a half before we announced the acquisition of Thrive. We invested $1 million. And then in June of 2020 we invested I believe around $5 million.

Q. And in June of 2020, after that second investment, was Exact considering getting -- deepening its relationship with Thrive?

A. Yes.

We were impressed with the work that they had done over the course of that time period. We were very impressed with their team and their science. They were people that we felt we could work with over the long term.

And so we were getting to know each other. We met periodically with the leadership of the company, and we were impressed, so we wanted to deepen that relationship. We didn't know what it would lead to at the time, and -- but eventually it led to an acquisition.

Q. But you started that process -- when did you start that process of deepening the relationship with Thrive?

A. Well, it really started from the time we made the million-dollar investment, and then periodically I would meet with their CEO every few months. We would talk to them. Our scientists would talk with their scientists. And then over time it just gradually, those interactions became more frequent.

Q. And when did Exact decide to purchase Thrive?

A. There was negotiation that occurred in September -- well, let me take a step back.

It -- we -- the decision to acquire Thrive occurred in a relatively short period of time in the September-October time frame of last year, in part because Thrive had to make a decision about whether they were going to go public or -- or be acquired.

And we felt that a combined approach using our technology and their technology would create the very best multicancer screening test. And we felt that the time to work on that was sooner rather than later so that we could bring that test to the most people possible as soon as possible.

So it was driven in large part by their decision to have to go raise a lot of money, increase

their valuation, and then be more difficult to join forces with going forward, and so it was in that September-October time frame, to make it short.

Q. And did Exact's acquisition of Thrive advance its mission, which I believe you earlier described as to eradicate cancer and the suffering it causes through the early detection of cancer?

A. Yeah. We believe that it will.

Q. And do you know Dr. Lengauer?

A. I do.

Q. Where does Dr. Lengauer work?

A. He splits his time between Exact Sciences and a venture capital firm and other projects.

Q. And what work does he do at Exact Sciences?

A. His focus is on the scientific advancement of CancerSEEK, and he is deeply involved in that development process.

Q. Was he involved in CancerSEEK's prior clinical testing?

A. Yes.

Q. And is he familiar with technical specifications of the CancerSEEK test?

A. Intimately.

Q. And do you consult with him when you have questions about CancerSEEK technical specifications?

A. Yes. Among other people, yes.

Q. And overall, what is your opinion of Dr. Lengauer?

A. He's brilliant. He's a wonderful colleague. He is tireless and he's committed to the cause, so it's a joy to work with Christoph.

MS. MUSSER: All right.

And Judge Chappell, that concludes the public part of my examination.

JUDGE CHAPPELL: All right.

Mr. Marriott, would you like to do your public cross at this time or hold it?

MR. MARRIOTT: Your Honor, I think -- I think it would make the most sense to hold it, if that's okay.

JUDGE CHAPPELL: All right.

So, Ms. Musser, you're requesting in camera?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right.

At this time we're going to go into an in camera session.

The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back to public session.

I need the lead or questioning counsel for each party to view the list of participants on the Zoom

screen and verify that there are no participants in the courtroom who should not be there.

If there is anyone who should not be there, they should -- you are to instruct them to use the Raise Your Hand function on the Zoom screen, and OpenExchange will move them into a waiting room.

Go ahead.

MS. MUSSER: Your Honor, other than the individuals already raising their hand, I don't see anyone else.

JADA: Hello, everyone that's raised their hand -- oh, we've got one more. Just a moment.

MR. MARRIOTT: Your Honor, it looks to me like there may be a person still on from GRAIL, Marissa Song.

THE WITNESS: Your Honor, may I take a two-minute break? I just need to fix a contact.

JUDGE CHAPPELL: Go ahead while we're wrapping up the in camera situation. Go ahead.

JADA: All right. Everyone has been moved and confirmed.

JUDGE CHAPPELL: Thank you, Jada.

(Whereupon, the proceedings were held in in camera session.)

(The following proceedings were held in in camera session.)

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(End of in camera session.)
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(The following proceedings continued in public session.)

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(Pause in the proceedings.)

JUDGE CHAPPELL: All right, thank you.

Proceed now with the public version of your cross exam.

MR. MARRIOTT: Thank you, Your Honor.

CROSS EXAMINATION (cont.)

BY MR. MARRIOTT:

Q. Mr. Conroy, I would like to talk to you about some of the clinical studies concerning CancerSEEK. There are two published studies concerning CancerSEEK, right?

A. Yes, I believe so.

Q. And the first study involving CancerSEEK was published in the journal Science in 2018. Is that right?

A. I -- I don't remember the journal, but if you show it to me, I will be able to tell you whether that's the one.

Q. Okay. And you recall that first study was referred to as the Cohen study. Does that help?

A. Yes.

Q. Why don't we take a look at RX 3142 in

evidence. This is the Cohen study. Do you see that, Mr. Conroy?

A. I do.

Q. So the title of this study is "Detection and localization of surgically resectable cancers with a multi-analyte blood test."

Do you see that?

A. Yes.

Q. And Joshua D. Cohen is listed among many authors, right?

A. Yes.

Q. Now, the Cohen study applied CancerSEEK to 100 -- to 1005 patients, correct?

A. That's what this paragraph says.

Q. And all of those patients had nonmetastatic clinically detected cancers. True?

A. I don't know.

Q. Do you see here in the paper itself that it says that those 1005 patients had "nonmetastatic clinically detected cancers"?

A. I do see that, yes.

Q. And you recall that this study evaluated eight different types of cancer, right?

A. You may want to -- I just want to be careful. Do you want to ask me whether I read this study in

detail? I just don't want to -- us to have this back-and-forth.

Q. You recognize the Cohen study as one of the first -- in fact, the first published study on the CancerSEEK test, right?

A. Yes.

Q. And you recognize this exhibit, RX 3142, in evidence, as that study, right?

A. I recognize the -- this, yes.

Q. Okay. And you don't have any reason to dispute, do you, sir, that this study focused on eight cancer types?

A. No.

MS. MUSSER: Objection. Foundation.

JUDGE CHAPPELL: Response?

MR. MARRIOTT: Your Honor, I think the witness already answered the question and said no, and it is the first published study on a -- on a CancerSEEK test about which we have now had hours of testimony.

JUDGE CHAPPELL: I'll allow the answer.

Go ahead.

BY MR. MARRIOTT:

Q. And those specific cancer types -- withdrawn.

So the -- the Cohen -- the Cohen study, Mr. Conroy, looked at eight cancer types: ovary,

liver, stomach, pancreas, esophagus, colorectal, lung, and breast. Do you see that?

A. I do see that.

Q. And to the best of your knowledge, it didn't look at any other cancer. True?

A. I guess so. I remembered it also looking at prostate, so I am questioning my own memory here. It is three years ago, but I'll take it for what it says here. I'm sure this is accurate.

Q. Okay. I want to ask you -- we talked a little bit in an earlier session about the concept of specificity and sensitivity. Do you remember that discussion?

A. Yes.

Q. And the Cohen study found with respect to CancerSEEK the following: It said that the median sensitivities of CancerSEEK among the eight cancer types evaluated was 70 percent, and it ranged from 98 percent in ovarian cancers to 33 percent in breast cancers, right?

A. Yes. That's what this paper says.

Q. And it -- and at that sensitivity, the specificity was greater than 99 percent. Do you see that?

A. I do see that, yes.

Q. The researchers on this test concerning CancerSEEK could not be certain that the few false-positive testing individuals identified among the healthy cohort did not actually have an as-yet undetected cancer. True?

A. That's what this says.

Q. And one of the most important attributes of a screening test is the ability to detect cancers at relatively early stages, right?

A. I agree with that statement, yes.

Q. And you would further agree, would you not, that the median sensitivity of CancerSEEK among the eight cancer types evaluated was 70 percent?

A. In this study, yes.

Q. And the Cohen study, it had several limitations. Is that fair to say?

A. I think that is fair to say.

Q. And, in fact, they're acknowledged by the authors, that the patient cohort in the study was comprised of individuals with known cancers, most diagnosed on the basis of symptoms of disease. Fair to say?

A. Yes. That's a limitation.

Q. Okay. And moreover, most individuals in a true screening setting would have less advanced disease,

right?

A. Yes.

Q. And another limitation here was that the study's controls were limited to healthy individuals, right?

A. Well, that's what this says. You know, I'm not an expert on the actual study.

Q. Okay. But you understand that a true cancer screening -- that in a true cancer screening setting, some individuals might have inflammatory or other diseases which could result in a greater proportion of false-positive results than observed in the study, right?

A. I -- I agree with that statement, yes.

Q. And in the Cohen study, the researchers were not able to use a completely independent set of cases for testing. True?

A. That appears to be true, yes.

Q. And the proportion of cancers of each type in the cohort was not representative of those in the United States as a whole. Fair to say?

A. That's usually the case with case-control studies, and it appears to be the case here.

Q. And when weighted for the actual incidence in the United States, the researchers here estimated that

the sensitivity of CancerSEEK was 55 percent among all eight cancer types, right?

A. That's what they said, yes.

Q. Okay, thank you. We can bring that down.

I want to ask you now about the DETECT-A study. I'll show you RX 3419 in evidence. Do you see this, Mr. Conroy?

A. Yes.

Q. And the title of this study is, "Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention."

Do you see that?

A. Yes.

Q. And do you recall that this study was also published in Science Magazine?

A. Yes.

Q. And it was published in July of 2020. Does that sound right?

A. Yes.

Q. So the -- this is referred to sometimes as the Lennon study. Does that sound familiar?

A. Um-hum.

Q. Or the DETECT-A study. DETECT-A was an exploratory prospective interventional study, correct?

A. Correct.

Q. And DETECT-A enrolled only women to attend to ovarian cancer. True?

A. Yes.

Q. And the DETECT-A study used a three-step testing process. Sound right?

A. Yes.

Q. And that process was a baseline blood test and a confirmation blood test and then imaging using a PET-CT scan. True?

A. Yes.

Q. And the baseline test, that represented an early version of CancerSEEK, right?

A. That is correct.

Q. And the confirmation blood test was given to participants that scored positive on the baseline test, right?

A. Correct.

Q. And then diagnostic PET-CT imaging was used to confirm the results of blood testing and to localize the potential cancer, right?

A. Yes.

Q. Now, of the 10,006 participants who enrolled in this study, 9 -- 9000 -- 9911 were actually tested, right?

A. Yes.

Q. And of the 9911 participants, 490 scored positive in the baseline test compared to the blood test. True?

A. Yes.

Q. And of those, 134 tests were confirmed in a confirmation test component. True?

A. Yes.

Q. And of those 134 participants with positive blood testing, 127 were evaluated by imaging, right?

A. Yes.

Q. And 64 of those 127 participants had imaging results that were concerning for cancer. True?

A. Yes.

Q. And then of those 64 patients, 26 were subsequently found to have cancer, right?

A. Correct.

Q. So the baseline blood test and confirmatory blood test missed 70 people with cancer, right?

A. Where does it say that?

Q. Well, is that true, sir, that the baseline blood test and confirmatory test missed 70 people with cancer?

A. I don't know.

Q. Why don't we look at page 1, the third column. Do you see where it says, "Of the 96 cancers incident

during the study period, only 26 were first detected by blood testing"?

Do you see that?

A. Yes.

Q. And that means that the baseline blood test and confirmatory blood test missed 70 people with cancer, right?

A. Yes.

Q. So the DETECT-A blood test identified only ten cancers, right?

A. Ten types of cancers? Is that --

Q. Ten types of -- yes, and thank you for that clarification. Ten types of cancers.

A. Yes.

Q. And those ten types -- as a matter of fact, why don't we look at Figure A, which is on page 9 of the report. The ten types of cancer identified were appendix, breast, carcinoma, unknown primary origin, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine, right?

A. Yes.

Q. And some of the patients were found to have cancers not detected by the baseline blood test. True?

A. Yes.

Q. And, in fact, cancer didn't -- CancerSEEK did

not detect six cancers by the baseline blood test: bile duct, bladder, liver, pancreas, sarcoma, and stomach, right?

A. Correct.

Q. Now, Mr. Conroy, the investigators here stated that a source of potential harm associated with the DETECT-A protocol was the radiation exposure from diagnostic PET-CT scan, right?

A. Correct.

Q. And the diagnostic PET-CT confers a higher radiation exposure than a standard CT. True?

A. Marginally, yes.

Q. And the study stated, in fact, that diagnostic PET-CT is not well suited to be a primary screening modality for the general population. Fair to say?

A. I agree with that, yes.

Q. And that's in part because of low disease prevalence and a relatively high rate of incidental findings in that setting, right?

A. I want to make sure I understand your question. As a primary screening modality, yes. As a reflex to a positive screening test, I -- no.

Q. And the reason it's not well suited to be a primary screening modality is in part because of the low disease prevalence and a relatively high rate of

incidental findings in that setting, right?

A. Well, in addition to just doing a PET-CT on the whole -- all adults over the -- a certain age, 100 million people, is financially and operationally impractical.

Q. Okay. So there were also some limitations on the DETECT-A study, right?

A. Yes.

Q. And one of them was that the analysis only considered the initial followup after the baseline test. True?

A. Yes.

Q. And the researchers observed that the longer followup will undoubtedly reveal more undetected cancers, thereby increasing the number of false-negatives, right?

A. Yes.

Q. And another limitation of the study was that not all enrolled individuals completed the prescribed course. True?

A. Yes.

Q. And, finally, the -- the study only included women and certain races and ethnicities, right?

A. Yes.

Q. So in a single clinical trial, CancerSEEK has

not found more than ten different types of cancer. True?

A. That I don't believe is true.

Q. Okay. Well, in clinical trials, CancerSEEK has never identified bone cancer, bladder cancer, cervix cancer, head and neck cancer, or leukemia, correct?

A. I -- I don't know whether that's true or not. It depends on your definition of "clinical trial." So the answer is I don't know.

Q. Okay. So besides the Galleri test, Mr. Conroy, no other multicancer test is yet on the market. True?

A. What do you mean by "multicancer test"?

Q. No other multicancer screening test for asymptomatic patients is on the market, right?

A. Based on DNA? I don't believe so.

Q. Okay. And the success of the various early cancer screening tests in development, that's going to depend significantly on various scientific and regulatory variables. Is that fair?

A. The long-term success? Yes, on a whole host of variables, correct.

Q. Yeah. And each one of those variables -- each one of those -- withdrawn.

Each one of those tests in development, they could vary from one another, correct?

A. They -- yes, correct.

Q. They can -- they can be different based on type of cancer, right, that they detect?

A. Yes.

Q. And they can be different based upon the technologies that they use, right?

A. Yes.

Q. And these multicancer screening tests in development may end up having different sensitivities and specificities. True?

A. Yes.

Q. And different uses, right?

A. Yes, potentially.

Q. And some may be covered by payers and some may not be covered by payers, right?

A. Yes.

Q. And you can't say, as you sit here today, with any certainty which of the tests in development will actually come to market and be commercially successful, right?

A. Correct.

Q. Now, I think you -- excuse me, I'm just trying to make sure I can ask this question in a way that respects the public forum in which we are.

Now, you would agree with me, would you not,

sir, that CancerSEEK and Galleri may well turn out to be complements for one another? Isn't that right?

A. I'm not sure how. Maybe you could explain.

Q. Well, some -- some patients could benefit from taking both tests if and when both tests are available on the market. Isn't that right?

A. I am -- I am a little bit at a loss here as to how.

Q. All right. I'll withdraw the question, Mr. Conroy.

Let's see if we can agree on a few things. Developing a new and improved cancer test is a speculative and risky endeavor, right?

A. No.

Q. Okay. You're sure about that?

A. Well, it's -- I'm answering the question as you posed it, and that's all I'm supposed to do. So if you -- it is risky. In terms of speculative, I would say we work awfully hard to understand and narrow those risks, but, yes, there are risks, and you can't eliminate them.

Q. Okay. So --

A. So speculative and risky, I would say risky, absolutely, yes.

Q. Okay. But you wouldn't agree that developing a

new or improved cancer test is a speculative and risky endeavor?

A. It -- it's risky is the way I would describe it. Speculative to me implies something different.

Q. Would you agree with me, sir, that candidate products that may initially show promise may fail to achieve the desired results in large clinical trials?

A. Yes.

Q. And would you agree with me that they may not achieve acceptable levels of accuracy?

A. Yes.

Q. And would you agree that results from early studies or trials are not necessarily predictive of future clinical trial results?

A. Yes.

Q. Let's take a look, if we could -- your company is a public company, right?

A. Yes.

Q. So you make periodic statements to shareholders about the operation of the business. True?

A. Yes.

Q. And you make every effort to be truthful and accurate in those -- in those statements to your shareholders, right?

A. Yes.

Q. They count on you for that, right?
A. Yes.
Q. Okay. Let's take a look at Exact Sciences' 10-K dated 12/31/2020. Do you recognize this document, Mr. Conroy?
MS. MUSSER: Mr. Marriott, is this PX or RX?
MR. MARRIOTT: I apologize. It is -- this is RX 3197 in evidence.
MS. MUSSER: Thank you.
THE WITNESS: Where is the date on this?
BY MR. MARRIOTT:
Q. Well, that's a good question. We'll see if we can highlight it for you.
A. Oh, it looks like June 30, 2020. Yes.
Q. Okay. So why don't we take a look, if we could, at page 49. You signed this document, right, sir?
A. I did.
Q. Okay. Take a look --
JUDGE CHAPPELL: Can you please magnify that or do I need to grab a magnifying glass?
MR. MARRIOTT: Your Honor, I apologize. We will magnify that.
BY MR. MARRIOTT:
Q. All right. Do you see, sir, where it says,

"Developing new or improved cancer tests is a speculative and risky endeavor"?

A. Yes, I do.

Q. That's what you told your shareholders, right?

A. That's what was in the 10-K, yes. Our lawyers wrote this.

Q. Well, your lawyers are truthful and accurate in their statements, are they not?

A. Yes.

Q. And that's a truthful and accurate statement. True?

A. I've already answered that. I believe it's a risky endeavor. In terms of speculative, I -- I've already answered that.

Q. Okay. So you think this portion of your 10-K was incorrect, correct?

A. I probably wouldn't have written it the same way. I think the impact is minimal.

Q. Okay. We can take that down.

Would you agree with me, Mr. Conroy, that any cancer screening test will need to demonstrate in clinical studies a high level of accuracy?

A. What do you -- are you referring to sensitivity or specificity?

Q. I'm referring to accuracy.

Would you agree with me that any cancer screening test will have to demonstrate in clinical studies a high degree of accuracy?

A. Mr. Marriott, in clinical diagnostics, we don't use the term "accuracy." We refer to sensitivity, specificity, PPD and NPD. And so I don't -- I just don't understand the meaning behind that word in the -- as it relates to a clinical diagnostic test.

Q. Okay.

A. We can't put a number behind accuracy, but we can put a number behind sensitivity, specificity, negative predictive value, and positive predictive value, and I can give you my opinion on each of those. I have an answer. It's just not the one that you -- for the question you've asked, so...

Q. Why don't we take a look at your 10-K again.

A. Yes.

Q. Can we have page 49, please.

Do you see where it says in your 10-K, dated 12/31/2020, "Any cancer screening test we develop will need to demonstrate in clinical studies a high level of accuracy"?

Is that --

A. Yes.

Q. -- what you told your shareholders, Mr. Conroy?

A. That is what's in the 10-K.

Q. And that's what you told your shareholders, right?

A. Yes.

Q. Okay. We can bring that down.

Would you agree with me, sir, that cancer screening tests seek to identify relatively rare occurrences?

A. That's the hope, and the plan is for these tests to be able to detect the aggregate prevalence of cancer at some level of sensitivity and a reasonably high level of specificity.

Q. And if a -- if a -- if a cancer -- withdrawn.

If a clinical study -- if -- I apologize. I had a hard time getting that one out, Mr. Conroy.

If in a clinical study a candidate product fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected. True?

A. Even a small number of cancers may be significantly material? Yeah, that could be true. It depends on how many cancers there are in the prospective study.

If there were two and you missed one, yes, you would miss 50 percent. If there were 2000 and you

missed one rare cancer, it would give you a very small sensitivity hit.

Q. And any cancer diagnostic test will need to address an unmet medical need with accurate performance and utility, right?

A. Generally speaking, yes.

Q. And in developing your test, you may need to explore a number of different biomarker combinations, right?

A. We are, yes.

Q. And you may need to alter, you know, your candidate products and platform technologies accordingly, right?

A. Yes.

Q. And you may need to repeat clinical studies before you identify a potentially successful candidate, right?

A. Yes.

Q. Now, shifting gears a little bit, can we agree, Mr. Conroy, that product development is expensive and may take years to complete and can have uncertain outcomes?

A. We can definitely agree on that.

Q. And we can further agree, I hope, that failure can occur at any stage of development, right, sir?

A. Yes.

Q. And even -- and if, after development, a candidate product appears successful, Exact may need to obtain FDA and other regulatory clearances or approvals before you can market the product, right?

A. You sound a lot like our lawyers. The answer is yes.

Q. That's -- you know, I'll take that as a compliment.

The FDA's clearance or approval pathways, they're likely to involve significant time, right, as well as additional research and development and clinical study expenditures. True?

A. Yes.

Q. And at the end of the day, sir, there can be no guarantee that the FDA would clear or approve any future product or service that you may develop. True?

A. True.

Q. So you mentioned, I think, something about some of these factors earlier. The commercial success of your product, that's going to depend upon a variety of factors, like acceptance in the medical community and patient acceptance and demand, right?

A. Yes.

Q. And it's going to depend upon coverage and

reimbursement by third-party payers. True?

A. Yes.

Q. So is it -- is it accurate to say that healthcare providers may be reluctant to prescribe and patients may be reluctant to complete Exact's tests if they're not confident that patients will be reimbursed for those tests?

A. Yes.

Q. I want to talk to you a little bit, Mr. Conroy, about NGS sequencing, and you talked a little bit about this on the confidential record. I am going to try to do this in a way you're comfortable with on the public record. If not, please let me know.

But you use, at Exact/Thrive, NGS sequencing products, right?

A. No. We use Illumina next-generation sequencing products. You said Thrive.

Q. Yeah, I apologize. Thank you for correcting me on that.

A. See, I'm paying very close attention to you.

Q. Well, I appreciate that. That's what I think everyone expects.

So you talked a little bit about your use of Illumina sequencing products on the closed record. Am I right that you are familiar with the other sequencing

providers that exist in the marketplace?

A. I think any discussion of other next-generation sequencing technology should be in camera, but generally speaking, I am familiar with some of the additional next-generation sequencing products.

Q. Okay. Well, I will -- I will persevere with a few, and if you feel like we need to go in camera, please just raise your hand.

A. Sure.

Q. BGI has an NGS sequencer. True?

A. I believe they do.

Q. And at present, as you understand it, BGI is enjoined from selling in the United States, right?

A. I believe that's accurate.

Q. But BGI would be a replacement for Illumina's NGS sequencing technology if BGI's products were available in the United States. True?

A. I don't know that. Let me ask you, what do you mean by "replacement"? Replacement for CancerSEEK?

MR. MARRIOTT: Your Honor, I think the prudent thing here to do is let me just hold this line of questions so we can go in camera. I tried, but I'm afraid it's going to be hard to do this in a way that is going to make Mr. Conroy feel comfortable.

JUDGE CHAPPELL: You realize we were in camera

before?

MR. MARRIOTT: I do. I had hoped we wouldn't have to -- I will finish the rest of what I have here, but given the answers that I've got here, I think I probably need to go in camera. But I can do it at the end if that's okay.

JUDGE CHAPPELL: It will have to be at the end, but also I'll point out, the witness said he thought questions about sequencers should be in camera, but if he's talking about Illumina, you're Illumina's attorney, you should know that or not, right, what you can get into?

MR. MARRIOTT: Well, I'm not concerned about any of this, Your Honor, I think it is public, but it sounds like the witness has a different view, and I just don't want to run afoul of anyone's claimed confidentiality.

JUDGE CHAPPELL: Mr. Conroy, you understand any concerns regarding to Illumina, this is their attorney. He wouldn't ask if it was their concern. Do you understand that?

THE WITNESS: I do understand that. We are under NDA with a number of other companies, and I just want to be very careful to respect that.

JUDGE CHAPPELL: That's fine. I just wanted to

make sure it went beyond Illumina.

Go ahead.

MR. MARRIOTT: All right. So I will -- in view of that, I will skip that section, and apologies, but I guess we will have to come back to that a little bit later.

BY MR. MARRIOTT:

Q. In any case, Mr. Conroy, I suppose we can agree you are not an expert in sequencing, right?

A. Correct.

Q. You have never been trained on a sequencer?

A. No.

Q. Never used a sequencer?

A. Nope.

Q. Don't know the specs of Illumina's sequencers or anybody else's for that matter, right?

A. Correct.

Q. Okay. So I want to talk to you a little bit about Illumina's open offer. You were asked some questions about that earlier. You're a lawyer, right?

A. Not any longer, I am not. I was trained as a lawyer, correct.

Q. You were trained as a lawyer. You litigated for nine years; you were four years in-house. Correct?

A. Yes.

Q. Okay. No contract's perfect, we can agree on that, can't we?

A. I think we can agree on that.

Q. And no contract can address all potential issues that might eventualize over a long term, right?

A. That's correct.

Q. But that doesn't stop Exact from entering into contracts all the time, right?

A. That's correct.

Q. Now, I think you said earlier that you thought there were some costs associated with enforcing a contract. There are also costs associated with not entering into contracts, right?

A. What do you mean by that?

Q. Well, you view entering into a long-term supply agreement with your suppliers as important to your business. True?

A. Our long-term suppliers are important to our business.

Q. And you'd like to have a long-term supply agreement with Illumina, right?

A. I don't want to talk about this on this record.

Q. Okay. Well, when Illumina and GRAIL -- when Illumina -- when the Illumina/GRAIL transaction was announced, it was your expectation that Exact could

reach a long-term supply agreement that would be in the mutual best interests of both Illumina and Exact, right?

A. Yes.

Q. And you knew Mr. Francis deSouza, the CEO of Illumina at the time, right?

A. Yes.

Q. And you liked him, right?

A. Yeah.

Q. And you met with him on a bunch of different occasions and had a bunch of different conversations with him, right?

A. Several times and several conversations, yes.

Q. And you had what you thought was a good relationship with him that you thought could translate into a productive partnership. True?

A. Yes.

Q. And you still think today it's possible to have a productive partnership with Illumina, right?

A. Theoretically that's possible, yes.

Q. And you have not -- you understand Illumina's made an open offer, right? We've talked a little bit about that.

A. I understand they have made an open offer. I don't remember the two of us talking about the open

offer.

Q. Well, you -- that open offer, that includes a 12-year supply contract for Illumina's current and future sequencing products sold in the United States. You know that much, right?

A. I do, yes.

Q. And that open offer gives Exact -- it would give Exact, if Exact were to enter into it, a unilateral right to terminate the supply relationship with Illumina for any reason. True?

A. I don't know the details to that level of the open offer.

Q. Well, do you know that the open offer includes a guarantee for supply of products?

A. I don't know that -- to that level of specificity.

Q. Do you know that the open offer commits Illumina to providing Exact the same products and support services for purchase to which GRAIL or any other for-profit entity has access?

MS. MUSSER: Objection. Foundation.

MR. MARRIOTT: Your Honor, the question was "do you know."

JUDGE CHAPPELL: I'll allow it.

THE WITNESS: I haven't read the full open

offer. It's only been described to me by counsel.

BY MR. MARRIOTT:

Q. Okay. And do you know whether the open offer commits Illumina to providing Exact access for purchase to any pre-release sequencing product to which GRAIL or any for-profit entity is offered access?

A. I don't know.

Q. Okay. Do you know whether the open offer provides the opportunity for Exact to enter into a separate development agreement on commercially reasonable terms, including the design or modification of any supply product?

A. I don't know.

Q. Do you know whether it prohibits Illumina from discontinuing any supply product so long as Exact continues to purchase that product?

A. I don't know.

Q. Is it true, sir, that the open offer requires that in the event of a supply shortage, Illumina must allocate existing supply in any equitable manner and not favor GRAIL?

A. I don't know.

Q. So you haven't read the open offer, right?

A. That's what I just testified to.

Q. Yes. And so you don't actually know what

Illumina is or isn't offering in the open offer, right?

A. I know aspects of the open offer that my counsel has communicated to me.

JUDGE CHAPPELL: Let's take a short break here, a short break. We'll reconvene at 5:05. We're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: Okay, we're back on the record. Continue.

You are muted, Mr. Marriott.

MR. MARRIOTT: You would think I would get better at this by now. Thank you, Your Honor.

BY MR. MARRIOTT:

Q. Mr. Conroy, before the break --

JUDGE CHAPPELL: Do you see "muted" on your screen when you look at it?

MR. MARRIOTT: I do, Your Honor. It was blocked, so -- I do see it.

JUDGE CHAPPELL: I have a headset, so I have a mute button, and the reason I don't unmute sometimes, when I mute from my headset, I'm muted, but it doesn't show up on my screen.

MR. MARRIOTT: I have had that problem, but this one I just wasn't looking, so I can't use that excuse here, but I do know what you mean.

JUDGE CHAPPELL: Timing-wise, I am hoping that we can finish this witness today?

MR. MARRIOTT: I am absolutely hopeful of that as well, Your Honor.

JUDGE CHAPPELL: Go ahead. I am sure he is, too.

MR. MARRIOTT: We all are, Your Honor. It's been a long day.

BY MR. MARRIOTT:

Q. Before the break we were talking about the open offer, and I understand it sounds like you haven't read it. I want to ask you whether you were aware that the open offer has provisions concerning intellectual property.

A. I assume, as most supply agreements do, that it does. I don't know the substance of that agreement.

Q. Why don't we take a look at it. It's PX 0064 in evidence. I want to point you to Section 9(a), which is, as you can see, titled "Intellectual Property."

Do you see that, Mr. Conroy?

A. I do see that.

Q. And do you see by this provision, the open offer provides a "nonexclusive, nontransferable, personal, non-sublicensable right under Illumina's Core

IP to use the Supplied Products"?

A. I do see that.

Q. And do you have any understanding as to whether the open offer prevents Illumina from ceasing shipment of products for infringement of applications-specific IP?

A. I would have to read that section of the agreement.

Q. Why don't we take a look at that particular provision, which is in 9(b). Do you see here it says, "In no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina"?

A. I do read that, yes.

Q. And that's a -- that's a provision you'd like to have, right?

A. What is the definition of a "Supplied Product"?

Q. Well, without -- without going down what is something of a -- something of a complexity with -- I won't torture us with it at whatever time it is, 5:05, but would you like to have, sir, a right --

A. You're asking me a very specific question about a legal document and expecting me to answer it. I -- I will go back to saying that these are matters that our

lawyers look into, negotiate. If you want me to opine on particular provisions, I -- my only response would be I would have to ask our counsel.

Q. Okay. Exact/Thrive does not have any rights to the GRAIL intellectual property, right?

A. We do not.

Q. You don't have an IP license of any kind from GRAIL. True?

A. Correct.

Q. And as far as you know, Exact/Thrive doesn't have confidential information about Illumina's proprietary products or reagents, right?

A. Not to my knowledge.

Q. And Exact/Thrive has never had -- you can take that down, Mike.

Exact/Thrive has never had any expectation that it would be given access to GRAIL's IP as a mechanism to develop the CancerSEEK test, right?

A. As a mechanism to develop the CancerSEEK test? No, I don't believe so.

Q. Now, on the open offer, sir, you do understand that it includes various pricing protections, right?

A. Yes.

Q. And can we agree that Illumina has brought down its prices since 2013?

A. I wasn't a customer in 2013, so I can't answer that with any specific knowledge.

Q. Okay, fair enough.

As part of the transaction here, Illumina has committed not to increase prices on current products for a 12-year term. You understand that, right?

A. What I understand is there's a certain discount for a certain period of time and a further discount at a further period of time down the road.

Q. Why don't we take a look at the open offer in Section 5(c), and I'm asking you specifically now about commitments not to increase price. Do you see under Section 5(c) here, titled, "No Price Increases"?

A. I see that, yes.

Q. And does that -- does that -- is it consistent with your understanding that Illumina has agreed not to increase prices for a 12-year term under the open offer?

A. I think they -- their proposal is to increase prices every year based on inflation, and then to -- but to otherwise structure a discount based on volume and a discount that would further occur at certain volume levels at a future date. That's the -- my understanding of the open offer.

Q. All right. Do you see where it says, "The

inflation-adjusted (based on the Bureau of Labor Statistics Analytical Laboratory Instrument Manufacturing Index) in the Producer Price Index ('PPI') Volume Based Net Price (under Appendix 1) that customer shall have access to each supplied product purchased under this supply agreement over the 12-year term of this supply agreement shall not increase."

Do you see that?

A. I read that as you read it, yes.

Q. And, in fact, as part of the transaction here, Illumina has committed to lower the volume-based net price per gigabase of sequencing 43 percent by 2025. Do you understand that?

A. I'd have to take a look at the price grid.

Q. Well, why don't we take a look at Section 5(d), as in dog, of the agreement. Do you see that highlighted text, sir?

A. I just read it.

Q. Okay. And you understand from having just read it that Illumina has committed to lower the volume-based net price per gigabase of sequencing 43 percent by 2025, right?

A. Yes.

Q. Now, I want to ask you -- I want to ask you a little bit about audit rights, something we talked

about before. You understand that the open offer requires that Illumina submit to an annual compliance audit?

A. I think I've testified now repeatedly that I haven't read the agreement, so I -- I don't know what audit rights exist or don't.

Q. Okay. You're not an expert, in any case, in audit rights, right?

A. I'm experienced in audit rights being in agreements, but I wouldn't describe myself as an expert, no.

Q. And that's because you have a number of agreements in which you include audit rights. Isn't that right?

A. Yes.

Q. Okay. Have you ever done an audit, Mr. Conroy?

A. Have I ever been involved in an audit?

Q. Have you ever done an audit?

A. Personally? I think I have a long time ago.

Q. Now, is it true that Exact/Thrive does not currently share any strategic plans with Illumina?

A. No. No, we don't. Yes, it's true.

Q. No, you don't. And you don't currently share any pricing plans with Illumina. True?

A. That's true.

Q. And you've never tried to purchase data from Illumina, right?

A. I haven't. I don't know if anybody on our team has.

Q. And you have no plans, so far as you know, to purchase any data from Illumina in the future, right?

A. As far as I know, no.

Q. So let me -- let me ask you this, sir. Under current law, you're not allowed to offer a lab -- you are allowed, rather -- let me withdraw that question.

Under current law, you are allowed to offer a lab-developed test without FDA approval, right?

A. Yes, in certain situations. You can't just offer it. It's not that simple, but there is a path towards making a lab-developed test available, yes.

Q. But from a practical perspective, getting paid under Medicare without FDA approval would be impossible, right?

A. For a screening test that -- as we understand CMS to interpret CMS rules, regulations, and the underlying statute, correct.

Q. And getting paid by commercial payers without FDA approval would be improbable, right?

A. Broadly speaking, correct.

Q. And it would, in fact, be very challenging for

an MCED test to become viable long-term if it were ineligible for Medicare reimbursement, correct?

A. It would be viable only as a niche product because most individuals are not willing to pay for things out of pocket in the U.S., so correct.

Q. And reimbursement is going to depend on a lot of factors, right, including the sufficiency of the sensitivity and specificity of the test, right?

A. Yes.

Q. And it will depend on whether the test is reliable, safe, effective, and medically necessary. True?

A. Yes.

Q. Cancer screening is one of the leading causes of death in the United States, right? I'm sorry, bad question. Withdrawn.

Cancer is one of the leading causes of death in the United States, right?

A. Yes. It is the number two cause of death; the number one cause of death for people 85 or under.

Q. And detecting cancer early is, in your judgment, critical, right?

A. Yes.

Q. It can't be overstated, right?

A. Correct.

Q. And we can agree, can we not, that the majority of cancers are discovered too late?

A. Yes.

Q. And finding cancer early is important because by the time symptoms appear, the cancer can have grown and spread, right?

A. Correct.

Q. So screening cancer can find evidence of disease early when cancer is asymptomatic. True?

A. Yes.

Q. And that can change everything if you find it early, right?

A. Yes.

Q. Now, by detecting cancer earlier, surgical costs are lower. True?

A. Typically, yes.

Q. And treatment costs are lower, right?

A. Yes.

Q. And the odds of survival increase significantly, right?

A. Yes.

Q. Is it also right, Mr. Conroy, that the current cancer screening options are limited?

A. Yes.

Q. And USPSTF, which we've talked about, only

currently recommends screening for four types of cancer, right?

A. Correct.

Q. And that's lung, breast, colorectal, and cervical. True?

A. Correct.

Q. And the majority of cancers have no screening options at all, right?

A. Correct.

Q. The widespread adoption, sir, of an MCED test, a multicancer early detection test, will save lives. Do you agree with that?

A. I do agree with that.

Q. But the MCED market does not currently exist. True?

MS. MUSSER: Objection. Calls for an expert opinion.

JUDGE CHAPPELL: Respond or rephrase.

MR. MARRIOTT: Your Honor, I think the witness talked at some length about his perception of the supposed market in earlier testimony. I'm not looking for an expert opinion. I'm looking for his knowledge and understanding as the chairman and CEO of Exact/Thrive.

MS. MUSSER: If I may respond, Your Honor?

JUDGE CHAPPELL: Go ahead.

MS. MUSSER: The market in antitrust, of course, has a very precise definition as to what comprises a market, and so to the extent that Mr. Marriott is asking for his opinion of a market definition, we would object as improper expert testimony.

MR. MARRIOTT: And I'm asking in his lay understanding of the term "market" Your Honor.

JUDGE CHAPPELL: That wasn't in the pending question, so you will need to rephrase and give him a little more info on what you're asking.

MR. MARRIOTT: Fair enough. Happy to do that.

BY MR. MARRIOTT:

Q. You would agree, would you not, sir, that the MCED market, as you would use that term as a layperson, does not currently exist, correct?

A. What about the Galleri test which is presently being offered?

Q. I'm afraid you need to answer my question as opposed to ask a question.

A. Well, I believe there is a nascent market that has begun once Galleri became available.

Q. Okay. Can we take a look at your deposition, Mr. Conroy? Page 98, Counsel, lines 18 through 20.

Do you see, sir, where it says:

"QUESTION: Now, that market"-- referring, if you look up, to the MCED market -- "does not exist, correct?

"ANSWER: No."

Did you give that answer to that question, Mr. Conroy?

A. I don't -- I may have. I don't know the timing of this relative to the Galleri launch.

Q. Okay. We can take that down, please.

You don't know -- withdrawn.

The acceleration of any MCED test will save lives. True?

A. The acceleration of any test will save lives. You know, first of all, I -- and I have to answer this because I'm in the public. As a CEO of a company that is regulated by the FDA, one thing we don't do is talk about saving lives as it relates to a specific test, and there are reasons for that.

So because of that, I think I just need to answer -- you need to rephrase the question or I can't answer it, lest I get in trouble with the FDA.

Q. Well, I'm happy to try to rephrase it.

Is it your testimony, sir, that you cannot say whether the accelerated adoption of an MCED test would

save lives?

A. I wouldn't make that claim about our test -- I wouldn't claim that our MCED test would save lives in a public -- making a public claim. Do I -- do I believe that early cancer detection tests would have the net effect of earlier detection and saving lives? Yes, but it's important for me to answer this question this way, which is as a company offering screening tests, we don't make claims that we save lives.

Q. Thank you, Mr. Conroy.

Your Honor, I have nothing further in the public session. I can try to be brief about what I have in the in camera session.

JUDGE CHAPPELL: Any redirect on the public version?

MS. MUSSER: Yes. Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION (cont.)

BY MS. MUSSER:

Q. Do you recall, Mr. Conroy, that Mr. Marriott asked you some questions about the open offer?

A. Yes.

Q. And you testified that you haven't read the open offer. Did I get that right?

A. Correct.

Q. Is the supply agreement that Exact is negotiating with Illumina different than the open offer?

A. We have an NDA in place with Illumina, so I -- I will say yes; however, I just want to request, Your Honor, that any specific questions relating to our negotiations with Illumina be maintained in in camera session.

MS. MUSSER: And, Your Honor, I don't need to go into it any further, so we can stay public if that's okay with --

JUDGE CHAPPELL: All right.

BY MS. MUSSER:

Q. And who on behalf of Exact has been negotiating with Illumina?

A. Our chief financial officer, COO, Jeff Elliott, and Scott Coward, our general counsel.

Q. And is it fair to say that those individuals would be the best persons to ask about the specifics of those negotiations?

A. Yes.

MR. MARRIOTT: Objection. Leading.

JUDGE CHAPPELL: Rephrase.

BY MS. MUSSER:

Q. Who would be the -- yes, Your Honor.

Who would be the best people to ask about the specifics of Exact's negotiation with Illumina?

A. Jeff Elliott and Scott Coward.

Q. And do you recall being asked about the Cohen and DETECT-A studies in your conversations with Mr. Marriott?

A. Yes.

Q. Did the Cohen study use the current version of CancerSEEK when conducting that study?

A. No.

Q. Did the DETECT-A study use the current version of CancerSEEK when detecting -- when conducting that study?

A. No.

Q. And did the Cohen study use the same clinical trial design as the trial design planned for the SOAR study that Exact will be submitting for FDA approval?

A. No.

Q. How is it different?

A. The DETECT-A study studied only women, so that is one example of a difference. It was only in one health system, Geisinger. It was a smaller study. I think those are the -- it studied a different population in that the SOAR study will also study higher risk patient populations rather than average

risk patients.

Q. And do you know if any other company has conducted a prospective interventional design -- case study designed like DETECT-A?

A. I believe that GRAIL is in the process of doing a prospective study in a high-risk population. That hasn't been peer-reviewed yet, but it, as I understand it, is unlike DETECT-A in that it is a more narrow population.

Q. And what type of studies has GRAIL published data on that you're aware of?

A. Case-control studies.

Q. How does that differ from a prospective interventional design like DETECT-A?

A. So --

MR. MARRIOTT: Objection. Foundation. Calls for expert testimony.

MS. MUSSER: Your Honor, may I respond?

JUDGE CHAPPELL: Go ahead.

MS. MUSSER: Mr. Marriott showed Mr. Conroy two different studies throughout the course of his examination, so I'm simply following up on those questions that Mr. Marriott asked, with additional questions as to other related studies.

JUDGE CHAPPELL: Well, I will sustain the part

requiring more of a foundation.

MS. MUSSER: May I proceed, Your Honor?

JUDGE CHAPPELL: Go ahead.

BY MS. MUSSER:

Q. Mr. Conroy, do you know how GRAIL's previous study differs from the DETECT-A study?

A. Yes, I do, and am intimately familiar with case-control studies and prospective studies. It's an integral part of my job and has been for 15 years.

Q. And based on that 15 years of experience, can you explain the difference between a case-control study and a prospective study?

A. Yes. A case-control study is simply a way to describe a study where samples are collected from patients after they've already been diagnosed with disease. Those are the cases.

And the controls are people that are different than those cases. They are people typically without disease and -- or without the same disease that is in the cases, at least.

In case-control studies, sensitivity is significantly -- typically significantly better because the cases that you find are typically later stage, and sensitivity of DNA tests are typically more sensitive for patients with larger, more distributed metastasized

cancer, because there's more that gets into the blood.

Prospective study, conversely, is kind of all-comers. You go to your doctor's office, you sign up for a study, and you get a blood tube drawn before you know whether you have cancer, and then there is some other means of determining whether cancer exists.

For example, in the DETECT-A study, that means of determining whether cancer existed was a PET-CT or a -- 12 months later, did a patient have symptoms leading to a workup leading to a finding of cancer.

Q. Based on your 15 years of experience working with these types of studies, is it fair to compare the sensitivity results of a prospective study as well as a case -- to a case-control study?

A. No, it is not.

Q. Why not?

A. Because case-control studies almost always have higher sensitivities -- and typically slightly better specificities, but especially on the sensitivity side -- in a case-control study than in a prospective study. That's well known and understood.

Q. Can you please pull up RX 3142-4, and if you could zoom in on the second column, starting with, "Last," in the middle of the page.

Mr. Conroy, do you recall being asked about the

first part of this sentence, "Last, the proportion of cancers of each type in our cohort was purposefully not representative of those in the United States"?

A. Yes.

Q. And I don't believe you were asked about the second half of the sentence, but the second half of the sentence goes on, "as a whole because we wanted to evaluate at least 50 examples of each cancer type with the resources available to us."

Why did Exact or Thrive at the time want to evaluate at least 50 examples of each cancer type with the resources available to them? Do you know?

A. Yeah. Well, first of all, I believe this study was done by a group of researchers, including Bert Vogelstein, and Thrive was not the study sponsor. So it was an academic study.

Secondly, they wanted to power the study with a sufficient number of cancers so they could get a reasonable read on the sensitivity for each cancer, and in our field, we tend to look at the number 50 as a -- giving you a reasonably solid statistical view of sensitivity.

And so that's -- that's why there were 50 here or that's why they limited it to cancers where they could go and find 50 patients with those cancers.

MS. MUSSER: I have no further questions in the public portion.

JUDGE CHAPPELL: Anything further?

MR. MARRIOTT: Nothing here, Your Honor, not in the public portion anyway.

JUDGE CHAPPELL: Okay. At this time, we are going to need to go into in camera session to complete the -- before we do that, I want to talk about scheduling while we're on the public record.

Next week we are in court on the 9th and 10th. The following week, we are not in court on the 16th, and I'm waiting to hear from the parties about the 14th and 15th. I'm available if you have witnesses.

We're not in court September 22nd, and I have an update on the last week of September. We're going to be in court on the 30th, no court on the 29th, and on the 28th, that's a Tuesday, we're going to end trial at 3:45 p.m. on the 28th of September.

So just to reiterate, end at 3:45 on the 28th, no trial on the 29th, but we do have trial on the 30th and October 1st.

Any questions?

MR. MARRIOTT: No, Your Honor. Thank you.

MS. MUSSER: No, Your Honor.

JUDGE CHAPPELL: All right.

At this time, we will need to go into in camera session, and for the public who are still on the line, I'm going to recess trial as soon as this witness finishes in in camera, just so you know.

The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back into public session. I need the lead or questioning counsel for each party to view the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there.

If there is anyone not authorized, you are to instruct that person to use the raise hand function on the Zoom screen. Open Exchange will then move that person into a waiting room. Go ahead.

JADA: No one has raised their hand and the public line has been moved.

JUDGE CHAPPELL: Okay. And the public line has been muted?

JADA: That is correct.

JUDGE CHAPPELL: All right. We are in in camera session. I'm sorry, go ahead.

MS. MUSSER: Your Honor, I'm sorry. I see a Martin Yost from GRAIL and a Marcus Curtis from GRAIL, and I apologize if -- I don't know if those two should

be in camera.

MS. RATHBUN: They are both with Latham & Watkins, so they are allowed to be in camera.

JUDGE CHAPPELL: I couldn't understand that.

MS. RATHBUN: They are both with Latham & Watkins, outside counsel for GRAIL, and are allowed to be in the Zoom session.

JUDGE CHAPPELL: All right, thank you.

So we are ready to proceed. We are now in camera.

(Whereupon, the proceedings were held in in camera session.)

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(The following proceedings were held in in camera session.)

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(End of in camera session.)

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(The following proceedings continued in public session.)

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JUDGE CHAPPELL: Mr. Conroy, thank you. You're excused. You may stand down.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: We will reconvene tomorrow at 09:45.

Anything further?

MR. MARRIOTT: Nothing here, Your Honor.

MS. MUSSER: Nothing from Complaint Counsel, Your Honor.

JUDGE CHAPPELL: We are in recess.

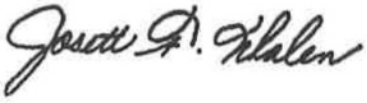
MR. MARRIOTT: Thank you, all.

MS. MUSSER: Thank you.

(Whereupon, at 5:49 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

We, Susanne Bergling and Josett Whalen, do hereby certify that the foregoing proceedings were recorded by us via stenotype and reduced to typewriting under our supervision; that we are neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that we are not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.



JOSETT WHALEN, Court Reporter

SUSANNE BERGLING, Court Reporter

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:	)	
ILLUMINA, INC.,	)	
a corporation,	)	
and	)	Docket No. 9401
GRAIL, INC.,	)	
a corporation,	)	
Respondents.	)	

Virtual Proceeding Via Zoom
September 3, 2021
9:48 a.m.
TRIAL VOLUME 8
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

APPEARANCES:
ON BEHALF OF THE FEDERAL TRADE COMMISSION:

STEPHEN A. MOHR, ESQ.
SUSAN A. MUSSER, ESQ.
DANIEL ZACH, ESQ.
WADE LIPPARD, ESQ.
SARAH WOHL, ESQ.
DYLAN NAEGELE, ESQ.
CATHERINE SANCHEZ, ESQ.
JORDAN ANDREW, ESQ.
STEPHANIE BOVEE, ESQ.
NICOLAS STEBINGER, ESQ.
NICHOLAS WIDNELL, ESQ.
RICARDO WOOLERY, ESQ.
MARIBETH PETRIZZI, ESQ.
BEN LORIGO, ESQ.
WILLIAM COOKE, ESQ.
PETER COLWELL, ESQ.
ERIC D. EDMONDSON, ESQ.
MATTHEW E. JOSEPH, ESQ.
SAM FULLITON, ESQ.
BRIAN O'DEA, ESQ.
LAUREN GASKIN, ESQ.
DAVID GONEN, ESQ.
WELLS HARRELL, ESQ.
BETTY JEAN McNEIL, ESQ.
NANDU MACHIRAJU, ESQ.
JOSEPH NEELY, ESQ.
DAVID VON NIRSHCL, ESQ.
SUSAN HUBER, ESQ.

Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2859
smohr@ftc.gov

APPEARANCES: (continued)

ON BEHALF OF ILLUMINA, INC.:

CHRISTINE A. VARNEY, ESQ.
RICHARD J. STARK, ESQ.
DAVID R. MARRIOTT, ESQ.
J. WESLEY EARNHARDT, ESQ.
SHARONMOYEE GOSWAMI, ESQ.
MICHAEL ZAKEN, ESQ.
JESSE WEISS, ESQ.
MOLLY JAMISON, ESQ.
ALLISON KEMPF, ESQ.
KALANA KARIYAWASAM, ESQ.
BENJAMIN ATLAS, ESQ.
Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019-7475
(212) 474-1000
cvarney@cravath.com

-and-

KARL HUTH, ESQ.

Huth Reynolds LLP
41 Cannon Court
Huntington, New York 11743-2838
(212) 731-9333
huth@huthreynolds.com

APPEARANCES: (continued)

ON BEHALF OF GRAIL, INC.:

MICHAEL G. EGGE, ESQ.
MARGUERITE M. SULLIVAN, ESQ.
ANNA M. RATHBUN, ESQ.
DAVID L. JOHNSON, ESQ.
MARCUS CURTIS, ESQ.
MARILYN GUIRGUIS, ESQ.
SEAN MULLOY, ESQ.
SIMON TROCH, ESQ.
NATHANIEL AMANN, ESQ.
Latham & Watkins LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, D.C. 20004-1304
(202) 637-2200
michael.egge@lw.com

-and-

ALFRED C. PFEIFFER, ESQ.

Latham & Watkins LLP
505 Montgomery Street
Suite 2000
San Francisco, California 94111-6538
(415) 391-0600
al.pfeiffer@lw.com

C O N T E N T S

P R O C E E D I N G S

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JUDGE CHAPPELL: We're back on the record.

Anything before we have the next witness?

MS. MUSSER: Yes, Your Honor. If I may, I just wanted to provide an update on your inquiry yesterday about the scheduling for the 14th and 15th.

JUDGE CHAPPELL: Right.

MS. MUSSER: So I just wanted to inform the court and I informed respondents this morning that complaint counsel does have witnesses that it will be able to call on the 14th. Those will be our final witnesses on the case, so after we complete our examinations that day, we will plan on resting our case, with the exception of the trial depositions that are being scheduled.

So I don't know if we'll have a full day, Your Honor. We'll be able to provide a more fulsome update later, but we would anticipate at least going through the morning.

JUDGE CHAPPELL: Okay. That's tentative based on how we go between now and then.

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: Okay. Thank you.

Anything further?

MR. MARRIOTT: Nothing here, Your Honor.

MS. MUSSER: Nothing from complaint counsel.

JUDGE CHAPPELL: Okay. Call your next witness.

MS. MUSSER: My colleague Nick Widnell will be calling our next witness today. Thank you.

JUDGE CHAPPELL: Thank you.

MR. WIDNELL: May it please the court.

Nicholas Widnell for complaint counsel, Your Honor, and complaint counsel calls Dr. Alexander Aravanis.

- - - - -

Whereupon --

ALEXANDER ARAVANIS

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Proceed when ready.

MR. WIDNELL: My apologies, Your Honor. We have a slight height difference and we're just adjusting the camera a little bit.

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DIRECT EXAMINATION

BY MR. WIDNELL:

Q. Dr. Aravanis, could you please state and spell your full name for the record.

A. Sure. My first name is Alex, A-L-E-X; last name is Aravanis, A-R-A-V-A-N-I-S.

JUDGE CHAPPELL: Is it Alex or Alexander?

THE WITNESS: My full legal name is Alexander.

BY MR. WIDNELL:

Q. And before we start, is there any reason you would be unable to provide complete and accurate testimony today?

A. No.

Q. All right.

Also, just as a preliminary matter, I just want to kind of walk through the testimony you've given in the investigation and in this litigation because I'll be referring to different parts of your testimony, and I just want to make sure we're all on the same page.

Do you recall giving testimony in your personal capacity in an investigational hearing or IH on March 19, 2021?

A. I do, yes.

MR. WIDNELL: And that, Your Honor, is -- that transcript is PX 7065 and has been admitted on JX 2.

BY MR. WIDNELL:

Q. And also during the investigation, do you recall giving testimony on behalf of Illumina pursuant

to rule 2.7 on March 30, 2021?

A. Yes, I do.

MR. WIDNELL: Okay. And Your Honor, that is PX 7073, which is also admitted pursuant to JX 2.

BY MR. WIDNELL:

Q. And then finally, during the actual litigation, do you recall giving testimony on June 25, 2021, both in your personal capacity and as a representative or on behalf of Illumina?

A. Yes, I do.

Q. Okay. And the testimony you gave on behalf of Illumina was pursuant to rule 3.33; correct?

A. Yes, that's correct.

MR. WIDNELL: And Your Honor, that transcript, both the personal testimony and the rule 3.33 testimony, is PX 7104, also on the record pursuant to JX 2.

THE REPORTER: Mr. Widnell, you're going to need to watch with the paper shuffling. It has to be really right near your microphone, so it's interfering with what's being said. Just be careful.

MR. WIDNELL: I will try and at least have a pause while I'm turning pages, which is one thing I can avoid. Otherwise, I'll try not to have any noise.

JUDGE CHAPPELL: It's also a problem if you

turn pages while the witness is answering. If you still want to shuffle pages, you can wear a headset with a microphone.

MR. WIDNELL: Yes, sir. Let me see if I can do this without it interfering, and if it turns out to be a problem, I'll switch to a headphone.

BY MR. WIDNELL:

Q. Dr. Aravanis, you were first employed by Illumina in 2013; correct?

A. Yes. That's right.

Q. And during your first period of employment with Illumina, your title was senior director of research; is that correct?

A. Yes. Yeah, that's right. Uh-huh.

Q. And you were also one of the cofounders of GRAIL; is that correct?

A. Yes.

Q. And as a cofounder of GRAIL, you were involved in the -- in some of the early research and development of technology relevant to GRAIL; is that correct?

A. Yes. That's right. Uh-huh.

Q. And you were involved in preparing the business plan for GRAIL; is that correct?

A. Yes.

Q. And you were also involved in the operational aspects of creating GRAIL as an independent company; is that correct?

A. Yeah. That's right.

Q. And one reason to form GRAIL as an independent company was it -- is that it would allow GRAIL to attract the best talent; is that right?

A. Yeah. There's more to it, but yes, that's correct.

Q. Okay.

And another reason was because GRAIL would have greater speed and agility; right?

A. Yes. For -- for certain aspects of development.

Q. Okay.

And another reason was because of the high investment involved; is that correct?

A. Yes.

Q. And that was because GRAIL could attract outside investors if it was a standalone company; is that right?

A. Yes, that's right.

Q. Okay.

And another reason was that Illumina had a lower risk tolerance than GRAIL as an independent

company might have; is that correct?

A. Yes, that's correct. There's I think a lot of context there, but that's basically correct.

Q. And by creating a standalone company, Illumina gave early notice to Illumina's customers that Illumina intended to participate in the cancer early detection space; is that correct?

A. Yes.

Q. Okay.

And that was important because otherwise Illumina's customers could respond negatively to the discovery that Illumina was launching a clinical product; is that correct?

A. No. I don't think that's correct.

Q. Okay.

Is it the case that the reason that you just agreed to is related to concerns about Illumina competing with customers?

A. No.

Q. Okay. I'm going to show you a document that's marked PX 2007.

And if we could turn to the -- oh, yeah.

So to start out with, Your Honor, this document is submitted pursuant to JX 2 and is Plaintiff's Exhibit PX 2007.

And Dr. Aravanis, if you look at the header of the email, do you see that you're one of the recipients of this email?

A. Yes. I see my name.

Q. All right. Go to -- yeah.

So that email was forwarding a draft presentation that, among other things, has this slide in it.

Do you see the "ScreenCo: Why form a new company?"

A. Yes.

Q. Okay. And ScreenCo was the name that Illumina was using for GRAIL at the time; is that correct?

A. Yeah. Correct.

Q. And if you look on the right-hand side, there's a column that says, "Separate entity help protects Illumina downside."

Do you see that?

A. Uh-huh. Yes.

Q. And then the last entry in that column is "Competing with customers: Reduce tension by giving early notice that we intend to play in this space."

Do you see that?

A. I do.

Q. So at least some people at Illumina involved in

forming GRAIL had a concern about how forming GRAIL could effect concerns by Illumina's customers that Illumina was competing with its customers; is that correct?

A. I don't think so. No.

Q. All right.

A. I'm happy to explain.

Q. Please.

A. Yeah. Since no company was developing cancer screening let alone multicancer early detection at the time, there was no concern of competing with customers.

I think there may have been some concern that maybe initially, you know, a customer might be confused about that, and so it was to -- I believe the notifications were to give them a heads-up and just clarify that this application was completely novel and had no overlap with products that they were developing and commercializing.

Q. And by giving that notice, Illumina would be conveying that there was no cause for concern for customers?

A. I think it was to just clarify that this was a completely novel product in a novel space.

Q. So how did giving that notice help protect

Illumina from a downside? What was the downside that was being protected?

A. I don't know if there was a downside. We just wanted to clarify with customers that, you know, what was -- what GRAIL was going to develop was a completely different product.

Q. So I guess the reason why I used the term "downside" is because that's the header at the top of that column, "Separate entity help protects Illumina downside."

Do you see that?

A. I do, yes.

Q. So do you agree that at least some people involved in forming GRAIL thought there was some kind of downside related to potentially competing with customers?

A. No. I think that -- and I didn't write this slide, but perhaps someone thought a downside -- there would be a downside if there was confusion about what GRAIL was doing, and someone might misinterpret it as competing, but since there was no, you know -- the GRAIL product doesn't compete with anything, you know, in actuality, there is no reason to be concerned.

Q. Okay. Thank you.

And just -- we can take that down.

And just continuing with sort of your career trajectory, around this time you also left to go to GRAIL; is that correct?

A. So I joined GRAIL in 2016.

Q. And your title at GRAIL was chief science officer; is that correct?

A. Eventually I was promoted to chief scientific officer. That wasn't my initial title.

Q. What was your initial title?

A. Vice president of research and development. Uh-huh.

Q. And GRAIL at the time was focused purely on an early detection cancer test; is that correct?

A. Yes. That's right.

Q. And at that time was GRAIL controlled by Illumina?

A. Can you -- could you be clearer what you mean by "controlled."

Q. So did Illumina have the ability to make important decisions for GRAIL?

A. So the -- the board at GRAIL, upon the founding of the company, had I believe more board members that were independent of Illumina than Illumina had, so if that's what you mean by "controlled," then I would say, you know, no.

Q. Did Illumina have the ability to determine what products GRAIL would research?

A. I don't believe so. No.

Q. I'm going to show you a document that is marked PX 2186.

Your Honor, this is a document that is admitted pursuant to JX 2.

And if we could zoom in on the -- so first off, do you see, Dr. Aravanis, the middle email on this document is an email from you?

A. Yes, I see that.

Q. And then can we go to the bottom of the page.

So in that email, you wrote, "Much of the large R&D and infrastructure investment for non-screening applications is the same as screening. Foregoing [sic] the large, early commercial opportunities for all the non-screening indications seems like a bad business move, but if generating revenue is not important early on, I guess it's okay."

What were you saying there?

A. So could I provide some context?

Q. Absolutely.

A. So the company wasn't officially spun off until March of 2016, so this was when -- this was prior to the company being spun off. There were

discussions about -- again, before it was an independent company, about, you know, should it solely focus on screening, should it also consider developing some other products, and so this was a -- you know, a -- you know, an active discussion.

Ultimately, we determined that it made sense for it to completely focus on cancer screening. And that was a decision by GRAIL, you know, not -- not Illumina.

You know, so what you're showing here is part of a larger discussion about should the business -- should GRAIL's business be a hundred percent focused on screening or mostly focused on screening and some other things. You know, ultimately we again came to the conclusion at GRAIL it should be completely screening, and I agreed with that.

Q. Can we go to the second page and actually the bottom section that starts "On February 4, 2016."

Can you read that or would it help for us to blow that up?

Let's just blow up a bit more, actually the rest of the text on that page.

So this is a part of that email chain. This is an email from Rick Klausner.

Was Rick Klausner also a founder of GRAIL?

A. Yes, he was. Uh-huh.

Q. And before that, he was at Illumina and he was the chief medical officer; is that correct?

A. Yes, that's correct.

Q. Okay.

And he is talking to -- about a conversation he had with Jay.

Would Jay be Jay Flatley, the CEO of Illumina?

A. Yes. That's right.

Q. And he says, "I talked to Jay about the question of whether GRAIL has the right under our agreement to commercialize 'liquid biopsy' assays as an LDT. Jay was clear and said 'no'...only screening..."

So is it the case that while in the process of (inaudible due to noise).

So is it the case that while Illumina was creating GRAIL, Illumina and GRAIL entered into an agreement whereby GRAIL could only investigate screening?

A. No. That's not correct.

Q. So just to be clear, you're saying that you are not aware of any agreement between Illumina and GRAIL from this time period that limited the products that GRAIL could research and develop.

A. That's correct.

I don't believe GRAIL ever had a restriction on the products it could research, develop and commercialize. There may have been specific supply agreements with certain terms for only certain, you know -- that could be applied to certain products or not, but there was never, to my knowledge, any actual restriction on what GRAIL could pursue.

Q. And do you have any reason to doubt that Mr. Flatley told Dr. Klausner that GRAIL could only research and develop screening products?

A. So my recollection about the context here is that this was specific to the rights to develop products using a particular supply agreement but not for GRAIL in general.

Q. Okay.

So the supply agreement you're referring to is the supply agreement between GRAIL and Illumina to provide sequencing?

A. Yes.

Q. Okay.

And if we could go up to what's number 4 I think on the...

So the paragraph, do you see it, "If there is only a price advantage for screening, why does Illumina own and control the majority of GRAIL and get a

20 percent royalty?"

A. Yes, I see that.

Q. So at least at this time, what was contemplated was that Illumina would own and control the majority of GRAIL; is that correct?

A. So I don't agree with the word "control" because GRAIL had a -- it was an independent company with an independent board. But I think you are correct that Illumina owned the majority of GRAIL when it was initially spun out.

Q. And just to be clear, this is an email that you actually wrote yourself; is that right?

A. It is, yes.

Q. Okay. Thank you.

I'd like to continue along your career trajectory.

I believe relatively recently you moved to Illumina. Is that correct?

A. Yes. That's right.

Q. So you left GRAIL in around May of 2020; is that right?

A. Yeah. That would be right.

Q. And you started on June 1, 2020 as the chief technology officer at Illumina; yes?

A. Yeah. Uh-huh.

Q. And as chief technology officer, you're part of the executive team at Illumina?

A. I am.

Q. And as chief technology officer, you're familiar with the technical aspects of Illumina's products; is that right?

A. Yes, I am.

Q. And that would include Illumina's sequencer, the NovaSeq sequencer?

A. Yes, it would.

Q. And the NovaSeq is Illumina's sequencer that has the highest throughput; is that correct?

A. Yes. That's right.

Q. At least currently. In terms of what's available on the market today.

And the NovaSeq contains different flow cells; is that right?

A. Yes.

Was the question does the NovaSeq have different flow cells?

Q. Yes.

A. Yes, it does have different flow cells.

Q. And the difference between different flow cells used on the NovaSeq is that they have different outputs; is that right?

A. Yes, that is right.
Q. And the NovaSeq using the S4 flow cell in particular has the highest output; is that right?
A. Yes, that's right.
Q. And flow cells have nanowells on their surface; is that correct?
A. Yes.
Q. And a nanowell is an individual well that is very small, where the sequenced DNA is located; is that right?
A. Yes, that's right.
Q. Okay.
And just to make sure everyone knows, what is sequenced DNA?
A. Did you say "what is sequenced DNA?"
Q. Yes.
A. So it's DNA that's been sequenced. What "sequenced" means is that the individual letters in that DNA molecule have been deciphered or read out.
Q. And what is the significance of having sequenced DNA in a nanowell on the flow cell?
A. Could you be more specific. What do you mean?
Q. I'm hoping for just a brief explanation of exactly what it is or what is the purpose of having DNA sequenced in a nanowell on a flow cell, what's the

practical use of that for the sequencer.

A. Are you asking what the -- what the value is of DNA sequencing?

Q. No. I'm just asking about the mechanism of what -- how sequenced DNA contributes to the mechanism of sequencing.

A. Are you asking how DNA sequencing works?

Q. With respect to particularly sequenced DNA in the nanowell. Yes.

A. Yeah.

So the DNA molecule to be sequenced that's in the nanowell, you know, is -- it's stuck in that nanowell, and then there's a series of chemistries and associated pictures taken that read out the sequence for that sequenced molecule, and so by isolating it in an individual well, that individual molecule sequence can be separately read and recorded.

Q. Okay.

And going back to the S4 flow cell, the S4 flow cell has over ten billion nanowells; is that correct?

A. I think ten billion is the maximum. Yeah.

Q. So do you recall testifying in your deposition that the S4 flow cell has north of ten billion nanowells?

A. I don't recall saying that. If I did, a more accurate statement would have been ten -- ten billion.

Q. Can we pull up that.

So I'm going to show you -- this is from your deposition -- page 121 lines 8 to 19.

So I think in your answer it's apparent that you were saying there are actually slightly more than ten billion nanowells; is that correct?

A. That's what it says here. You know, a more accurate statement would be, you know, ten billion. That would be the correct statement.

Q. So if you look at the paragraph just above the one that's highlighted, "So, you know, order of magnitude, you know, I would say it's ten billion, but there are some additional wells beyond the number that are sequenced," do you see that?

A. Yep.

Q. So it's actually -- the number of nanowells is slightly more than ten billion; is that correct?

A. Yeah. What I was trying to do here -- and I perhaps wasn't clear -- is that, you know, often all of the -- so I think the distinction here is what is the maximum amount of usable nanowells that produce data versus additional nanowells that are just part of the process but, you know, end up -- end up not being

usable, so, you know, it could be the -- so I think the distinction is are you talking about the -- the maximum number of usable wells? That's ten billion.

If you're saying physically are there other nanowells that -- you know, on the surface but that don't produce usable data, indeed there's probably more.

Q. Okay. Thank you. That's helpful.

And going back to the S4 flow cell, the S4 flow cell can generate up to ten billion single-ended reads then; is that right?

A. Yes, that's right.

Q. Okay.

And a NovaSeq can run two S4 flow cells at once; is that right?

A. That's right.

Q. And the run time for a NovaSeq using two S4 flow cells is 44 hours?

A. That sounds right.

Q. So the NovaSeq running two S4 flow cells can generate 20 billion reads in one run; is that right?

A. That's right.

MR. WIDNELL: Your Honor, the remainder of my direct examination covers subject matter that respondents have identified as being proprietary and

competitively sensitive or subject matter discussed in transcripts and documents that have been granted in camera status by the court. Therefore, I request to move in camera before continuing my direct examination.

JUDGE CHAPPELL: If you're well-versed, you can mute when you cough or sneeze.

THE WITNESS: Okay. I'll do my best.

JUDGE CHAPPELL: Thank you.

Mr. Widnell, are you familiar with the last in camera order which was issued in this case?

MR. WIDNELL: Yes, Your Honor. Yes. And --

JUDGE CHAPPELL: You've applied it to your questions regarding that, along with that?

MR. WIDNELL: I have.

Also in conjunction -- well, actually, I should back up.

My -- the last in camera order I'm aware of is for the second motion or -- has there been one that -- more recent than that? I may have missed something this morning or -- or yesterday if something came out then. But otherwise --

JUDGE CHAPPELL: I'm pretty sure one came out this morning on the third motion.

MR. WIDNELL: The third motion? Okay. I have

not actually had a chance to review that.

JUDGE CHAPPELL: This is where we are. And I haven't committed them to memory. The one on Illumina resolved everything except the depos and IHTs. And there's one on GRAIL that will come out soon, and my intent is it will do the same thing, because the requested information for IHTs and depos was still too broad.

So I don't know how much that would affect what you're doing. But the number of documents that have been requested were brought down under a thousand.

MR. WIDNELL: A lot of the reason for lines of questioning being in camera or us making that call is related to the deposition testimony. But I can take a quick look and see -- I could probably --

JUDGE CHAPPELL: Hang on.

Did you say a lot of it is regarding the depo testimony?

MR. WIDNELL: That's right.

JUDGE CHAPPELL: That's unresolved.

MR. WIDNELL: Yes.

JUDGE CHAPPELL: So just so we're clear, the one I issued was Illumina. The one on GRAIL is pending. I think a reply I saw for the first time this

morning, so that one is pending. But the depos/IHTs are still unresolved.

So with that, we will go to in camera session.

The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back to a public session.

I need the lead or questioning counsel for each party to view the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there.

If there is anyone who is not authorized to be in the in camera session, you are to instruct that person to use the Raise Hand function on the Zoom screen.

And I've noticed that a lot of people are hitting the Raise Hand function on their own, which is good.

Once the Raise Hand function is hit, OpenExchange will move that person into a waiting room.

Go ahead.

MR. WIDNELL: Just to be clear, we don't see any issues at this point. Are we all set?

MR. MARRIOTT: Let me -- I think -- if I may, I think the -- since we're talking about Illumina

information, it sounds like the Illumina in-house lawyers I think are fine. It looks to me like there are still some GRAIL in-house lawyers who may need to be removed, Ms. Song and -- and I may be missing others, so perhaps someone from GRAIL could help me, but I certainly recognize Ms. Song's name.

MS. RATHBUN: Ms. Song is the only GRAIL in-house counsel --

THE REPORTER: I'm sorry. We can't hear you. There's too much echoing.

MS. RATHBUN: Sorry. One moment.

JUDGE CHAPPELL: Perfect echo chamber.

MR. MARRIOTT: Well, it's actually amazing, Your Honor, we've had very little of that, so the echo --

JUDGE CHAPPELL: Right. That was classic. That was like yelling from the rim of the Grand Canyon.

MR. MARRIOTT: Liven up our Friday.

(Pause in the proceedings.)

MS. RATHBUN: Hey, Everyone, is that better?

JUDGE CHAPPELL: Much better. Thank you.

MS. RATHBUN: Ms. Song is the only in-house counsel for GRAIL on, so as soon as she's removed we should be all set.

JUDGE CHAPPELL: Okay. Waiting for Jada or Scott to let me know.

SCOTT: The public line has been moved and Marissa has been moved, so if that's all there is, then you should be good to proceed, Your Honor.

JUDGE CHAPPELL: Who's Marissa?

MR. MARRIOTT: That's Ms. Song.

SCOTT: Yeah.

JUDGE CHAPPELL: Oh, okay.

All right. So we're ready?

SCOTT: Yes, Your Honor.

(Whereupon, the proceedings were held in in camera session.)

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(The following proceedings were held in in camera session.)

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(End of in camera session.)

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(The following proceedings continued in public session.)

JADA: All right, Your Honor. It looks like everyone is back connected.

JUDGE CHAPPELL: All right. Go ahead when ready.

MR. MARRIOTT: Okay. Thank you, Your Honor.

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CROSS-EXAMINATION

BY MR. MARRIOTT:

Q. Good morning, I guess still it is, Dr. Aravanis.

A. Yeah. Good morning.

Q. Would you remind us, please, of your current role at Illumina.

A. Yeah. I'm the chief technology officer at Illumina, and I'm responsible for research and product development.

Q. And how would you describe for the court what you do in that role?

A. Yeah.

So I direct the research and product development programs, manage the teams that are developing -- you know, doing the research projects and product development, help develop our strategies in

those areas, and participate as a member of the executive team representing research and development.

Q. So how big is the R&D team today?

A. Approximately 1800 people.

Q. And how long have you been head of R&D at Illumina?

A. About three months.

Q. Is that head of R&D or is that product development?

A. The product development portion. My role expanded about three months ago to include product development. I've been at Illumina and been as the CTO longer than that.

Q. When did you become chief technology officer at Illumina?

A. In June of 2020.

Q. So let's talk a little bit about your educational background if we could.

Do you have an undergraduate degree?

A. Yes, I do.

Q. And what is your undergraduate degree?

A. It's a -- I have a bachelor's of science in electrical engineering, computer science and physics.

Q. And from where did you get that degree?

A. The University of California at Berkeley.

Q. Okay.

Do you have any graduate degrees?

A. I do.

Q. And tell the court if you would, please, what graduate degrees you have.

A. I have a master's of science in electrical engineering, a Ph.D. or a doctorate in electrical engineering, and I also have a medical degree.

Q. And where did you get your master's, your Ph.D. and your M.D.?

A. At Stanford University.

Q. And were you awarded any fellowships?

A. Yes, I was.

Q. And tell us if you would, please, what fellowships were you awarded.

A. I was awarded the National Science Foundation fellowship and the Stanford Graduate fellowship.

Q. Could you give the court an example or two of the research that you've done in neuroscience.

A. Yes.

While at Stanford, I invented a technique called optogenetics. This is a technique that allows the circuits of the brain to be mapped to understand diseases of the brain.

Q. And how about diagnostics? Give us an example

or two of any research you've done in diagnostics.

A. Yeah. I developed an at-home diagnostic for fertility testing and thyroid hormone testing.

Q. Do you have any professional publications?

A. Yes, I do.

Q. And on what subjects have you published?

A. I've published on cancer detection, new methods for DNA sequencing, discoveries in neuroscience. I've published on medical devices, medical diagnostics.

Q. So turning to your professional career before Illumina, would you just list for us -- and then maybe I'll ask you about them -- just list for us the jobs that you had after graduating from Berkeley but before starting at Illumina.

A. Sure.

I've worked at Hewlett-Packard laboratories, Lawrence Berkeley laboratories, Pria Diagnostics, EPOC Biosciences, and Sapphire.

Q. What was Pria Diagnostics?

A. Yeah.

So that was a company developing an at-home diagnostic for fertility testing and thyroid hormone testing.

Q. And what did you do there?

A. Yeah. I oversaw their research and product development.

Q. What's EPOC Biosciences?

A. Yeah. It was a company developing a medical device for use in the intensive care unit to monitor very ill patients.

Q. And what did you do at EPOC?

A. Yeah. I oversaw the research and development of that product.

Q. Okay. And finally, what is Sapphire? Tell us more about that, please.

A. Yeah. Sapphire was a company developing synthetic biology tools. This is a biotechnology that helps discover new genes or genes that could be related to disease or, for example, plant yield.

Q. And what was your role at Sapphire?

A. I was the chief scientific officer.

Q. And how long were you at Sapphire?

A. About five years.

Q. Did you have occasion while you were at Sapphire to use NGS sequencing?

A. I did.

So I -- I used multiple NGS sequencing technologies as part of the research and development.

Q. When did you first join Illumina?

A. In early 2013.

Q. And so tell us how it is that you came to join Illumina in early 2013.

A. Yeah. As a user of Illumina's sequencing technology, I got to know some of the research and development team at Illumina, including the chief technology officer. That relationship led to the offer of a position at Illumina.

Q. And what role did you take upon joining Illumina?

A. I was a scientific -- or a senior director of research.

Q. So give the court if you would a flavor for the duties and responsibilities that you had as senior director of R&D.

A. Yeah.

So I was responsible for directing and managing research projects.

Q. And at the time, what was the size of the R&D organization that you led?

A. About a hundred individuals.

Q. And what technologies were you responsible for or applications?

A. I was responsible for many, developing new sequencing approaches for, you know, therapy selection

in cancer, new approaches for noninvasive prenatal testing.

I also worked on improvements to fundamental sequencing technologies, new sequencing chemistries, new sequencing detection methods, new materials for using sequencing, and also development of software to analyze sequencing data.

Q. Could you give us an example of one of the projects you worked on.

A. Yeah. One project was to develop a comprehensive approach to genomic profiling of cancer or a single assay that could test for all of the major mutations related to therapy selection in cancer.

Q. Did you have any role in the formation of GRAIL by Illumina?

A. Yes, I did.

Q. And what was your role?

A. I was one of the cofounders of the company.

Q. And besides yourself, who else do you identify as a cofounder of GRAIL?

A. Jay Flatley, who was the chairman of the board of Illumina at that time; Rick Klausner, who was the chief medical officer at Illumina at that time; and also Mostafa Ronaghi, who is the chief technology officer at Illumina.

Q. When was GRAIL initially formed?
A. It was initially formed in late 2015.
Q. We'll come back to GRAIL, but did there -- in some more detail, but did there come a time when you left Illumina?
A. Yes.
Q. When was that?
A. That was in March of 2016.
Q. Okay. And what was your reason for leaving Illumina in March of 2016?
A. I left to join GRAIL.
Q. So how long had you been at Illumina when you decided to leave to join GRAIL?
A. Yeah. A little over three years.
Q. And why did you decide after a little over three years at Illumina to leave for GRAIL?
A. The opportunity at GRAIL was an extraordinary professional opportunity, and I also had personal reasons.
Q. So what were the personal reasons why you left Illumina for GRAIL?
A. My father had recently died of cancer, and my mother had been diagnosed with multiple cancers, including a late-stage cancer. I believed at the time that the type of cancer that she had, you know, might

be -- there's a potential to detect it early if we could succeed at GRAIL and so hopefully could help other families in the future not have to deal with a late-stage cancer diagnosis.

Q. What role did you assume upon joining GRAIL?

A. I was the vice president of research and development.

Q. So tell us if you would, please, what were your duties and responsibilities as vice president of R&D at GRAIL.

A. I developed the research and development program at GRAIL, so, you know, all of the research and development activities, experiments.

I also, you know, built and managed and led the research and development team.

Q. And how long did you serve as vice president of R&D at GRAIL?

A. A few years.

Q. Can you give His Honor some examples of the kinds of projects you worked on as VP of R&D at GRAIL?

A. Sure.

So one very important initial research project was to understand the signals in the blood related to cancer, so we started a study to collect the blood from 15,000 individuals with and without cancer and with

different types of cancer so we could understand, you know, in lung cancer, pancreatic cancer, ovarian cancer what the signals looked like in the blood and whether any of these signals might be useful for cancer detection, simultaneously also evaluated many technical approaches for, you know, detecting those variety of signals.

So I was responsible for all of this fundamental research to understand if what GRAIL set out to do, multicancer early detection, would be possible; if so, what signals to use and what technology to use in developing a product.

Q. I think you said you served as VP of R&D for a few years.

What did you do next?

A. I was promoted to chief scientific officer.

Q. And when was that?

A. I don't remember the exact date. It was a few years after we started the company.

Q. What were your duties and responsibilities as chief scientific officer at GRAIL?

A. It included all the duties that I had as vice president of research and development. It expanded to also include the laboratory operations and the clinical development also.

Q. And how long did you serve as chief scientific officer of GRAIL?

A. A few years.

Q. Did there come a time then when you left GRAIL?

A. Yes. I left GRAIL in May of 2020.

Q. And why did you do that?

A. I was offered the position of chief technology officer at Illumina.

Q. Why did you want to come back to Illumina as chief technology officer?

A. Yeah. Again, it was an extraordinary professional opportunity to come back to Illumina and, you know, lead research and technology development for its next wave of sequencing technologies and also the opportunity to potentially create other, you know, important applications like GRAIL was pursuing.

Q. And how would you further characterize for the court your duties and responsibilities now as chief technology officer at Illumina?

A. Yeah. It's a very broad role, to -- to set our -- our overall strategy around technology and new products, to form and manage key research projects, and then to also oversee our product development efforts.

Q. Dr. Aravanis, have you been awarded any patents over the course of your career?

A. Yes, I have.

Q. How many?

A. I don't know the exact number.

Q. Let me see if I can refresh your recollection.

I count -- I've counted more than 20 patents bearing your name in the United States, 40 pending applications in the United States, and a hundred patents or pending applications internationally.

Does that sound roughly right?

A. It does, yeah.

Q. Can you give the court an example or two of the kinds of inventions for which you have received patents either in the U.S. or abroad?

A. Yeah.

I've been an inventor of new approaches to sequencing, new chemistries that can be used for sequencing, new detection methods, new ways of analyzing sequencing.

I've also been an inventor on methods for cancer detection, discoveries of novel signals and uses of those signals to detect cancer.

Q. So we've heard some evidence during the course of this trial about Illumina's business, but I'd like

to ask you if you would, please, describe Illumina from your perspective for the court.

A. Yeah. Illumina develops and commercializes genomics technologies for the purposes of basic research and also clinical applications.

Q. And what is Illumina's mission?

A. Illumina's mission is to unlock power of the genome.

Q. What does that mean exactly?

A. We know that the more information we can get from the genome, particularly the human genome, the more we can understand, you know, how human biology works, how diseases work, how we can detect those diseases earlier and how we can treat those diseases, and so by making the technologies that enable the information the -- the genome to be accessed, at lower cost, with more accuracy, with more speed and in different ways we feel furthers that mission of unlocking the power and ultimately improving human health.

Q. I want to talk to you a little bit about sequencing.

What training and experience do you have in sequencing?

A. Yeah.

So I've used multiple sequencing technologies in research and development at companies, you know, other than Illumina. And at Illumina I've been an inventor of new sequencing technologies and I've overseen the research and development for new sequencing technologies.

Q. Give us a little bit more flavor on the role you've played in developing Illumina sequencing technology.

A. Sure.

So, you know, so I've been involved in everything from developing a long-term technology roadmap for the types of innovations that might be possible in new chemistries, new detection methods, new materials, setting up research projects to do the fundamental research to find out what's possible and make those inventions. And then I've been in the process of combining those inventions into new products and then working with and managing teams that are combining these, you know, innovations into new types of sequencers, you know, going through all of the development work to make them into robust products that can also be manufactured.

Q. Can you tell us how many of your patents or pending patent applications relate to sequencing?

A. I don't know the exact number. It's a -- it's many of them.

Q. So by way of background here, what I'd like to do, with His Honor's permission, is to have you tell us a little bit more about sequencing in some detail. And I want to begin by laying the groundwork for that by having you explain to us for the record some concepts like DNA and genes and the genome.

And to be clear here, I'm not asking for your opinions, Doctor. I'm asking for your personal knowledge based upon experience.

And maybe we can bring up RDX 6 at 2.

And I'm going to have a series -- I have a series of -- now I'm hearing an echo, Your Honor.

Okay. It seems to be gone.

I'm going to have a series of demonstratives here. These are just demonstratives, not being offered into evidence.

But referring to RDX 6 at 2, tell us what DNA is.

A. Yeah.

DNA is a biological molecule. You could think of it as a very long, you know, string, for example.

That molecule is very repetitive. It's actually only made of four components, four different

bases, you know, linked up to each other in a long chain with different orders of these four bases.

The four bases are shown here, A, T, C and G. Those are the four letters often referred to the four letters of the DNA code.

DNA also has this property that it's -- you have two strands together, so that's sometimes you hear a double helix. These two strands wind around each other.

The information between the strands is complementary, meaning that if you have one strand, it's always mirrored by its complementary base on the other side.

Q. And where is DNA found?

A. DNA is found in most cells in the human body.

Q. And how many different cell types are there in the human body?

A. Oh, there's hundreds.

Q. How is DNA packaged?

A. Yeah.

So, in cells, DNA is in a subcompartment called the nucleus, so you could think of it as, you know, like a bubble. And the DNA is compacted into that, that nucleus structure within the cell.

Q. What are genes?

A. Yeah.

So genes are the parts of the DNA that are translated into proteins.

Q. And what does a gene do?

A. Yeah.

So, you know, when these -- when these pieces of DNA are translated into proteins, these proteins serve a large number of biological processes.

Some proteins can become things like hemoglobin, which carry oxygen in the blood. They could be enzymes which do metabolism, like break down glucose or sugar.

Some proteins also serve as structure or structural materials. For example, your hair and fingernails are made of proteins.

Q. So we've heard some reference during trial to the concept of the genome.

What is the genome?

A. Yeah.

So the genome is all of the DNA and its functions.

Q. And what percentage of the genome is comprised of genes?

A. Yeah. It's actually only a small fraction of the genome, about 1.5 percent, that is actual genes

that get translated into proteins.

Q. What can you tell us about how one genome compares to another?

A. Yeah.

So between two different human -- sorry. There's some background noise.

Between two different human beings, the vast majority of their genome, you know, or their DNA is identical, 99.5 percent. There's a very small fraction that differs between any two people, about a half percent. However, this half percent is very important because it defines that, you know, each human being is unique, you know, the way they look, affects, you know, their susceptibility to disease.

THE REPORTER: I'm sorry. There is some interference going on.

JUDGE CHAPPELL: Let's take a short break, and everybody check your connections and see if you can figure out where this background noise is coming from.

We'll reconvene at 11:25.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Proceed.

MR. MARRIOTT: Okay. Thank you, Your Honor.

BY MR. MARRIOTT:

Q. So, Dr. Aravanis, give us a sense of the --

THE REPORTER: I'm sorry. There's an echo on your part, Mr. Marriott.

BY MR. MARRIOTT:

Q. Okay. Let me try again.

Doctor, can you give us a sense of the length of the human genome?

A. Sure.

So some -- you know, some examples to give a sense of how long it is physically.

If you were to take all of the DNA in the human body, so all the DNA from each nucleus in every cell, and you were to pull it so that it was -- pull it out taut, and you were to line all those pieces of DNA up, it would be very long, just the DNA from a single human being.

A few examples.

You could actually go to the moon and back 90,000 times.

You could go to the sun and back 225 times.

If you were to spend time reciting each letter in that code at a rate of one per second, you know, around the clock, it would take 13 centuries, so, you know, a very long molecule.

Q. And so with all that background then, Doctor, what is DNA sequencing?

A. Yeah.

So DNA sequencing is a technology to actually read this code out, right, so you have these long molecules of DNA and you have these four bases in different orders. And for a variety of reasons you'd actually like to know what those exact letters are, and so what DNA will do -- DNA sequencing technology will do is actually give you that, that list of letters.

Q. And what's the purpose of sequencing? Why do we do it?

A. There are many, many uses of DNA sequencing. Almost every area of life science or clinical medicine DNA sequencing is used, is used in it. A good application would be in finding the right therapy for a cancer patient.

So you can sequence the DNA from a tumor. And tumors have cancerous cells and those cells have mutations, so by using a DNA sequencer on the DNA from a cancer cell you can see which letters have changed relative to what the letters would normally be. Knowing those changes can tell you which drugs might be most effective for that patient.

Q. All right. So I want to have you tell us a little bit about the Illumina sequencing workflow if you could.

So maybe we can just start by you listing for us the phases of the workflow, and then I'll ask you to tell us about each one in turn.

A. Sure.

So, you know, the first step is to isolate and extract your DNA, so you're not going to find the DNA just as, you know, pure DNA sitting around. You're going to have blood or some other tissue. You need to extract it.

Then you go into something called library preparation, which is taking the DNA and preparing it in special ways, depending on the application, for the -- you know, for the -- for the sequencing.

And then the sequencer will put out sequence data, so, you know, lots of data, and then that DNA has to be analyzed, you know, for the purpose of interest.

Q. All right. So let's take each of those in turn in a little bit more detail.

So what happens and how does it happen in the isolation and extraction phase?

A. Yeah. Let's take a blood sample, for example,

right.

So while a blood sample has DNA in it, it has many other things, all the other components of a cell, proteins and carbohydrates and lipids and, you know, fats, and so on.

So what you do is you have a series of chemical steps. And what the chemical steps do is they remove all of the non-DNA materials from the DNA portions a step at a time, and then you eventually get to something where it's very pure in terms of just the DNA material.

Q. Okay. So what about library prep? What happens in that phase of the workflow?

A. Yeah. You know, and the details of library prep depend on the exact application, but in general, you often want to break the DNA up.

So the DNA may be too long to sequence, so what you would do then is chop it up using either a mechanical method or an enzyme.

Once the DNA is in smaller pieces, you then attach adapters to the DNA, so you have your DNA fragment and you put other little pieces of DNA -- you stick them to either side of the original DNA fragment from the sample. And then that's important in the sequencing step because it helps it stick to the flow

cell, you know, in the sequencer.

There can be other steps in the library preparation. Depending on what application you're doing, you might want to just focus on certain regions of the genome, and there are steps that can do that.

Q. All right. So a person extracts their sample. They isolate it. They do the library prep.

What then do they do with the prepared library during the core sequencing step?

A. Yeah.

So you then input your DNA into a flow cell, which is basically a glass slide. Those adapters stick to the flow cell. You then load it into the sequencer and then, you know, push "Go."

And then what the sequencer does is, through a series of chemistries and pictures it takes, it reads out the actual sequence, the letters for each of the DNA molecules that stuck to the flow cell.

Q. And then what happens following that during the data analysis phase?

A. Yeah.

So the sequencer is going to put out, you know, kind of this generic sequence data. And then that sequence data -- I mean, all it is is just, you know, long strings of letters. You want to make some meaning

of it, depending on the application.

And so the analysis again varies by application, but it will often focus -- it will look for DNA from certain regions of the genome of interest, for example, a gene related to cancer. And then it may do an analysis, again, using the cancer example, of saying, well, are there any changes in the sequence that are different than what you would expect.

And then it might report out and say, hey, in these genes, these changes occurred and it -- you know, in some applications it might even say, you know, here -- you know, there's drugs that can address this type of cancer with this type of mutation.

Q. Do different applications have different workflows?

A. Yes.

So what really defines applications is what's up-front of a sequencer and what's downstream of a sequencer.

The sequencer itself is totally generic. You know, you put DNA in. You get these strings of letters out, you know, the same for all applications, so again kind of a generic sequencing, you know, instrument that doesn't know the application.

And then the -- but, you know, the tailoring,

say, for a cancer application versus a genetic disease testing is really all about the -- how you do the isolation, how you do the library prep, and how you do the analysis.

Q. All right. So which, if any, of these sequencing workflow steps is different from one MCED test to another?

A. Yeah. You know, all of the differences between, you know, different tests would be around the isolation, extraction, library prep and data analysis. The core sequencing steps are the same.

Q. How many different patient samples can be processed at the same time?

A. Yeah. A large number can be processed at the same time, especially on a high-output sequencer. The exact number depends on the application.

So some applications like sequencing a whole genome for a human, you know, that requires a fair bit of sequencing, so, you know, you might be able to do a couple dozen samples on a high-output sequencer.

You know, if it's a test, for example, you know, a carrier screening test, you might not need very much sequencing at all and you could do hundreds or even thousands on a sequencer.

Q. So how is it possible to process multiple

different DNA samples at the same time on the same flow cell?

A. Yeah.

So the way you -- so on the sequencer, the DNA from different samples gets mixed together, so you could imagine, you know, you need a way to know which DNA sequences came from which original sample and which patient. The way you keep track of it is by putting labels on the fragments in the adapter step in the library prep, right.

So patient one might have label A, and so all of the adapters that get, you know, attached to the DNA fragments from patient A's sample have label A, and then you might have -- then you have a different label for patient B.

And that label is tracked within the sequencer, and it's actually part of the sequencing, so when you do the data analysis, even though all the data is mixed together, you can see, you know, for each fragment and the sequence associated with it, oh, this has label A, it must have come from patient A. And then you can group together all the fragments with label A and analyze it to understand, you know, what diagnoses patient A might be in and keep it separate from patients C, D, E and F.

MR. MARRIOTT: So, Your Honor, we have two demonstrative videos we'd like to show, again purely demonstrative, both excerpts given the length of the original videos just too long to be I think of utility. Then we'll ask Dr. Aravanis a few questions about these.

Each of them has some audio. My view is, Your Honor, that there's no need for the court reporter to take down the audio, but of course that's for Your Honor. This is to let the court see the -- a lab with a bunch of sequencers for the first video and second to see the NovaSeq in particular, and then I have some questions for Dr. Aravanis about it.

JUDGE CHAPPELL: How do you plan to submit the demonstrative for the record?

MR. MARRIOTT: We can do as we did in what we provided to complaint counsel, Your Honor, we can simply provide the hard copies. And in the case of the video, we can give the court the file that actually shows the video itself. As I said, they're excerpts of two longer videos that just seemed too long to take the court's time with.

JUDGE CHAPPELL: Josett, do you have a preference?

THE REPORTER: Yes, Your Honor. I usually just

put a blurb saying that the video was played.

JUDGE CHAPPELL: No. I'm fine with that. I mean how it's given to you for the record.

THE REPORTER: What Mr. Marriott suggested is fine.

JUDGE CHAPPELL: Okay.

So the blurb is fine, no need to transcribe.

Go ahead.

MR. MARRIOTT: Thank you, Your Honor.

Why don't we go ahead then and we'll play this first video, which is narrated by Dr. Helen Speirs, who I understand is a genomics deputy director at a university in Australia, so go ahead and play that.

JUDGE CHAPPELL: Do we have the demonstrative number for the record?

MR. MARRIOTT: We do, Your Honor. It is DX 6, and this is slide 11.

JUDGE CHAPPELL: How long is this?

MR. MARRIOTT: RDX 6.

I believe it's about two minutes, Your Honor.

JUDGE CHAPPELL: All right.

(Video played.)

BY MR. MARRIOTT:

Q. All right. Doctor, how does what we saw in that video compare with what's done in cancer

screening?

A. It's very similar.

So, you know, as -- as the narrator was saying, right, the instrument, whether or not you're sequencing a koala or a pine tree or a multicancer early detection sample, is basically the same.

Q. And how does the data that comes out of the sequencing vary from one machine to the next?

A. You know, it depends on the exact sequencer, but very similar. It's just a string of letters.

Q. And where is the MCED -- where in the MCED development -- I'm sorry. Withdrawn.

Where is any IP in MCED development focused in that sequencing workflow?

A. You know, the unique aspects of any given MCED test would be in the up-front workflow, so when she was talking about preparing the DNA, or after -- you know, so that's before the sequencer or after the sequencer when you're, you know, analyzing it.

You know, you know, most people using a sequencer, I don't think they care about what's going on in the sequencer. They have their DNA, they want to put it in, and then they just want to get, you know, the list of letters out the other side.

MR. MARRIOTT: We've heard a lot about the

NovaSeq 6000 during the course of trial. And we have another demonstrative here. This is our last video, Your Honor. And this is also an excerpt from a video available on the Illumina website.

So why don't we play this one. This is a little bit longer. And then we'll ask the doctor some questions about that.

(Video played.)

BY MR. MARRIOTT:

Q. All right. Doctor, does that video --

JUDGE CHAPPELL: First of all, you need to identify that for the record.

MR. MARRIOTT: Thank you, Your Honor.

That's RDX 6 at slide 12.

May I proceed, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. MARRIOTT:

Q. So does the video we just saw, which is at RDX 6 at 12, Doctor, accurately describe the NovaSeq workflow?

A. Yes, it does.

Q. And how does that workflow vary from one Illumina machine to another?

A. It's very similar between different instruments, you know, I mean, slightly different place

you put the containers in, push the button, but very similar.

JUDGE CHAPPELL: I have a question.

If you're running an actual patient sample, is there a contamination factor? Do you worry about needing gloves, masks, dust contamination, things like that?

THE WITNESS: Definitely, Your Honor.

So -- so in a clinical laboratory, the individual would be wearing protective gear like that.

And the other thing I would add is that most of the risk of contamination or infection is upstream when you're dealing with, for example, a blood sample. The process of purifying the DNA removes, you know, most things that could be hazardous or infectious, so by the time you get to the sequencer you've dramatically reduced that, but in a clinical laboratory individuals would be wearing protective gear.

JUDGE CHAPPELL: And once you get to using a sequencer when you get to that step, there's no blood involved, it's only DNA; is that correct?

THE WITNESS: That's correct.

JUDGE CHAPPELL: All right.

BY MR. MARRIOTT:

Q. Is the process any different from one MCED test

to another, the process that we saw described in the video?

A. No. It's the same instrument, same consumable. It's generic.

Q. Let me ask you a few questions about the Human Genome Project, Doctor.

First of all, what is the Human Genome Project?

A. Yeah. The Human Genome Project was a major scientific product -- project to sequence the very first human genome.

Q. And what can you tell us about that effort?

A. Yeah.

So it was a very large effort. You know, it took over 13 years, so it started in the late '80s. It was a global effort, multiple scientific institutions around the world working together. It was very expensive, you know, $2.7 billion, you know, in total. And all of that work for over a decade and multiple billions of dollars across the world culminated in the first -- the first sequence of the human genome, and it was published in 2000.

JUDGE CHAPPELL: How was that funded? Who paid for it?

THE WITNESS: It was -- it was primarily funded by governments around the world.

BY MR. MARRIOTT:

Q. What type of sequencing was used in the Human Genome Project?

A. Yeah. The type of sequencing was first-generation sequencing, so it used a special sequencing chemistry called Sanger sequencing chemistry.

Q. So we've heard in this case about next-generation sequencing.

What is next-generation sequencing?

A. Yeah. Next-generation sequencing is a much higher throughput type of sequencing.

As an example, the first-generation sequencing that was used in the Human Genome Project, you might be able to sequence a hundred molecules on one instrument per run. Next-generation sequencing instruments today can simultaneously sequence millions or even billions of sequences in a single run.

Q. How would you describe the range of applications to which NGS sequencing can be applied?

A. Oh, there's many, many applications for different areas of science and medicine. There's new applications being published almost every day.

Q. And how, if at all, does the sequencing workflow change from one application to the next?

A. The differences again are around where the DNA comes from, how it's prepared, and how it's analyzed. The sequencer is the -- is generic and the same in all of them.

Q. To what extent, if at all, Doctor, are the core sequencing instrument consumables customized from one application to the next?

A. The consumables that are used in a sequencing run, the chemistries and the flow cells are not customized. Those are generic.

Q. And can you tell us whether we've now identified all potential applications for sequencing?

A. Definitely not. As I mentioned, there's, you know, new research and new clinical applications emerging all the time.

Q. How would you characterize the degree to which sequencing is used as a tool for clinical diagnostics?

A. I think we're still in the early days.

So there's some exciting initial applications that are being used, but even in those areas, for example, selecting therapy for cancer patients, you know, most tumors today are not yet sequenced, so I think there's a long way to go to get the full -- you know, for patients to get the full benefit of this technology.

And then there's many new applications emerging, and some of those could be even bigger than the ones we have today, so I would say it's -- we're still early in seeing how this technology can benefit medicine.

Q. Can you describe the different oncology applications for which sequencing is used today.

A. There's many.

So there's a lot of research applications where people sequence cancer cells to understand cancer biology and how cancer is behaving and how you might treat it.

There's also therapy selection applications, so this is where you sequence a tumor to understand whether or not any of the mutations that are present might be targetable by a drug.

There's also an application for monitoring, sometimes called minimal residual disease, where in a cancer patient who's being treated you want to know how effective the treatment is, and looking for cancer signals in the blood can tell you, you know, how effective the treatment might have been.

And then another application is early cancer detection, so in individuals who are asymptomatic and don't have cancer, trying to detect cancer early.

Q. Let's turn a little bit from the science and the technology to the business.

How would you describe Illumina's core business today?

A. Illumina's core business is to constantly innovate, improve sequencing, you know, create new sequencing technologies, develop them and commercialize them so that, you know, these customers who want to do science, who want to do clinical applications are -- have better and better tools to unlock the genome.

Q. How many different kinds of sequencers does Illumina sell?

A. Today I think there's eight different sequencing instruments.

Q. Can you identify for us some of the instruments offered by Illumina?

A. Sure.

Are you going to show a visual? Oh, okay.

Yeah.

So this is the on-market instruments today.

They use very similar chemistries. The main difference is the size of the instrument, how much data it can produce, are the primary differences between these different instruments.

A couple of the instruments are also FDA-cleared.

Q. Just for the record, can you list for us what those instruments are?

A. The FDA-cleared ones?

Q. The eight instruments that appear on RDX 6 at 16.

A. Yeah.

So just listing them, the NovaSeq 6000, the NextSeq 1000/2000, the NextSeq 550, the MiSeq, the MiniSeq, the iSeq 100, the NextSeq 550Dx, and the HiSeqDx.

Q. So we've heard a lot about consumables, Doctor.

What exactly is a consumable?

A. Yeah.

So they're the materials that are actually consumed in a sequencing run, right, so every sequencing run you need a new set of consumables, but you use the same instrument.

An analogy might be like a razor and a razor blade. The -- you know, the razor is the instrument and then, you know, you need a new razor blade every time, you know, you want to do a another sequencing run or another set of consumables.

Q. So referring to RDX 6 at 17, what are we seeing in these images?

A. You're seeing the consumables that are needed in a sequencing run.

So you're seeing liquid reagents, which are the sequencing chemicals. You're seeing buffers which are used to wash, you know, the sequencing instrument between cycles or between runs. And you're also seeing the flow cell, which is where the DNA is actually stuck to.

Q. How many different kinds of consumables does Illumina sell?

A. Yeah. I mean, for each instrument there might be a handful of different consumables.

Q. So we've heard talk of and you just mentioned the flow cell.

What exactly is the flow cell?

A. Yeah.

So the flow cell is where the actual sequencing is done. The flow cell, you know, in a simple way is just a glass slide. It's enclosed so that you can -- you can push or pull through -- fluid through the flow cell over the surface.

You can see here that there's lanes, which are those channels, right, through which the fluid goes

through. The DNA in the first step is stuck, you know, onto the surface of the flow cell.

And they're also importantly transparent, right, so that you can image them during the flow cell -- during the sequencing cycles.

So as it was shown in that first video, you know, there's, you know, millions or billions of DNA molecules stuck to the glass slide, and then you pass the sequencing chemistry through which labels one base at a time. You take an image with a fluorescent microscope, and depending on the color, you can assign a base. And then you do that, you know, over and over.

These flow cells, again, you use them once per run and then they're disposed of.

Q. How have they evolved over time?

A. Yeah. Over time they've gotten larger, so you have more surface area to do more sequencing, and also the density on them, so the number of DNA sequences you can have in a small area, has increased.

Q. All right. Let's shift gears a little and talk about Illumina's competitors.

Does Illumina track other companies offering or seeking to offer NGS sequencing products?

A. Yes, it does.

Q. And do you have personal knowledge of what NGS sequencer -- sequencers other companies are offering?

A. Yes, I do.

Q. What other companies make NGS sequencers today?

A. Yeah. There's numerous.

Some of them would include BGI MGI. It's a Chinese manufacturer of NGS sequencing technologies.

Thermo Fisher makes an NGS sequencing product.

Oxford Nanopore makes an NGS sequencing product.

Pacific Biosciences makes an NGS sequencing product.

And so does a company called Genapsys.

Q. And what, if any, companies have NGS sequencers in development, to your knowledge?

A. So I believe there's a couple dozen companies that are developing NGS sequencing instruments.

Q. Let me ask you a little bit more about some of the companies you specifically identified.

What sequencing products does Thermo Fisher manufacture?

A. Yeah.

So Thermo Fisher makes an instrument called Ion Torrent. I think there's a few different

instruments. It's an NGS sequencing platform.

Q. And how does Thermo's NGS offering compare to Illumina's?

A. Yeah.

So the -- the type of data it can -- it generates can be used as an alternative for many Illumina applications. It uses a different type of sequencing chemistry and a different detection mechanism than Illumina, but it produces similar types of sequence data.

Q. Now, I believe --

MR. WIDNELL: Objection. Foundation.

Your Honor, it's not clear what his basis for saying that one can be a substitute for another for one of Illumina's customers is.

JUDGE CHAPPELL: Do you want to rephrase or lay a foundation?

MR. MARRIOTT: Sure, Your Honor. I'm happy to do that. I'm also happy to respond, too, if that would be of -- I think I've laid the foundation, so may I respond? And I'm happy to lay more if you like -- well, let me just lay the foundation to keep it simple.

JUDGE CHAPPELL: Yes.

BY MR. MARRIOTT:

Q. You're currently, you testified, the

chief technology officer of Illumina; right?

A. Yes.

Q. And you were the head of product development for a time; right?

A. Yes. Correct.

Q. And you've previously served as senior director of R&D; correct?

A. Yes.

Q. And you've used sequencing instruments for now over a decade; correct?

A. Yes.

Q. And in your position as chief technology officer of Illumina, is it part of your job to track, monitor and follow other companies that are offering NGS sequencing equipment?

A. Yes, it is.

Q. Do you have knowledge of the sequencing offerings of the companies you already specifically identified: Thermo Fisher, BGI, PacBio, Oxford Nanopore, and Genapsys?

A. I do.

Q. And can you testify from personal knowledge about how those offerings compare to the offerings of Illumina?

A. I can.

Q. Okay. Complaint counsel --

MR. WIDNELL: Your Honor? Your Honor, may I respond just briefly? I just wanted to make sure that my objection was clearly understood because I wasn't objecting to him describing the characteristics of competing products. I was objecting to him drawing conclusions about whether customers could substitute one for another.

MR. MARRIOTT: I'm happy to lay some still further foundation if that would be helpful.

JUDGE CHAPPELL: Please do.

BY MR. MARRIOTT:

Q. Based on your years of experience with NGS sequencing and Illumina's products and your knowledge of products of the companies you specifically identified, do you know from personal knowledge whether those products are alternatives or substitutes for the Illumina offerings?

A. Yes. I can provide specific examples.

Q. Okay.

So complaint counsel has argued I believe that the Thermo Fisher offerings are not a viable alternative to the Illumina offerings.

Do you agree with that?

A. I don't agree.

Q. And why not, sir?

A. You know, for many applications the Thermo Fisher platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost.

Q. Does Thermo Fisher have an NGS sequencing product that could be used for multicancer screening?

A. Yes.

MR. WIDNELL: Objection. Foundation.

MR. MARRIOTT: Your Honor, I believe it's the same foundation I've provided now.

JUDGE CHAPPELL: Overruled.

THE WITNESS: Yeah.

So I was going to say yes. I'm most familiar with the Galleri test, having developed that. And the Galleri test can be, you know, run successfully on a Thermo Fisher system.

BY MR. MARRIOTT:

Q. Do you know whether Thermo Fisher markets its NGS offerings as an alternative to Illumina?

A. Yes, it does.

Q. Does Illumina view Thermo Fisher as a competitor?

A. Yes, it does.

Q. You mentioned BGI.

What sequencing products does BGI manufacture?

A. BGI manufactures multiple sequencing instruments and consumables. At a high level, it's -- they're very similar to Illumina's offerings in terms of the different categories of high throughput, mid throughput, low throughput, so they have again an array of instruments kind of that are, you know, comparable in terms of sequencing output.

Q. And are BGI's systems used for liquid biopsy applications?

A. Yes, they are.

Q. Does BGI have an NGS sequencing product that could be used for multicancer screening?

A. Yes, it does.

Q. Does BGI compete with Illumina for liquid biopsy applications in the countries in which it operates?

A. Yes.

Q. And do you know whether BGI markets its NGS offering as an alternative to Illumina?

A. Yes, it does.

Q. When do you expect that BGI will enter the U.S. market?

A. 20- --

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: I'll sustain that.

We don't know how he would know that, so you need to lay a foundation or move on.

MR. MARRIOTT: Okay.

BY MR. MARRIOTT:

Q. Has Illumina evaluated in the course of its -- does Illumina presently have patents that block BGI from entering into the United States marketplace?

A. It does.

Q. And can you tell us, please, sir, when those patents expire.

A. In 2023.

Q. And will those expiring patents present any impediment to BGI entering in the U.S. marketplace in 2023?

A. They will not.

Q. And has Illumina made projections as to when it expects that it will face competition in the U.S. from BGI?

A. Yes. We believe we will face competition from BGI in 2023.

Q. Does Illumina view BGI as a competitor?

A. Yes.

Q. You mentioned PacBio, sir.

Who is PacBio?

A. "PacBio" is shorthand for Pacific Biosciences. They're a commercial provider of next-generation sequencing products.

Q. And can you tell us about PacBio's NGS offering.

A. PacBio has two. They have a long-read technology, which is very complementary to Illumina's sequencing technologies.

And recently they've acquired a company called Omniome for $800 million. That company has a short-read sequencing technology that they and PacBio claim is a superior sequencing technology to Illumina's and a direct replacement.

JUDGE CHAPPELL: Hold on a second. I need to take a couple minutes for a technical issue.

Jada, Scott, leave us in place, just hold on.

(Pause in the proceedings.)

Okay. Go ahead.

MR. MARRIOTT: Thank you, Your Honor.

BY MR. MARRIOTT:

Q. Does PacBio with its acquisition of Omniome have an NGS offering that could be used for multicancer screening?

MR. WIDNELL: Objection. Foundation.

MR. MARRIOTT: I think it's the same

foundation, Your Honor.

JUDGE CHAPPELL: Just -- how about just rephrase with "do you know" first of all so we'll know if there's a foundation.

MR. MARRIOTT: Sure. Happy to do that.

BY MR. MARRIOTT:

Q. Do you know whether PacBio has an NGS sequencing product that could be used for multicancer screening?

A. What I know is that they have one in development.

Q. Do you know whether PacBio markets its NGS offering as an alternative to Illumina?

A. It does.

Q. And what impact do you expect PacBio's acquisition of Omniome will have on competition for NGS sequencers?

A. It will increase it.

Q. You mentioned Oxford Nanopore.

Tell us, what is Oxford Nanopore?

A. Yeah. Oxford Nanopore is another company that develops and commercializes next-generation sequencing products.

Q. And do you know whether Oxford Nanopore has an offering -- withdrawn.

What type of sequencing is Oxford Nanopore known for?

A. They're known for a type of sequencing called nanopore sequencing.

Q. Is it possible to do short-read sequencing on Oxford Nanopore's platforms?

A. Yes, it is.

Q. And how does the Oxford Nanopore NGS offering compare to Illumina's?

A. Yeah. The Oxford Nanopore platform is a very high-output sequencing platform. The amount of data and cost per data is comparable to the high-end Illumina systems. It can sequence both long reads, much longer reads than Illumina, but also short reads.

Q. And do you know whether Oxford Nanopore has an NGS sequencing product that could be used for multicancer screening?

MR. WIDNELL: Objection. Again, to the extent that this is asking for whether or not it meets requirements for MCED customers, I still don't believe that there's been a foundation established that Dr. Aravanis can speak to that.

MR. MARRIOTT: The question, Your Honor, asks whether he knows.

JUDGE CHAPPELL: I'll allow that.

THE WITNESS: Yes. Well, maybe just -- I want to make sure I understand the question.

BY MR. MARRIOTT:

Q. Let me just ask the question again so there's no doubt about it.

Do you know whether Oxford Nanopore has an NGS sequencing product that could be used for multicancer screening?

A. Yes. It -- I believe it can be. Yeah.

Q. And is Oxford Nanopore's platform used for liquid biopsy oncology testing?

A. Yes. There are examples of that.

Q. And do you know whether Oxford Nanopore markets its NGS offering as an alternative to Illumina?

A. Yes, they do.

Q. And what do you know, if anything, about the costs of doing short-read sequencing on Oxford Nanopore's systems today?

A. They would be very low cost.

Q. And what do you know about the projected costs of doing short-read sequencing on Oxford Nanopore's systems in the future?

MR. WIDNELL: Objection. Foundation.

The witness is being asked to speculate about the future.

MR. MARRIOTT: Your Honor, the question asks whether he knows. And as the chief technology officer of a company that thinks about competition and what competition will be faced in the future, I think that's adequate foundation.

JUDGE CHAPPELL: The question begins with "what do you know." That does not require speculation. Overruled.

THE WITNESS: Yeah. Oxford Nanopore has said that they are going to dramatically reduce the cost of their sequencing in the coming years. They have a track record of successfully reducing the cost, so you know, I -- I'm confident that they will be able to do that.

BY MR. MARRIOTT:

Q. Complaint counsel has argued here that Oxford Nanopore is not a viable alternative for an MCED test.

Do you agree with that?

A. I don't agree.

Q. Does Illumina view Oxford Nanopore as a competitor in NGS sequencing?

A. Yes, it does.

Q. You were asked -- or you mentioned a company called Genapsys.

What is Genapsys?

A. Genapsys is another company that develops and commercializes next-generation sequencing products.

Q. And what, if any, NGS offering does Genapsys currently have?

A. Genapsys sells an NGS instrument and consumable.

Q. And how does the Genapsys NGS offering compare to Illumina's?

A. It's a different technology for next-generation sequencing but produces the type of data that could be used as a substitute for some applications.

Q. And do you know whether Genapsys has an NGS sequencing product that could be used for multicancer screening?

A. Today, I think that would be difficult. They have shared a product roadmap, and if they're able to deliver on those products, then yes, you know, it would be a platform that could be used.

Q. And do you know whether Genapsys markets its NGS offering as an alternative to Illumina?

A. Yes, it does.

Q. So what do you know about when the companies that have NGS products in development are expected to

bring their products to market?

A. Yeah.

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: Overruled.

THE WITNESS: Yeah.

So PacBio has said that the Omniome technology, the next-generation sequencing products based on their Omniome acquisition, they plan to offer that product in 2023 but with a -- they said a very attractive price. And they've also claimed that the sequencing will be superior to Illumina, and so they've -- that's what they've stated, in 2023 they're going to offer, you know, that additional competitive technology.

Singular is a public sequencing company developing a next-generation sequencing product. They've said they're going to launch their product in 2023.

BY MR. WIDNELL:

Q. Do you know whether -- withdrawn.

Would an alternative NGS platform need FDA approval before it could be used for development or commercialization of an MCED test like Galleri?

A. No.

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: Objection overruled.

BY MR. MARRIOTT:

Q. Dr. Aravanis, when you were at GRAIL, did you consider using any NGS platforms other than Illumina?

A. Yes, I did.

Q. And which platforms specifically did you consider, sir?

A. We considered BGI MGI for the GRAIL test.

We considered Thermo Fisher.

We considered Oxford Nanopore.

And we considered Genapsys.

Q. And did GRAIL ever switch to a non-Illumina sequencer?

A. It did not.

Q. And why did it not switch?

A. As we evaluated the cost of sequencing and the need to find an alternative, it turned out to be -- excuse me. I just -- I'm going to clear my throat. Hold on.

(Pause in the proceedings.)

Apologies. I'm recovering from a cold.

When we looked at the cost of Illumina sequencing and the performance we were getting, we considered it adequate.

We also knew that the amount of sequencing we were going to need in the future for subsequent

versions of the Galleri test were going to further decrease.

We also had confidence that Illumina's sequencing costs would decrease.

So when we looked at our overall -- excuse me.

So when we looked at the overall priorities in terms of where we should focus research and development to have the biggest impact, finding an alternative sequencer, given that the cost was modest, it was going to decrease in the future, and Illumina is a very reliable vendor, it was a low priority.

Nevertheless, you know, as a matter of good business, we did want to have contingencies. We -- excuse me -- evaluated the platforms that I mentioned and determined that many of them would be a viable alternative.

Given that we were happy with the Illumina platform, we knew it would get -- its costs would decrease, and we had viable alternatives, there was no need, no business need, to explore it further.

JUDGE CHAPPELL: Hold on.

Let's take five for the witness. We'll stay in place, just hold on.

Do what you need to do, sir, get some water, and we'll stand by.

MR. MARRIOTT: Thank you, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Okay. Sir, is your voice back?

THE WITNESS: Yes, Your Honor. I think I can continue.

JUDGE CHAPPELL: Take a sip whenever you need it.

THE WITNESS: Okay.

JUDGE CHAPPELL: Of water.

Go ahead.

MR. MARRIOTT: Thank you, Judge.

BY MR. MARRIOTT:

Q. Dr. Aravanis, tell the court if you would what steps would be involved in GRAIL switching from an Illumina NGS platform to another NGS platform.

A. Sure.

One important step would be to do an analytical bridging study, so this is a study to demonstrate that the test performs similarly on an alternative sequencing platform.

In addition to that, there -- depending on the sequencer, there might be other steps where minor modifications to some of the library prep or analysis would also be required.

Q. How long would it take to switch?

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: Overruled.

THE WITNESS: You know, I'd say it depends on how different the sequencing platform is.

If it's a platform that produces very similar data, it could be a couple months.

If it's a platform that had more substantially different data, I would think worst case would be, you know, six to twelve months.

BY MR. MARRIOTT:

Q. And how costly would it be?

A. Again, if the data was very similar, then it could be, you know, a few hundred thousand dollars.

If it was a more extensive bridging study that took longer, you know, it could be in the, you know, millions of dollars.

Q. And how frequently do your customers switch from one Illumina NGS platform to another?

A. Every few years.

Q. And how much more difficult would it be to switch from an Illumina NGS platform to a non-Illumina NGS platform?

A. For some of the platforms that produce very similar data and companies that are actually making

sequencers to make that switching very easy I think it would be on the shorter side, again, you know, a few months and a few hundred thousand dollars.

Q. All right. So in your role at Illumina, do you project what the competitive landscape for NGS sequencers will look like over the next five to ten years?

A. We do.

Q. And what do you project the landscape for the NGS marketplace to look like over the next five to ten years?

A. There's going to be many new sequencing platforms, so a tremendous intensification of competition.

So there's many other platforms today. We believe those platforms will be competitive, you know, become more competitive I should say, and there will be even more platforms in the coming years.

Q. So are you familiar with the cost of NGS sequencing?

A. Yes, I am.

Q. And so referring you to RDX 6 at 19, how has the cost of NGS sequencing changed over time?

A. There's been a dramatic reduction in the cost of sequencing.

As shown here in the visual, you know, the original Human Genome Project was about $3 billion. Even at the time to do another genome would have been, you know, several hundred million dollars. Today, in large part, you know, due to Illumina, the cost of sequencing a genome is about a thousand dollars. Actually, it's even less. It's now $600.

Q. What, if any, plans that you can tell us about on the public record does Illumina have to further drive down the cost of sequencing?

A. Yeah. You know, Illumina has ambitious plans to do this. We have hundreds of engineers and scientists working on all aspects of cost reduction.

Earlier this year we talked about our plans to eventually get to a hundred-dollar genome. We talked about some of the technology breakthroughs that we think will ultimately enable that.

Q. And how is it that Illumina has been able to lower the prices of sequencing as it has?

A. Yeah. Through tremendous innovation.

Q. And what -- withdrawn.

Complaint counsel here has criticized Illumina's open offer on the ground that it guarantees price reductions that are less significant than what Illumina would do in the ordinary course.

Can you address that, please.

A. Yeah.

So I believe the open offer letter says, you know, that we'll achieve at least a 43 percent reduction. I think the "at least" is important. We have every incentive and hope to do that faster.

The reason why it's 43 percent is that's a number we feel we can confidently deliver on in terms of cost reduction. If we can achieve it faster, you know, that will be fantastic.

You know, as I said, we have longer-term goals to bring down the cost even more. But there's uncertainty in that science and commercialization and manufacturing right now, so it wouldn't be -- you know, it wouldn't be the right thing to do to customers to commit to something we didn't have confidence in yet.

Q. I want to switch gears a little bit here, Doctor, and talk to you a little bit more about GRAIL.

Earlier you said that you were involved in the formation of GRAIL.

Where did Illumina get the idea to develop a multicancer early detection test?

A. Yeah. The idea came from a couple projects that Illumina was doing.

One was related to noninvasive prenatal

testing. Illumina was operating a noninvasive prenatal testing business, and in the first hundred thousand women that received that noninvasive prenatal test some unusual signals were identified. It turned out those signals were undiagnosed cancers.

This was an important discovery and insight that cancer detection from the blood might be possible.

In addition to that, we were developing liquid biopsy technology to look at cancer signals in late-stage cancer for the purposes of therapy selection for advanced cancer patients. There was data from that applied to some early-stage cancer samples that also suggested that early-stage cancer detection might be possible.

Q. So can you describe in more detail the path from Verinata realizing that there were anomalies in the NIPT samples to Illumina realizing those anomalies were cancer signatures?

A. Yes.

So the laboratory director at Illumina who was responsible for the testing collected these unusual signals. She approached leadership at Illumina about them, including the chief medical officer and also myself, you know, and told us, you know, that we should

look into it in more detail.

We ultimately formed a team and a program to, you know, evaluate these signals, to follow up with patients carefully and their prescribing physicians, which eventually led to the discovery that these women had undiagnosed cancers.

Q. And at the time, what, if any, other work was Illumina doing in the field of oncology?

A. Yeah. Illumina was doing many things. It was developing a CDx, a companion diagnostic for therapy selection. It was developing a liquid biopsy assay for therapy selection. And it was also developing a comprehensive approach to therapy selection, looking at a very large gene panel.

Q. And to your knowledge, at that time were other companies exploring the development of NGS-based multicancer screening detection tests?

A. No. I'm not aware of any.

Q. All right. So what did Illumina then do to pursue the idea of a multicancer early detection test?

A. As the results were fully appreciated from the NIPT discovery and we did additional work using other oncology assays on early-stage cancers, we developed a hypothesis that multicancer early detection might be possible but also appreciated that a significant

amount of research and clinical development would be required.

Q. So how did GRAIL come into the picture?

A. Yeah.

So ultimately myself and the other founders and Illumina and Illumina's board came to the conclusion that to pursue this application in the research phases and maximize the chance of success, it made sense to found GRAIL and have an independent company to explore this application.

Q. What specific contributions did Illumina make to GRAIL to help explore developing an MCED test?

A. It contributed myself and 40 Illumina employees who were world experts in genomics technology, cancer biology, assay development, software analysis of genomic signals. It contributed laboratories, significant capital, and intellectual property.

Q. At the time that GRAIL was formed, what was Illumina's view as to whether it would succeed?

A. You know, Illumina's view was that it was a noble goal. If it was possible, Illumina had to support it because the potential implications and for lives saved was immense, but was also, you know, humble that this was very difficult. Scientifically, there was a lot of risk. It may turn out that -- at the

time, we knew that it might turn out it was not possible. Even if it was possible, it would be very technically challenging to develop such a product. And the clinical development for cancer screening approaches in general was known to be very challenging, expensive and timely.

So while Illumina appreciated the promise and this as being worthy, it, you know, also was again realistic about, you know, the substantial risk there was in achieving, you know, a multicancer early detection test.

Q. What was the industry reaction to the formation of GRAIL?

A. I would say very, very skeptical. I'd say, you know, appreciated again the noble goal.

The comments I remember at the time by industry analysts and other companies was that this sounds like it will be very hard, may not work at a scientific level and, even if it did, will take a very long time and be very challenging from a cost and clinical development. Yes.

Q. So why the name GRAIL?

A. It was a way of showing humility. The Holy Grail was never found, so it was a way of acknowledging that it was a very worthy goal. If you

could achieve it, there would be tremendous benefits. But we also knew that, you know, in doing this we might not succeed.

Q. Do you know whether Verinata would have formed some version of GRAIL if Verinata had not been a division of Illumina?

MR. WIDNELL: Objection. Calls for speculation or an expert opinion.

JUDGE CHAPPELL: He said "do you know." Objection overruled.

THE WITNESS: Yeah.

So I know that they would not have formed a -- a, you know -- they would not have pursued this application.

BY MR. MARRIOTT:

Q. Why?

A. What the laboratory director who had seen these initial signals told me was that, you know, quote, no one would, you know, listen to her about pursuing this, that it was a distraction, that Verinata did not have the resources to do this, and that actually for some time at Illumina she was trying to get people interested in it, and she was glad that ultimately she could get, you know, leadership like Rick and myself interested in it and develop a program

like that.

She told me that, you know, but for Illumina no one would have developed a program in this area and, you know, also was very encouraging to form GRAIL because, you know, without it she thought that this interesting discovery and the potential benefits might never be realized.

I would also --

MR. WIDNELL: Your Honor, I just want to object. Everything that's been said is hearsay. We've had no opportunity to test it in any way.

JUDGE CHAPPELL: You will have your opportunity on cross-exam -- or redirect.

MR. WIDNELL: Thank you, Your Honor.

BY MR. MARRIOTT:

Q. Dr. Aravanis, were you finished with your answer?

A. Yeah. Yes, I was finished with my answer. Yes.

Q. What was the name of the laboratory director, if you recall?

A. Meredith Halks-Miller.

Q. So did there come a time when Illumina made the decision to partially spin GRAIL out of Illumina?

A. Yes. In late 2015.

Q. And why was that decision made?

A. Yeah.

So when we looked at the challenges in developing a multicancer early detection product, we appreciated that the research phase in particular was going to be very challenging.

So a large number of cancer samples would have to be collected, you know, tens of thousands, in a very dedicated and expensive, high-risk research program. We thought that as an independent company, GRAIL would have a better chance of succeeding in doing that activity.

You know, we didn't think that from a commercial standpoint or necessarily, you know, that GRAIL would be well positioned, but for the research phase we believed that GRAIL would be more successful as an independent company.

Q. Did Illumina's ownership interest in GRAIL change over time?

A. It did.

Q. And how did it change?

A. You know, it decreased from a majority ownership upon the -- when the company was initially spun out and eventually went to -- in a subsequent fund-raising round to a much lower percentage. I

don't remember the exact number. Maybe around 20 percent.

Q. How, if at all, did Illumina's relationship with GRAIL change as its ownership in GRAIL decreased?

A. Yeah.

So as -- after the ownership decreased to the -- I don't know -- around 20 percent level, the relationship became one of a vendor and an important customer. And that's how I would characterize it.

Q. And did Illumina's ownership interest drop eventually to about 12 percent on a diluted basis, fully diluted basis?

A. That sounds right. There were subsequent fund-raising rounds.

Q. What involvement did Illumina have with GRAIL after it was spun off?

A. There were some -- there were some projects that were holdovers from when GRAIL was part of Illumina. And to just efficiently complete those activities and rather than have the companies do redundant work, there was collaboration around those. They were not related to cancer screening. They were just an efficient way to get some of the remaining work done that some of the employees who had left Illumina to GRAIL were doing.

You know, once that was completed, there was no further interactions between the companies other than as a vendor and a customer.

Q. Did Illumina customize any NGS products for GRAIL before it was spun out?

A. I don't -- I don't -- I don't believe there was anything customized before the spinout. No.

Q. Did Illumina customize any NGS products for GRAIL after it was spun out?

A. What Illumina did was box things differently.

So given that GRAIL was a very high-volume customer and was spending a lot of time kind of unboxing the reagents, Illumina kind of put more bottles in a box and some other kind of packaging activities like that just to make it easier and less wasteful in terms of the packaging materials.

Q. So, Dr. Aravanis, what involvement did you have personally in the development of GRAIL's multicancer early detection test?

A. Yeah. I wrote the research and development plan and I led the research and development program to develop the test.

Q. I want to take you through the development process a little bit. Maybe I can just ask you to start by listing for us the different phases or steps

that were involved in developing the GRAIL MCED test, and then maybe I'll ask you questions about each one.

But what were the steps involved -- what are the steps involved in developing an MCED test?

A. Yeah.

There's a research phase, then, if that's successful, a test development phase and, if that's successful, a clinical trial.

Q. And then what follows the clinical trials?

A. A commercial launch if the clinical trial is successful.

Q. So let me ask you about the research phase.

Tell us what's involved in the research phase of developing an MCED test.

A. Yeah.

So by way of my experience at GRAIL, the research phase was a multiyear process. One thing we needed to accomplish in the research phase to develop a multicancer early detection test was to understand the types of signals in cancer, not just one cancer but actually every major cancer since we wanted to have a test that could detect as many cancers as possible, so that meant recruiting individuals, hundreds of individuals with each major cancer type.

We also had to enroll individuals with many

stages of cancer, so not just late-stage cancer but also early-stage cancer.

So, for example, in pancreatic cancer, we needed many samples of individuals with Stage I pancreatic cancer, Stage II, Stage III, Stage IV. Many of these samples are very difficult to find.

We ultimately recruited 15,000 individuals in that research phase with and without cancer to be able to catalog all of the different cancer signals. This hadn't been done before.

We also needed thousands of other individuals, and this came from another study, you know, to add to the individuals without cancer.

The reason it was important to have I think in the end in the research phase about 10,000 individuals who didn't have cancer is that, you know, there's many other diseases that can put signals into the blood, you know, autoimmune, heart attacks, and so on.

So in addition to the discovery study to see what signals were in the blood of people with various cancers and without cancers, we also had to determine, you know, what technology, if any, might be able to effectively detect these signals.

So we did a large research experiment where we looked at many approaches for cancer detection, most of

them, you know, not successful. Ultimately, we found one.

And since we were successful in categorizing the signals in cancer and we found a technical approach that we thought might be possible to develop into a product, you know, we were then able to move on into the test development phase.

Q. So how many people at GRAIL would you estimate were involved in the discovery phase?

A. Hundreds.

Q. And how long did that phase, the discovery phase, take?

A. Several years.

Q. So we've heard some discussion in the course of trial about biomarkers.

What is a biomarker?

A. Yeah.

So a biomarker is a molecule in the blood and that -- and that particular molecule might have a relationship to a disease, so the, you know, amount of that marker could go up or down depending on a particular disease.

Q. What biomarkers did you use initially at GRAIL?

A. We looked at many types of biomarkers.

We looked at mutations in the DNA, in the cancer DNA in the blood.

We looked at chromosomal changes, so this is changes in the amounts of chromosomes in the blood.

We also looked at not just DNA but RNA signals in the blood.

There was many -- in each of these there were many different subtypes, but I'll just go over the major categories.

And then we also looked at epigenetic signals, in particular, methylation of the DNA.

Q. And how many biomarkers would you estimate that GRAIL investigated?

A. You know, tens of millions.

Q. And during this phase, what signals or biomarkers did GRAIL identify as being of greatest interest?

A. The signal that was the most promising was the methylation signal.

Q. And what technique does the GRAIL test use to detect cancer?

A. It uses a next-generation sequencing approach that can detect the methylation signals in the DNA.

Q. So referring if I may to RDX 6 at slide 20, would you please explain to us how targeted methylation

works.

A. Yeah. Sure.

So maybe just to start with methylation patterns in general, so these are unique patterns in the DNA that affect which genes are turned on and off. And then by affecting which genes are turned on and off, it affects what the cell becomes and how it behaves.

So if you think, for example, of a lung cell versus a liver cell, they have the same DNA in them. That's not different. What's different is the methylation patterns, so the places in the DNA that are methylated or unmethylated, which is this chemical change, is very different even though the underlying DNA coda is the same. And so this fingerprint really determines, you know, what a cell is and what a tissue, you know, is.

There's about 30 million methylation sites in the DNA -- or sorry -- in the human genome. In our research phase at GRAIL, we identified about a million sites that were informative for cancer.

And then in the product development phase we developed a more efficient assay to just sequence those one million sites and not all of the DNA. And we did that to have a test that was much lower cost and much

easier to manufacture.

Q. So how many methylation markers does Galleri use, to your knowledge?

A. It uses a million.

Q. Would it be possible to create a test like Galleri using far fewer methylation markers?

A. No. I think that's very unlikely.

Q. And do different cancer types have the same methylation markers?

A. No, they do not.

So the methylation patterns between different cancers can be quite different. Methylation patterns actually within a cancer, even of the same type that looks the same, can also be quite different. And this is actually why you need so many markers, which is that you need many markers to be able to understand which type of cancer, to distinguish it from someone who doesn't have cancer, and then -- and also be able to detect all of the different types within a single cancer. There wouldn't be enough information from a small number of markers.

Q. And what, if any, challenges did GRAIL face in developing its test during the discovery phase?

A. There were many challenges.

So coming out of the research phase, the

methylation chemistry for the library prep was not adequate. It wasn't efficient enough. It lost too much of the methylated DNA, so we had to invent a new method of library preparation that was much more efficient.

As I -- as we discussed, we didn't want to sequence the 29 million sites that weren't useful. That would have been wasteful, so we needed a method to selectively and efficiently enrich for just those DNA fragments from the million relevant sites. To do that, we invented a new enrichment approach to efficiently recover just those fragments.

And then the sequencing, as we discussed, is generic and no invention there.

And then on the analysis side we used machine learning methods and -- to decipher and be able to predict cancer from these complex signals.

So, you know, for any given cancer, you know, in these million sites you could have many different types of changes. You know, some of the changes are unique to the individual. No human being could look at such signals and actually determine what they mean, so we had to develop a very sophisticated machine learning approach that could take the signals and then make a prediction of cancer and make a prediction of the type

of cancer.

So those were some of the challenges in the research and test development phase.

There were also challenges on the -- in the clinical development. As I mentioned --

Q. Let me stop you there, Doctor, just so we keep these a little bit more compartmentalized.

A. Yeah.

Q. So let's turn to the test development phase more broadly.

Describe for the court if you would what's actually involved in the test development phase of an MCED test.

A. Yeah.

So the test development phase is to construct an assay, so, you know, a library prep and an analysis that performs the test you want, right.

So you have to actually find the right chemistries or invent them that manipulate the DNA and prepare it the ways that you need, the efficiencies, the costs that you want to achieve. You have to come up with ways to automate that.

In this example, you need a test that can be performed, you know, you know, ultimately, you know, you know, millions of times, you know, in a laboratory,

so you have to miniaturize, you know, these chemistries, learn how to have robots, you know, process them.

And then you also have to develop an analysis of the signals.

And there's also many steps through which you have to do verifications and validations of the system, so rigorous tests that show that, you know, the overall process is repeatable and reproducible when you do it over and over. When different people run it, you get the same result. When, you know, you run it on different instruments, you get the same result. When you get slightly different batches of a chemistry, you get the same result. You have to document all of this quite rigorously. You have to create systems that follow all of these processes, both during the development and then when the test is actually used.

Q. So how many people at GRAIL were involved in the development phase of Galleri?

A. Hundreds.

Q. And how long would you say the development phase took for Galleri?

A. A couple years.

Q. Can you describe for us the functions and the features of the test that GRAIL decided through this

process to develop?

A. Yeah. It ultimately was a targeted methylation assay, so it had its own -- we talked about the steps in an NGS workflow, so had a method for doing high-throughput automated extraction.

It had a method for doing the library preparation, which was the inventions that I described for preparing efficiently the methylation -- methylated DNA fragments for sequencing, for enriching for the relevant regions.

Again, it goes onto the same generic sequencer and generic sequencing consumables.

And then it has the -- you know, GRAIL's proprietary machine learning algorithms to actually take those signals and then make a prediction about whether or not the patient has cancer and, if they do have cancer, make a prediction about what type of cancer.

Q. What challenges did GRAIL face that were specific to the test development phase?

A. Yeah.

So I think I mentioned this already, but many of these steps didn't exist, so no one at that time had ever developed a -- you know, a production, clinical, targeted methylation assay based on NGS, had automated

it. And no one had ever done it for cell-free DNA.

As I mentioned, you know, existing technologies were not efficient enough, not automatable enough, not robust enough, so significant efforts by many engineers and scientists to solve these challenges and make the inventions which made the assay work.

Q. What does it mean to verify an MCED test?

A. Yeah. It's to show that at a technical level it does what it's intended to do.

So if it's intended to process a certain amount of DNA and enrich a certain amount of DNA and target certain methylation sites and then produce, you know, a certain amount of sequence data, you know, a verification test is to actually run, you know, run the system, and show that it performs within spec.

Q. And what does it mean to validate an MCED test?

A. Yeah. There's different types of validation.

But, for example, for an analytical validation, it's to show that the test measures what you expect to measure and it measures it, you know, repeatably and reliably.

Q. Let's turn to the clinical trial phase.

What clinical trials or studies has GRAIL done for Galleri?

A. Yeah.

So there's three studies that were involved in the development of Galleri.

The first is the one in the upper right. It's the CCGA study. That was the study that collected samples from 15,000 people with and without cancers, you know, every major type of cancer, different stages of cancer.

In addition to blood from all 15,000 individuals, clinical data was also collected from all of these individuals. This was required for the research phase to have the -- you know, again, the cat lit -- the catalog or the atlas of signals and then to test all of the different potential technical approaches to measure these signals.

The other study that was also used in the research and test development phase was samples from the STRIVE study, so the STRIVE study enrolled a hundred thousand women, collected blood from all of these women and their clinical data.

Several thousand samples from the STRIVE study were used to supplement additional needs that the CCGA study did not meet, in particular, having thousands more individuals without cancer so that, you know, could ensure that the test had a very low false

positive rate.

And then the PATHFINDER study was used in the -- you know, in the clinical -- in the clinical trial after the test development.

Q. So you said there were four phases to the development of the Galleri test, and I just want to understand how strictly separated these phases are.

So did all of these trials referenced here on RDX 6 at 21 -- did they take place, strictly speaking, during the clinical trial phase or to what extent does one phase bleed into the next?

A. Yeah.

So the CCGA was used during the research phase, and the research phase couldn't have been done without that.

Part of the STRIVE study again was used in the research phase because CCGA and STRIVE were also used in the test development phase.

The PATHFINDER study was begun towards the end of the test development phase for the clinical validation.

Q. And what personal involvement did you have in these studies?

A. I was involved in the conception of the studies, the design of them, and in the execution of

operating them.

Q. And to what extent are there results from these studies?

A. Yeah.

So today there are results that GRAIL has released from -- you know, actually, many, many results from the CCGA study. And then it's also released preliminary results from the PATHFINDER study.

Q. And what can you tell us at a high level collectively about the results of these trials?

A. I would say that the results were positive.

In the CCGA study, the initial results showed that multicancer early detection could be possible. It showed that methylation was the most promising result.

Then as the -- after the research phase, in the test development phase, the CCGA showed that a much lower-cost targeted methylation assay could also achieve high performance for multicancer early detection.

And then the PATHFINDER study showed that in an actual, you know, interventional clinical trial where you're testing patients, you're giving them the results back, you could find undiagnosed cancers in asymptomatic patients, and you could find early-stage cancers in a significant number, and you could also do

it at a very low false positive rate. I believe less -- about half percent. And the test could also at over 90 percent accuracy predict the type of cancer that the patient had.

Q. So let's turn to the commercial launch phase. What are the pathways to selling an MCED test?

A. There's two -- there's two basic ways you could launch an MCED test. One is as a laboratory-developed test, referred to as an LDT. The other would be as an FDA-approved IVD.

Q. And when did GRAIL commercially launch the Galleri test?

A. In June of 2021.

Q. And what pathway did GRAIL pursue in launching Galleri in 2021?

A. Yeah. The Galleri test was launched as an LDT.

Q. And what exactly is an LDT?

A. It's a test that's developed in a single laboratory, validated in that single laboratory and only offered through that single laboratory. It follows a set of regulations called CLIA regulations.

Q. Does an LDT require FDA approval?

A. It does not.

Q. And can an LDT be distributed for use by a lab

that did not develop the test?

A. It cannot.

Q. And why did GRAIL launch the Galleri test as an LDT?

A. There were two reasons.

One is, given the promise of the test, GRAIL wanted to make the -- this potentially lifesaving technology available as soon as possible so that patients and physicians could use the test, so it was the fastest route to make it available and to try to start, you know, making a dent in the number of people who are diagnosed with late-stage cancer.

In addition to that, the data from the LDT phase could be used to support and supplement the PMA that GRAIL plans to submit for FDA approval.

Q. And what does "PMA" stand for?

A. Premarket application.

Q. And are there different kinds of premarket applications?

A. There are.

Q. What are the different kinds of premarket applications?

A. Two of them related to diagnostics are -- one is a site-specific PMA. That's for a test for a company that wants to receive FDA approval for running

the test at a single laboratory.

There's also a true distributed IVD for which you can submit a PMA. If approved, then that would allow a kit for the test to be distributed and run by other laboratories.

Q. And just for the clarity of the record, looking at the realtime, I think I may have just called it a PMA, suggesting there's no approval there.

"PMA" stands for premarket approval; right, so you submit a PMA approval application?

A. Yeah. Thank you for the correction. Yes, a premarket approval application.

Q. And does GRAIL -- I think you -- does GRAIL have plans to seek a premarket approval at some point for the Galleri test?

A. It does.

Q. And why?

A. So FDA approval will help with reimbursement and adoption.

Q. And what is required for premarket approval of an MCED test?

A. Yeah.

So a successful PMA application is required.

Q. Now, how many different cancers does the Galleri test detect?

A. 50.

Q. Was it always the plan for GRAIL to screen for 50 different cancers?

A. The initial plan from when the company was founded was to develop a pan-cancer testing approach that tested for multiple cancers. At the time, we didn't know, you know, how many cancers that would be, but it was to test for a large number -- to develop a test for a large number of cancers.

Q. Did GRAIL consider developing a single-cancer screening test?

A. It did as a route to multicancer but ultimately abandoned it as taking -- that it would take far too long, the benefit would be low, and the benefits of a multicancer test would be much more significant.

Q. All right. So why did GRAIL take the approach of launching a test, developing a test that screens for 50-plus cancers instead of developing a test that screens for one and then adding other cancers later on?

A. So for each test you were to develop, right, you would have to go through a somewhat similar process to what GRAIL did, right, so you'd have to go through a research phase, you'd have to go through a test

development phase, you'd have to go for a clinical phase. You know, the time, you know, might be similar for each cancer. And so if you were going to do this serially and each one took four or five years, right, then for 50 cancers you're talking about, you know, a very long time, right, you know, a couple hundred years.

So obviously that's, you know, undesirable and not practical, so there's a lot of benefit, you know, if you could do multicancer.

The other is just the inherent benefit of multicancer, right, so a single test has more benefit if it, you know -- if it detects more cancers.

Q. How do biomarkers vary from one cancer to the next?

A. They tend to be very different, so while there are some signals that overlap, most signals do not.

Q. And what steps would a test developer have to follow to convert a single-cancer test into a 50-cancer test?

A. So when we looked at this at GRAIL, you would have to do a research study, a discovery study, and collect the relevant samples for the new cancer type to find the signals. You would then have to determine what the right technology would be for detecting that

cancer. You would then have to go into a new test development phase to make a new test, you know, for this additional cancer. And then you would have to start a new clinical trial appropriate for that cancer and then run that clinical trial.

Q. Well, so how is it that GRAIL could develop a test for 50 cancers in what I'll call one development cycle, but you say that a company developing tests for one cancer would have to repeat those steps for additional cancers?

A. Yeah.

So GRAIL did this work in parallel by doing a much larger version, a much larger research phase, a much larger test development and clinical development.

So, again, you know, the CCGA study was 15,000 individuals. You know, that's probably the -- I mean, you know, by many factors the largest study I've -- I know about for developing an early stage -- or for the research phase of an early-stage cancer detection test, right, so if you were doing a single cancer, you might collect a couple hundred, you know, of an individual cancer. But by doing 15,000 and collecting multiple hundreds of every major cancer type, what GRAIL did was effectively do all 50 at the same time, but it had to be an unprecedented size of

study, much more complex and much more expensive.

Q. How long have people been trying to develop blood-based cancer screening tests, to your knowledge?

A. For a long time. Many, many decades.

Q. And why has there been so little success?

A. It's very hard to do, for a variety of reasons, which GRAIL encountered.

One is, you have to learn what the signals are in the blood, which requires, you know, you know, again, collecting and cataloging the signals of, you know, 50 cancers in this case.

You also have to find a technology that could detect the signals with the type of characteristics. That's very hard to do, to find a technology that could detect so many cancers and for cancer screening could do it at such a low false positive rate.

And for multicancer there's also value if you can predict the cancer, something else that, you know, had never, you know, been demonstrated.

So, you know, lots of efforts over the decades, many companies, many academics, probably billions of dollars spent, and unfortunately, you know, no -- no products or successes to show for it.

Q. Couldn't a company just collect a bunch of samples from various sample banks and forgo a clinical

trial?

A. I don't think that would work.

Q. Why not?

A. So what we found at GRAIL is that, you know, the cancer signals in the blood are subtle. There's a lot of signals in people that don't have cancer, and so to be able to understand which signals are relevant, you have to do this where you have a unified collection approach across, you know, all of the cancers the same way.

GRAIL collected samples from 142 sites across North America simultaneously to capture all of the different types of cancers, you know, again, you know, hundreds of examples, so that, you know, they could be compared.

In a similar way, it had to collect in I believe in the development of Galleri about 10,000 individuals, the samples from individuals without cancer, and again had to be collected in a uniform way, high quality, same sample collection protocol, same clinical data collected in the same way so it could be comparable.

If you were just to mix and match samples collected in different ways from different purposes, you would end up finding signals that are just

artifacts of those methods. And were you to develop a test in that way, you know, likely it wouldn't perform well.

And unfortunately, that is the reason why, despite many companies, large amounts of money and, you know, many academic scientists, there hasn't been success to date. This trying to mix and match things that aren't comparable has been very problematic.

Q. So one of complaint counsel's experts has suggested that once a company has a test for a single cancer, it's pretty straightforward to expand to add all other cancers.

What can you tell us about that?

MR. WIDNELL: Objection, Your Honor. He's basically asking for an opinion about expert testimony.

MR. MARRIOTT: Your Honor, I'm actually not. The experts on complaint counsel's side have assumed things that they call facts and used them as the basis of their opinions, and I'm asking about an assumed fact in an opinion of an expert.

JUDGE CHAPPELL: Why don't we ratchet down the controversy. Ask your question you want to ask the man and don't refer to anybody's expert. Rephrase.

MR. MARRIOTT: Okay. Fair enough, Your Honor.

Thank you.

BY MR. MARRIOTT:

Q. If a company has -- what can you tell us about whether, if a company has a test for a single cancer, it's straightforward to expand that test to all other cancers?

A. That doesn't make sense to me. I don't understand why that would be.

Q. Okay. And why not?

A. You know, to develop a test for a new indication, like a new cancer, you have to go get samples related to that different cancer. You have to find the signals. Then you have to develop a technology for that. Then you have to do a -- the relevant clinical trial.

There's no shortcut. I mean, there's hundreds of diagnostics developed. I've never heard of an example where because you developed a test for one thing, you can now -- it's a shortcut to develop a test for something different. That's not the way good clinical development works.

Yeah, that doesn't -- it doesn't -- I don't see where the shortcut is.

Q. Could you describe for us, please, how the Galleri test works.

A. Yeah.

So at a high level, the Galleri test detects methylation signals in the blood that are coming from a cancer. It then, based on the types of signals, predicts whether or not there's a cancer present or not. And it also predicts the type of cancer, assuming that it's predicted a cancer. And then a report is produced that is given to the physician to share with a patient.

Q. Can you identify the specific cancers that the Galleri test has identified?

A. Do you mean in the PATHFINDER study or what are you referring to?

Q. In any of its studies, can you identify for us the cancers, the 50 cancers that -- and I realize it's not meant to be a memory test, but can you give us a sense of the cancers that the Galleri test has identified?

A. It's essentially every major cancer you've ever heard of, so I could -- lung cancer, stomach cancer, head and neck cancer, liver cancer, ovarian, pancreatic, and on and on. It's every major cancer. There are some that it doesn't, but it's every major one.

Q. What is the specificity of the marketed version

of Galleri?

A. 99.5 percent.

Q. And what does that mean?

A. That means that if you take, say, 200 individuals who -- let's say you knew somehow that none of them have cancer -- how often would you get a result erroneously that one of them would have cancer.

So in this case, if you were to give the test to 200 people who didn't have cancer and you really knew they didn't have cancer, one in 200 you would get what's called a false positive or the test would indicate a cancer signal was detected, and then upon doing a diagnostic workup you would find that that's not true.

Q. And how does that compare to the specificity of other screening tests?

A. It's very high. I'm not aware of any screening tests with such a high specificity. Most screening tests are, you know, in the 80s or low 90s, not 99.5 percent.

Q. What's the specificity, if you know, of a mammogram?

A. I think it's in the high 80s.

Q. What's the sensitivity of the marketed version of Galleri?

A. Yeah. The sensitivity varies by cancer type, so for each of the 50 cancers there's a different sensitivity.

There's also a different sensitivity by stage of cancer, so a different sensitivity for, you know, Stage I pancreatic cancer, you know, a different sensitivity for Stage II.

So depending on how you group these together, you can get different averages. I think a very relevant number is that if you look at a subgroup of the 50 cancers that are particularly deadly and that account for two-thirds of all cancer deaths, the Galleri detects 70 percent of those in early stage.

Q. And do you know whether the Galleri test has successfully detected cancer in asymptomatic patients?

A. Yes, it has. It's detected many individuals with early-stage cancer who are asymptomatic.

Q. And do you know whether the test has led to a curative therapy for any of those patients?

A. It has.

So if you look at the preliminary results from the PATHFINDER study, GRAIL shows examples of an individual, for example, who was detected with pancreatic cancer, turned out it was Stage II pancreatic cancer. The individual went -- underwent

curative therapy for that cancer.

There was another individual with -- detected with early-stage head and neck cancer, and again often not detected at early stage, but for this individual it was and so could receive curative intent therapy.

There was another individual who had small bowel cancer at early stage, and the test detected that.

There are other examples in the PATHFINDER study.

Q. Switching gears a little bit here, when did Illumina decide to reacquire all of the shares of GRAIL?

A. Yeah.

So I think there was a board decision to do that in September of 2020.

Q. And did you personally support Illumina's decision to reacquire GRAIL?

A. I did support it.

Q. And please tell us why.

A. You know, the GRAIL Galleri test holds tremendous promise. You know, if the test is widely deployed, you know, there's the opportunity to save, you know, many thousands of lives. There's few things in cancer diagnostics or therapeutics that have the

same potential to avert deaths from cancer.

Our analysis was that Illumina is in a unique position to accelerate adoption of the GRAIL Galleri test. And by accelerating that and leading to, you know, many million -- millions of more people getting the test faster, we think in that, you know, period we'll save many additional thousands of lives, so it's hard to, you know, imagine, you know, a more incredible opportunity to improve, you know, human health.

You know, in addition to that, there would be other, you know, business benefits. It would help us, you know, diversify our business.

It would also give us access to additional clinical data and test data that we think could lead to new breakthroughs, like the one from -- we had from noninvasive prenatal testing that actually led to the -- which contributed to the founding of GRAIL.

Q. I believe you said before, Dr. Aravanis, that you supported Illumina's spin-off of GRAIL.

How do you reconcile your support for both the spin-off of GRAIL and Illumina's reacquisition of GRAIL?

A. Yeah.

So, you know, when we -- when we spun off

GRAIL, we believed that was the -- the -- the best way to give GRAIL the chance to do the early-stage research required to see if multicancer early detection was possible.

We knew that GRAIL wasn't set up to do commercial development, you know, regulatory processes, and so in the future, bringing the company back in, you know, might make sense.

So it was really about, you know, optimizing the research phase. And then when we saw what happened in the research phase, we could reevaluate what made sense, if it was successful, to help commercialize.

Q. So what's different, if anything, about GRAIL now compared to when Illumina spun it out in 2017?

A. Yeah. I mean, it went from a scientific idea to a first product, and so the -- the science has been proven out. A lot of the clinical results have been established. The test -- a first test has been developed and a first product has been launched.

Q. And what, if anything, is different about Illumina now compared to when Illumina spun GRAIL out in 2017?

A. You know, Illumina has developed substantial additional capabilities in market access, in its

regulatory capabilities, you know, in its overall scale, size of R&D, so, you know, again, a lot of, you know, improvements and increases in capabilities since Illumina spun out GRAIL.

Q. I want to ask you some questions now if I may about the marketplace for MCED tests, picking up on a theme raised by Mr. Widnell during his earlier examination.

In your roles at Illumina and then GRAIL and now Illumina again, have you tracked to what extent other companies are developing cancer screening tests?

A. Yes, I have.

Q. And what do you know about whether other companies are developing an early cancer screening test?

A. There appear to be some in an early research phase.

Q. Are you aware of any company that has developed an early cancer screening test comparable to the Galleri test?

A. No. I'm not aware of any tests that are comparable to the Galleri test.

Q. And what would you expect to see in the public domain if a test developer was within five years of launching an MCED test similar to Galleri?

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: Do you want to rephrase, more in the line of what do you know rather than what someone might expect?

MR. MARRIOTT: Sure. Happy to do that, Your Honor. Thank you.

BY MR. MARRIOTT:

Q. What do you know, Dr. Aravanis, about what would be seen in the public domain if a company were within five years of launching an MCED test similar to Galleri?

A. So I would expect to see the same types of reports, publications, you know, meeting presentations and clinical trials that GRAIL did.

Q. What is ClinicalTrials.gov?

A. Yeah. It's a government website where clinical trials are registered.

Q. And what's a discovery study?

A. A discovery study is a research study for the purpose of understanding -- or sorry -- for the purpose of discovering potential signals that could be useful in, for example, a diagnostic.

Q. Do you know whether you would see a discovery study registered on ClinicalTrials.gov if an MCED test developer were close to developing a test?

A. I believe you would expect to see that.

So, as we discussed, for an MCED test, you know, GRAIL needed, you know, to have a test for 50 cancers, needed about 20,000 individuals, you know, with and without cancer. A clinical, you know, study that was enrolling 20,000 individuals, you know, you know, would -- you know, would be listed on ClinicalTrials.gov. That would be highly unusual to have a 20,000-participant study that wasn't listed on ClinicalTrials.gov.

Q. How long does it take --

MR. WIDNELL: Your Honor, my apologies, but I understand that the question started with how, but the witness answered with "I believe I [sic] would expect." I think that's -- that's -- there's still a foundation question there about what his basis is.

JUDGE CHAPPELL: Respond or rephrase or lay a foundation.

MR. MARRIOTT: Doctor -- thank you, Your Honor.

Doctor -- I'll try to lay a little better foundation.

JUDGE CHAPPELL: Based on the objection, the current answer will be disregarded.

BY MR. MARRIOTT:

Q. Dr. Aravanis, do you know what steps an MCED

test developer would take in terms of registering trials on ClinicalTrials.gov if it were close to having developed an MCED test?

A. Yes.

Q. And what do you know about what would appear on ClinicalTrials.gov if an MCED test developer were at a point where it had developed an MCED test?

A. If a company had -- I just want to clarify I understand. You're saying that the company has gone through the research phase, gone through the test development phase, and now is ready to do a clinical trial. At that point, what would I expect to see on ClinicalTrials.gov? Is that the question?

MR. WIDNELL: Objection, Your Honor. That's still what he's expecting, not what he knows.

JUDGE CHAPPELL: Sustained.

BY MR. MARRIOTT:

Q. Yeah, the question was a little bit different, so -- but let me see if I can -- I can do this in a different way and ask you this, Doctor.

How long does it take --

JUDGE CHAPPELL: Let me just tell you, you're here to tell us what you know, not to guess or speculate. All right?

THE WITNESS: Okay. Yes, Your Honor.

MR. MARRIOTT: May I proceed, Your Honor?

JUDGE CHAPPELL: Go ahead.

BY MR. MARRIOTT:

Q. How long does it take to go from registering a discovery study on ClinicalTrials.gov to obtaining results that could be used to advance the development of an MCED test like Galleri?

A. A couple years.

Q. When did GRAIL publicly initiate its discovery study on ClinicalTrials.gov for the Galleri test?

A. In 2016.

Q. And how long did it take GRAIL to go from registration of the discovery study to obtaining the data that it needed to advance the development of the Galleri test?

A. For the discovery phase it took a couple years.

Q. What is an IDE?

A. "IDE" stands for investigational device exemption. It's given by the FDA to allow a clinical trial to proceed.

Q. And is an IDE required to develop an MCED test similar to Galleri?

A. Yes.

Q. And are IDEs grants public?

A. No, they're not public.

Q. And in your experience as a developer of an MCED test, do companies typically disclose that they receive an IDE for major clinical trials?

A. Yes, they do.

Q. Was GRAIL granted an IDE from an -- for an interventional study involving Galleri?

A. It was.

Q. And did GRAIL publicly disclose that it received an IDE for an interventional study involving Galleri?

A. Yes, it did.

Q. And why did GRAIL publicize the fact that it received an IDE for Galleri?

A. It was a significant milestone in the development of the test. An IDE for multicancer early detection had never been given by the FDA before.

GRAIL also wanted to demonstrate that it was working with the FDA and, you know, following best practices and developing its test with extreme rigor.

Q. What's an interventional study?

A. It's a study where, in the case of a diagnostic, the result is being given to the physician and the patient and used in their care and potentially affects their care.

Q. And are interventional studies registered on ClinicalTrials.gov?

A. Yes, they are.

Q. How long does it take to go from the registration of an interventional study on ClinicalTrials.gov to obtaining results that could be used to advance the development of an MCED test like Galleri?

A. In the case of Galleri, it took 18 months from registration to the preliminary results.

Q. So what role, Dr. Aravanis, do peer-reviewed journals play in the development of an MCED test?

A. They're very important. Peer review is a way of validating the science and the results during the different stages of development.

Q. And did GRAIL make the decision to publish in peer-reviewed journals the results of any of its studies concerning Galleri?

A. Yes, it did.

Q. And why did it do that?

A. You know, GRAIL believed that the best scientific and clinical processes for development of clinical products should be transparent. It wanted the scrutiny of the scientific and clinical communities and welcomed their feedback.

It also appreciated that for the results to be believed, you know, peer review was very important.

Q. Are you aware of any peer-reviewed articles describing a test similar to the Galleri test?

A. Could you -- what do you mean by the "similar to the Galleri test"?

Q. Fair enough.

Are you aware of any peer-reviewed articles that describe a test that does what the Galleri test does?

A. No, I'm not.

Q. Is it possible to perform a discovery study for an MCED test like Galleri using samples stored in a biobank?

A. I don't believe so.

Q. And why not?

A. As we discussed before, to find the relevant signals for an MCED test, you need samples that were actually collected that are relevant to what you're trying to detect.

So, for example, take pancreatic cancer. If you want to develop a test for early-stage pancreatic cancer, you need samples from individuals with early-stage, you know, pancreatic cancer, right, so you would need samples from individuals with Stage I and

Stage II pancreatic cancer. And you need large numbers of those.

Such biobanks don't exist because, you know, the number of individuals with those cancers is very unusual, so without a dedicated effort to find these types of relevant samples in a clinical trial, I don't see how a biobank with some other samples could be relevant.

Q. Is it possible to perform a discovery study for an MCED test like Galleri using biomarkers identified from running a commercial MRD or therapy selection test?

MR. WIDNELL: Objection, Your Honor. This is straying into opinion testimony.

JUDGE CHAPPELL: Do you want to respond or lay a foundation or rephrase?

MR. MARRIOTT: I can rephrase it, Your Honor. Thank you.

BY MR. MARRIOTT:

Q. So in developing the Galleri test, Dr. Aravanis, did you -- did you use biomarkers identified from running a commercial MRD or therapy selection test?

A. We did not.

Q. And why not?

A. So to develop a test for early-stage cancer, you need signals and samples from early-stage cancer, right. We know the signals in early-stage cancer can be substantially different. You also need signals from a large number of people who don't have cancer.

Tests for individuals with late-stage cancers would be different signals than early-stage cancers, so may not be relevant signals.

Moreover, those tests are generally used only for a small number of cancers, you know, primarily, say, lung cancer or colorectal cancer, right, so you wouldn't find, for example, pancreatic cancer samples that are -- especially at early stage that are run in any of these tests, so while, you know, you would have data from these other tests, it wouldn't be from the samples and patients that you would need.

Q. Are there challenges unique to running clinical trials for an MCED test that's focused on cancers for which there are no existing screening protocols?

A. There are.

Q. What are those challenges?

A. Yeah.

So for cancers where there is no existing screening methodology, those cancers tend to present

very late stage in disease, so finding early-stage -- patients with early-stage cancers is very hard and very rare.

So one of the significant challenges that GRAIL had in developing a cancer test that detected many cancers that were not screened for -- and that's 45 of the 50 cancers that GRAIL tests for are not currently screened-for cancers -- it had to set up clinical trials and in the case of the CCGA study had to develop 142 trial sites to find rare examples of individuals with these unscreened cancers at early-stage disease. It was, you know, unprecedented in scale and complexity and cost to do that.

Q. How would you compare the Galleri test to other tests in development as you -- as you're aware of them?

A. I'm not --

MR. WIDNELL: Objection. Foundation.

It's not clear what his basis for a comparison would be.

JUDGE CHAPPELL: Rephrase.

BY MR. MARRIOTT:

Q. Dr. Aravanis, are you -- do you -- as part of your job as chief technology officer of Illumina and in your prior position at GRAIL, are you -- do you have a

practice of following developments in the marketplace about other MCED tests in development?

A. Yes, I do.

Q. And do you have knowledge of what other companies have said publicly and what appears or doesn't appear in peer-reviewed journals about other MCED tests in development?

A. Yes. I do follow that public information.

Q. And do you recall the document that Mr. Widnell showed you during the in camera portion of your testimony, which I won't refer to in any detail, which described work you had done in thinking about other potential competitors in this space?

A. Yes. I -- I remember that document.

Q. With that, how would you compare the Galleri test to other tests in development?

A. I -- I'm not aware of any of the tests being developed by any of those companies that has overlap with the Galleri test or would compete with it.

Q. And while you were at GRAIL, did you consider other companies developing early cancer screening tests as competitors or potential competitors to Galleri?

A. Yeah.

So those companies listed we thought were the

most likely companies to potentially develop something similar. It's turned out now with the benefit of the time that's passed that based on the public information, that hasn't occurred, that they are not developing anything that would be a substitute or a competitive product.

Q. I'm going to ask you a few questions about what you understand -- withdrawn. I know that's -- "understand" is not a good word in this context, Your Honor.

JUDGE CHAPPELL: That's right.

Hang on. Before you do that, let's go ahead and take our lunch break.

MR. MARRIOTT: Okay. Fair enough.

JUDGE CHAPPELL: We will reconvene at 2:50, 2-5-0.

We're in recess.

(Whereupon, at 1:43 p.m., a lunch recess was taken.

AFTERNOON SESSION

(2:50 p.m.)

JUDGE CHAPPELL: Okay, we are back on the record in public session.

Proceed.

MR. MARRIOTT: Thank you, Your Honor.

BY MR. MARRIOTT:

Q. Dr. Aravanis, is Galleri intended to compete with any single cancer screening test?

A. It is not.

Q. Why not?

A. The single cancer screening tests I'm aware of are to be used in current standard of care applications. The Galleri test is not intended to be used for those purposes.

Q. Do you know whether Galleri will compete with a test that screens for fewer than ten cancers?

A. You know, given the different number of cancers, all the different types of indications, I think that's unlikely.

Q. Do you know whether Galleri will compete with a test that does not identify tumor of origin?

A. I don't believe so.

Q. And why not?

A. A test that does not determine tumor of origin

presumably would be used in a very different clinical context, for example, with an imaging modality. So, again, a very different use case.

Q. Does Illumina have any plan to raise costs to GRAIL's rivals?

A. No.

Q. And why not?

A. You know, Illumina's business is based on growing sequencing markets, so lowering the cost, allowing people to do more sequencing. So existing customers today do more samples, do more science and discovery work.

Illumina's business has also been driven by new applications that are developed. So by lowering costs, you know, many of the applications today became possible, and people innovated and created those. So Illumina is hoping for more of those applications to be developed. And so there's a strong incentive for us to continue to decrease cost, and that's our plan.

Q. And do you know what impact foreclosing a GRAIL rival would be on Illumina's sequencing business?

A. It would harm it. We would decrease our revenue.

Q. Do you know what impact foreclosing a GRAIL rival would have on Illumina's reputation?

A. It would be very detrimental. So our business is based on customers using our platforms for their applications, developing new applications. Were we to do something like that, you know, they could potentially move to other systems, right?

So they have those opportunities today, and we expect them to have even more sequencing alternatives in the future. Were we to do something like foreclose on a customer's business, you know, I think we would jeopardize the existing customer relationships.

I would also add just at a kind of reputational level, to do something like that I think, you know, is not consistent with our mission and values.

Q. What is the cost of sequencing as a percentage of the development costs of an MCED test like Galleri?

MR. WIDNELL: Objection. Foundation. To the extent that counsel is asking about Galleri, that's one thing, but if he's asking the witness to speculate about other MCED tests, there is no foundation.

JUDGE CHAPPELL: Rephrase or lay a foundation.

MR. MARRIOTT: I am happy to rephrase, Your Honor.

BY MR. MARRIOTT:

Q. What is the cost of sequencing as a percentage of the development cost of Galleri?

A. It was about 10 percent of the overall development cost.

Q. And what is the cost of sequencing as a percentage of the revenue of Galleri?

A. It's less than 10 percent.

Q. And what percentage of the cost of MCED tests do you project will be attributable to sequencing costs over the next several years?

MR. WIDNELL: Objection to foundation again. He's asking about multiple MCED tests and not just Galleri's.

JUDGE CHAPPELL: Rephrase and make sure what you're talking about there.

BY MR. MARRIOTT:

Q. What percentage of the cost of the Galleri test do you project will be attributable to sequencing costs over the next several years?

A. It will go down to 5 percent and then even less over time.

Q. Has Illumina made any determination as to whether MCED test developers will be able in the future to reduce the amount of sequencing that tests require?

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: That's a fair question. Overruled.

THE WITNESS: Yeah. So it will decrease over time. So for the Galleri tests we discussed, you know, GRAIL has innovations that will lead to a decreased usage of sequencing over time. You know, that, by itself, would reduce the amount of cost associated with sequencing per test.

You know, Illumina has -- is also going to lower the cost of sequencing over time. Other sequencing providers are going to also. So this will compound the overall reduction in sequencing costs as a fraction of the test.

MR. MARRIOTT: Your Honor, I'm just pausing because I think I may have seen a witness about to come later appear in this phase. I think we probably need to fix that.

MS. MUSSER: Yes. I was just alerting Your Honor to the same thing.

UNIDENTIFIED SPEAKER: Okay, apologies. I'll leave.

JUDGE CHAPPELL: Thank you.

MR. MARRIOTT: Let me see where you were, Doctor, before I interrupted.

BY MR. MARRIOTT:

Q. All right. I'm sorry, Dr. Aravanis, did you have an opportunity to finish your answer to that

question or would you like it back?

A. I did. I did complete my answer.

Q. Has Illumina made any commitment about not raising costs to GRAIL rivals?

A. It has.

Q. And what are those commitments?

A. So Illumina has an open offer letter to companies that may develop similar products to Galleri and others in the oncology space. That letter guarantees that prices will never be raised. It also guarantees a price reduction over time of at least 43 percent.

Q. Do you know whether the projected size of the clinical testing market will give Illumina an incentive to harm GRAIL's rivals?

A. I don't believe so.

Q. And why not?

A. You know, again, Illumina's larger business is based on many customers using Illumina's sequencing platform for their clinical applications, developing new clinical applications. You know, we want that to continue and grow. Raising prices would be counterproductive to that.

In addition to that, I would say that we know that, you know, customers have alternative sequencing

options today, and they're going to have many more in the future.

Q. Aside from ordinary-course customer support, how much cooperation does an MCED test developer require from Illumina if it's developing an MCED test as an LDT?

A. I don't believe there's any additional assistance required beyond standard, you know, servicing of the instruments and maintenance, things like that.

Q. And how much cooperation does a developer need if it's developing an MCED as an FDA-approved IVD distributable kit?

A. Very little assistance.

Q. Has Illumina made any determination as to when MCED test developers will seek distributed IVD kits for cancer screening tests?

A. It has not.

Q. Is GRAIL developing its test as an IVD distributable kit?

A. It is not.

Q. And why not?

A. Developing a distributed IVD NGS product is a very long and complex process. For the foreseeable future, GRAIL believes that it can address, you know,

the market needs as an LDT and as a site-specific PMA.

Q. Does Illumina have any incentive to create sequencing systems that are optimized for Galleri but that don't work for a rival third-party test?

A. No, it does not.

Q. And has Illumina optimized any of its products for Galleri?

A. It has not.

Q. Does Illumina have any pattern or practice of optimizing its sequencers for a particular application?

A. No, it does not.

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: Do you want to rephrase or --

MR. MARRIOTT: I'm happy to --

JUDGE CHAPPELL: -- ask a foundational question?

MR. MARRIOTT: Sure.

BY MR. MARRIOTT:

Q. As the chief technology officer of Illumina, Doctor, do you know whether the company has a pattern and practice of optimizing sequencers for particular application?

A. It does not.

Q. Do you know whether Illumina can materially disadvantage a GRAIL rival because the open offer

doesn't require Illumina to give them access to pre-release NGS products until 45 days after those products are accessible to GRAIL?

MR. WIDNELL: Objection, Your Honor. This is coming very close to opinion testimony that goes to legal questions in this case or economic questions in this case.

JUDGE CHAPPELL: Response?

MR. MARRIOTT: Sure. I don't -- I don't -- I apologize, Your Honor. I don't think that it -- I don't think that it does go to legal questions directly, nor do I think that it goes to opinion questions directly. It is a -- it is a question designed to respond to a factual allegation elicited from the Government during one of their examinations, and it asks about the open offer and how the open offer operates or doesn't operate and what incentives it creates or doesn't create.

JUDGE CHAPPELL: Well --

MR. WIDNELL: May I respond, Your Honor?

JUDGE CHAPPELL: Yes, go ahead.

MR. WIDNELL: Just to focus, the objectionable part of the question, I think, was when he asked if it would materially disadvantage the company. That seems like a legal conclusion to me.

MR. MARRIOTT: I'm happy to take out the word "materially" if that will resolve the concern.

JUDGE CHAPPELL: Rephrase.

BY MR. MARRIOTT:

Q. Do you know whether Illumina can disadvantage GRAIL rivals because the open offer doesn't require Illumina to give them access to pre-release NGS products until 45 days after those products are accessible to GRAIL?

A. I don't see how that would disadvantage another test developer.

Q. And why do you say that?

A. These tests are developed over many years. Forty-five days is a very inconsequential amount of time relative to the years it takes to develop one of these products.

Q. Do you know whether Illumina can disadvantage a GRAIL rival by telling GRAIL about new Illumina NGS products before giving anyone access to those products?

MR. WIDNELL: Objection. Foundation. It's not clear how he would know how an MCED -- another MCED test developer would be disadvantaged or not.

MR. MARRIOTT: Your Honor, I believe the same question was asked of an MCED developer representative.

JUDGE CHAPPELL: The question currently posed

is "do you know." I'll allow it.

THE WITNESS: You know, knowledge that a future sequencer is going to come out without access to it, to do testing and development, is not a meaningful advantage.

BY MR. MARRIOTT:

Q. Does Illumina monitor investment in MCED testing?

A. It does.

Q. And what can you tell the Court about the investment activity in MCED testing since the announcement of the Illumina/GRAIL transaction?

A. We're aware of multiple companies raising additional money to develop MCED tests; new companies being founded and very well financed.

Q. And has Illumina made any determination as to whether this transaction will promote innovation?

A. Yes. Illumina believes it will significantly increase innovation in the field.

Q. And what impact would it have on Illumina's sequencing business if Illumina impeded innovation in NGS sequencing tests?

A. It would be detrimental to our business. The growth of our business depends on existing customers innovating, you know, using more and more sequencing,

and new applications being developed.

Q. And what impact, if any, would it have on Illumina's reputation if Illumina impeded innovation in NGS screening tests?

MR. WIDNELL: Objection. This is getting pretty much into pure speculation.

MR. MARRIOTT: I'm happy to respond, Your Honor, if you like.

JUDGE CHAPPELL: I'm looking at the question.

The question's fine. Overruled.

THE WITNESS: Yes, impeding innovation would be very -- have a very negative impact on our reputation. I believe, you know, some customers would not invest in developing new applications on our platform, could eventually move to other platforms, all of which would be negative for our business.

BY MR. MARRIOTT:

Q. What impact would it have on Illumina's ability to attract and to retain the most talented scientists if Illumina impeded innovation in NGS testing?

A. Yeah, you know, many employees come to Illumina because of our culture and our values. The -- you know, impeding innovation would be counter to that, I think, from a -- you know, retaining the talent we have and attracting new people who want to work on

developing new sequencing technology applications. It would be problematic.

Q. Let me shift gears and ask you a little bit about NIPT. Are you knowledgeable personally about the NIPT space?

A. Yes, I am.

Q. And are you knowledgeable about Illumina's acquisition of Verinata?

A. I am.

Q. And what can you tell the Court about Verinata's market share since the Illumina acquisition?

A. It's decreased.

Q. And how, if at all, has the output of NIPT tests changed since 2013 when Illumina acquired Verinata?

MR. WIDNELL: Foundation. Objection.

JUDGE CHAPPELL: Overruled.

THE WITNESS: Since the acquisition, the cost of noninvasive prenatal testing has decreased by over 90 percent. The number of tests performed has gone up by a factor of a hundred. The number of companies offering noninvasive prenatal tests has decreased -- I'm sorry, has increased significantly. The coverage of patients for noninvasive prenatal testing has increased by at least 100 million women, you know,

since the acquisition.

BY MR. MARRIOTT:

Q. And do you know whether there have been any new entrants in the NIPT space since 2013?

A. Yes, a significant number. I don't know the exact number.

Q. Were you involved in the Illumina analysis of the GRAIL acquisition?

A. Yes, I was.

Q. And tell His Honor what your role was, please.

A. I was a cosponsor of the project that evaluated the acquisition.

Q. And at a high, sort of summary level, what was the strategic rationale for the GRAIL merger?

A. Excuse me. First and foremost was to, through the acquisition, to accelerate the adoption of Galleri, and by doing so, increasing the number of tests, you know, performed for patients by millions than would otherwise happen in the absence of the acquisition, by doing additional millions of tests, potentially saving tens of thousands of additional lives.

Q. Based on your experience at Illumina and GRAIL, are you knowledgeable about the efficiencies that the reunification of Illumina and GRAIL will generate?

A. Yes, I am.

Q. And can you please explain to the Court, at a high level, what benefits you expect to come with the reunion of Illumina and GRAIL, and then I'll try to take you through each of these in turn.

A. Yes. The biggest and most important is saving lives, decreasing the number of people who have to die from a late-stage cancer diagnosis.

In addition to that, we'll be able to accelerate the FDA approval of GRAIL. We'll be able to eliminate the royalty associated with the current relationship.

There are supply chain and operational efficiencies that will help with both the scale-up of the testing and decrease the cost of testing faster than it would otherwise.

There are multiple R&D efficiencies associated with the acquisition. We'll be able to eliminate the double-marginalization and pass the savings on to payers of the test and patients, and we'll be able to accelerate international expansion of the test.

Q. All right. So let me start with the point about saving lives. What role will cancer screening have on saving lives? If we can, I'll refer you to Demonstrative RDX 6 at 23, if I may.

A. So --

MR. WIDNELL: Objection. Your Honor, this is basically opinion testimony that is delving into the field of expert testimony.

JUDGE CHAPPELL: You need to rephrase with, instead of asking for speculation or conjecture or predictions, what facts does he know. He's a fact witness.

MR. MARRIOTT: Your Honor, I will do that happily, and just to clarify, I believe what the witness said previously is that based upon his experience, right before I put the demonstrative up, that he is knowledgeable about the efficiencies this transaction will generate. Those efficiencies are necessarily future efficiencies, Your Honor, because the transaction has not -- has not yet reached a point where the companies have been able to integrate, and I intend to ask him about specifically what the company has determined those efficiencies will be.

JUDGE CHAPPELL: Well, and that's fine. I haven't heard that foundation, because if predictions and determinations, calculations have been made, that's a fact. That's not speculation. So with that in mind, go ahead.

BY MR. MARRIOTT:

Q. Why don't we go back, if we could, to the prior

slide, please, which is RDX 6 at 22.

Dr. Aravanis, has Illumina determined that there will, in fact, be efficiencies arising from the reunification of Illumina and GRAIL?

A. It has.

Q. And are those the efficiencies that you testified to here a few moments ago and that appear on RDX 6 at 22?

A. Yes, they are.

Q. All right. So, with that in mind, let me turn, if we could, to RDX 6 at 23 and ask you, what will cancer -- based on the determinations that you've made, what will cancer screening -- what will the effect of cancer screening be on saving lives based upon your research and your experience in this space?

A. Cancer screening from the Galleri test will significantly reduce the number of cancer deaths.

Q. And why do you say that, sir?

A. Today, of the 50 cancers that the Galleri test tests for, 45 of those are currently unscreened for. So that's a tremendous unmet need in cancer screening. The ability to find those 45 cancers earlier, when their prognoses are better, will lead to improved treatments and improved outcomes.

Q. Have you conducted any study on the life-saving

benefits of an MCED test?

A. Yes.

Q. Why don't we take a look, if we could, please, at RX 3178 in evidence. Do you recognize RX 3178, Dr. Aravanis?

A. Yes, I do.

Q. And what is this, please?

A. This is a publication describing modeling work on the reductions in late-stage cancer deaths by using the Galleri test.

Q. What's the name of the study?

A. The title is "Modeled Reductions in Late-stage Cancer with a Multi-Cancer Early Detection Test."

Q. What was your role, sir, in this study?

A. I'm an author on the study, so was involved in all aspects of the study and writing the publication.

Q. And who else was involved in the study?

A. Two GRAIL employees, Earl Hubbell and Christina Clark, and an investigator at the National Cancer Institute, Christine Berg.

Q. And when was this study published?

A. Early in 2020.

Q. And was it published in a peer-reviewed publication?

A. I'm sorry. I want to correct something. It

was early in 2021, it was published.

Q. And was it published in a peer-reviewed publication?

A. Yes. It was published in a peer-reviewed journal.

Q. And please, if you would, describe the study for the Court.

A. Yeah. The study --

MR. WIDNELL: Objection. Your Honor, this is still basically expert testimony, and I'm not doubting that they could potentially introduce Dr. Aravanis as an expert, but they haven't. This is -- this is talking about modeling effects of the -- of the MCED test in the future in terms of what its effects may ultimately be, and that is, I think, fairly clearly expert testimony.

JUDGE CHAPPELL: Do you want to respond?

MR. MARRIOTT: Sure, Your Honor. Thank you.

It's a study that the witness has just testified that he actually personally did and conducted. So I think -- you know, maybe he is an expert, but he's offering here testimony about something he actually did, a study he performed.

JUDGE CHAPPELL: Lay witnesses generally do not talk about studies. Since he did it, I will allow one

or two more questions, and then you are going to have to move along.

MR. MARRIOTT: Okay. Thank you, Your Honor.

BY MR. MARRIOTT:

Q. Dr. Aravanis, can you please describe the study for the Court?

A. Yes. The study estimates the benefits of using the Galleri test in a population like the United States.

Q. And what was the upshot of the study? What are the results of the study?

A. That using the Galleri test, you know, in a population, for example, of 100,000 individuals, you would find approximately 500 cancers earlier than they would be found otherwise. And finding those 500 cancers earlier, you would avert 100 deaths in those 100,000 individuals and reduce the total amount of cancer death by 26 percent.

Q. We can take that down. Thank you.

And as a -- as a participant in the study and as an author of the study, do you have a view as to whether that study is reliable, Doctor?

A. Yes. The work was done in a rigorous way, carefully evaluating all of the inputs into the model, using high-quality data, and it went through a

peer-review process where it was reviewed by independent scientists.

Q. While you were at GRAIL, did you make any determination as to whether the Galleri test would -- would meet an unmet patient need in cancer screening?

A. Yes, I did.

Q. And what was that determination?

A. The conclusions of that were that 45 of the 50 cancers that the Galleri test screens for currently have no screening test today. Also, that if you take all of the people who die of cancer, over 70 percent die of a cancer for which there is no screening test today. That means that they had no opportunity through testing to find that cancer early when potentially the treatment and prognosis could have been better.

Q. We can take that down. Thank you.

Can you give us an example of the successes that Galleri has had in detecting cancer in asymptomatic patients?

A. Yes. If you look at the data in the Pathfinder study, it shows multiple individuals who had early cancers that were detected by the Galleri test.

Q. And have you evaluated what would happen if the widespread adoption of Galleri could be accelerated by a year?

MR. WIDNELL: Objection. This is calling for expert testimony again.

JUDGE CHAPPELL: I've already said you're going to move on from the study. I'm not allowing any more questions about the study. And if this is a new subject, which it best be, lay a foundation.

MR. MARRIOTT: Well, I thought it was a new subject, Your Honor. I will -- I will endeavor to lay a foundation for it.

BY MR. MARRIOTT:

Q. Have you made any determination, Dr. Aravanis, as to what the effect would be of accelerating the adoption of the Galleri test by a year?

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: It's a yes or no question, and he can tell us what that determination is, if he knows, but that's all.

THE WITNESS: The answer is yes.

BY MR. MARRIOTT:

Q. All right. And what is that determination?

A. It -- the -- by accelerating the Galleri test adoption by one year, approximately 20,000 additional lives could be saved.

Q. Now, switching gears, Doctor, to another topic, have you evaluated the impact that FDA approval would

have on the widespread adoption of the Galleri test?

A. Yes.

Q. And does GRAIL need FDA approval to achieve widespread adoption?

A. It does.

Q. And why is that?

A. Widespread adoption of the Galleri test will require coverage by public -- by public payers, like Medicare and Medicaid. They will require FDA approval before covering the Galleri test.

Q. And at a high level, what is required to get FDA approval for a test like Galleri?

A. Yeah, demonstration that the test was developed and will be operated in accordance or in compliance with FDA quality system regulations and clinical evidence demonstrating the performance of the Galleri test.

Q. And what experience, if any, does GRAIL have in getting FDA approval?

A. None.

Q. And what experience, if any, does Illumina have in securing FDA clearance and approvals?

A. Illumina received the first FDA clearance for a next-generation sequencer. It's received over 70 clearances and registrations around the world in 45

countries. It's received multiple clearances and a PMA approval in the United States.

Q. And what hurdles do you expect GRAIL would encounter if it tried to seek FDA approval alone?

MR. WIDNELL: Objection. Foundation. Also, he's effectively asking for an opinion by asking what GRAIL expects.

MR. MARRIOTT: I'm happy --

JUDGE CHAPPELL: As properly worded, that objection is sustained. We don't want to know what he expects. We want to know what he knows.

MR. MARRIOTT: Fair enough, Your Honor. I'll rephrase the question.

BY MR. MARRIOTT:

Q. Have you made any determination as to whether GRAIL would encounter difficulties if it sought FDA approval as a standalone company?

A. Yes.

Q. And what have you determined?

A. That GRAIL will encounter substantial challenges in their submission process.

Q. And how can Illumina help GRAIL to obtain FDA approval of Galleri?

A. Illumina has a large regulatory team that's experienced in FDA submissions. It has processes,

templates, infrastructure for doing and writing and submitting, you know, PMA applications.

In addition to that, upon submission, Illumina has similar, expertise capabilities, processes for working with the FDA after submission to achieve approval.

Q. Has Illumina experienced any challenges in getting FDA approval of its own products?

A. Yes, it has.

Q. And given those challenges, why is it that you believe that Illumina would be able to assist GRAIL in achieving accelerated FDA approval?

A. Yeah. Illumina has made applications and has multiple pending applications for first-in-kind products for next-generation sequencing. In doing that, it's broken new ground working with the FDA on how to develop applications for these types of processes.

They're very complex diagnostics. The applications are complex, and it's learned a tremendous amount in doing that and incorporated those into the current processes and templates for making applications. Those benefits will be conferred to GRAIL as part of the acquisition.

Q. What is Illumina's plan to accelerate FDA

approval of Galleri?

A. Illumina's plan is to give GRAIL capabilities that are known to be a gap, for example, a sophisticated quality management system, GRAIL will need that. It will also need additional studies, templates, processes that it doesn't have or are currently deficient today. So we will give those to GRAIL and help them use them as part of a submission.

Q. Do you know whether the firewall that Illumina has put in place in the open offer impedes Illumina from realizing the FDA acceleration efficiency you've described?

A. No. I don't see how it would impede it.

Q. And why is it that you believe the acquisition here would accelerate the FDA approval of Galleri?

A. By itself, GRAIL today doesn't have all of the necessary capabilities, staff, quality system, templates, processes to -- to do an application. It will take it substantial time to develop those capabilities, whereas Illumina can provide those capabilities immediately and, therefore, submit their application sooner than they would otherwise.

Q. Let me ask you a little bit about payer approval. Are you knowledgeable about the role of payer approvals in obtaining widespread adoption of an

MCED test?

A. Yes, I am.

Q. And is payer approval important to the widespread adoption of an MCED test?

A. Yes, it is.

Q. At a high level, what is required to get private insurers to pay for a cancer screening test?

A. The most important thing is clinical utility, evidence showing the benefit of the -- of the test.

Q. And what, if any, experience does GRAIL have in obtaining payer coverage?

A. None to my knowledge.

Q. And what experience does Illumina bring that could help get coverage for Galleri?

A. Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing for genetic disease over the last two years.

In the United States, we have now achieved 200 million people who can receive coverage for comprehensive genomic profiling using NGS technology. These were largely driven by Illumina's market access efforts.

Q. And why couldn't GRAIL do those kinds of things on its own without Illumina?

A. It doesn't have the same level of expertise, processes, infrastructure, doesn't have the reputation, track record, size of business that would be required to enter into those types of relationships.

Q. And what is Illumina's plan to achieve payer coverage for Galleri?

A. To apply the same approaches that Illumina used in other areas where it's increased market access and reimbursement.

Q. And would the firewall that Illumina has put in place under the open offer impede Illumina from realizing payer acceleration?

A. No, it would not.

Q. Let's talk a little bit about R&D efficiencies, Doctor. What role does R&D play in Illumina's business?

A. At Illumina, you know, innovation is incredibly important to the company, and we invest tremendously in research and development. Close to 20 percent of our revenue -- I believe in the most recent year that was approximately $650 million -- was invested in research and development.

Q. And how does Illumina's investment in R&D compare to the investments of its peers?

A. Compared to peers of similar size, I believe

it's -- it is substantially larger.

MR. WIDNELL: Objection. Foundation.

JUDGE CHAPPELL: That's sustained.

MR. MARRIOTT: May I endeavor to lay a foundation, Your Honor?

JUDGE CHAPPELL: Go ahead.

BY MR. MARRIOTT:

Q. Dr. Aravanis, are you aware of the level of investment that Illumina makes as compared to that of its peers?

A. I am.

Q. And how does Illumina's investment in R&D compare to that of its peers?

A. It's larger.

MR. WIDNELL: Objection. Your Honor, I apologize, but he hasn't explained what his basis for answering the question is. He's just said that he's aware.

MR. MARRIOTT: I can ask that additional question if you like.

JUDGE CHAPPELL: Do that.

BY MR. MARRIOTT:

Q. Dr. Aravanis, can you tell us, please, how it is you know the level of investment made by Illumina and its peers in R&D?

A. Yeah. So investment levels in R&D are shared by public companies, so looking at those reports from comparable companies in the industry, I have an under -- provides the information on what the levels of investment are. So it's based on that that I make the statement that Illumina's, you know, level of R&D investment is higher than, you know, comparable companies in the space.

Q. Could you describe for us, please, the educational and professional background of the R&D team at Illumina?

A. Yeah. Of the approximate -- of the approximately 1800 people in the core research and development group at Illumina, about a quarter of those, you know, close to 500, have advanced scientific or advanced engineering degrees.

Q. And how, if at all, have Illumina's R&D efforts contributed in the fight against COVID?

A. Yes, Illumina has made a major contribution in the fight against COVID. Early in 2020, Illumina set out to develop a COVID sequencing assay. So this is a product to sequence the viral genome in a COVID patient sample. Illumina did so in record time, a couple of months. It received the first emergency use authorization from the FDA for a COVID sequencing test.

There's now over 70 countries in the world that use Illumina's products for COVID sequencing. There's approaching a million sequences now on the COVID viral genome produced by Illumina's systems. When you hear about things like the DELTA variant or other types of variants, most of that data that's leading to those conclusions and understandings about these increased variants, how they might be affecting transmissibility, disease severity, vaccine efficacy, Illumina's data is being used in all of those important public health and medical decisions.

Q. Now, you said that the transaction will create R&D efficiencies. Can you categorize for us the types of R&D efficiencies that the transaction will create?

A. Yes. There are R&D efficiencies that will benefit the GRAIL division, and there's R&D efficiencies also from the transaction that will benefit the rest of Illumina.

Q. So how will the transaction allow for improvements to the Galleri test?

A. Yeah, there are several types of R&D efficiencies that will benefit the Galleri test.

Q. And are there -- sorry, go ahead. I thought you were finished.

A. Should I -- should I specifically discuss those

efficiencies?

Q. Please, if you would.

A. Okay, excuse me.

One of those is improving the performance of the Galleri test. So Illumina is developing applications in multiple areas: noninvasive prenatal testing, genetic disease testing, therapy selection. We believe that some of those innovations that we're making in those other areas we will be able to apply also to future versions of the Galleri test, improving the performance and, therefore, increasing the clinical value of the test.

Another type of R&D efficiency will be to lower the cost of the Galleri test faster. Illumina has significant experience and capabilities in miniaturizing assays, simplifying assays, developing new components for assays that can lower cost, internalizing manufacturing of expensive components, and by internalizing the manufacturing of them, reducing the cost of the overall test. Illumina can manufacture its own enzymes and, therefore, this makes the internalization and manufacturing at lower cost possible.

Q. Could you give us some examples of the specific ways that Illumina will be able to improve the Galleri

test?

A. Sure. So if you take noninvasive prenatal testing, for example, over the years, Illumina has made some significant innovations to lower the cost, improve the performance, and decrease the turnaround time of the test. So it included simplifying the work flow, combining chemistries and reagents to do multiple steps in a single step, making the amount of reagents or chemicals used smaller through miniaturization, also developed automation techniques that allow the testing to be reproduced at scale, also came up with ways to speed up the chemistry and steps.

Over time, the noninvasive prenatal testing work flow that was originally from Verinata went from a two-day work flow to approximately a three-hour work flow. All of those capabilities, you know, and similar types of -- will be applied to the Galleri test, and we'll achieve similar types of benefits.

Q. And why couldn't Illumina do all that as a nonequity partner of GRAIL?

A. To perform that kind of research and development requires knowledge of the underlying technology. So that would require GRAIL to share, you know, information on its assay, so all of the chemistries, the materials in it, the protocol.

It would also require it to share with us all of its software and bioinformatics. Without that, those type of innovations wouldn't be possible.

Q. Now, you said that the transaction would also lead to R&D developments and efficiencies unrelated to Galleri. How will the transaction lead to R&D developments unrelated to Galleri?

A. Yes. There's a couple ways that we think the transaction will lead to R&D benefits to the larger Illumina. One is novel discoveries. So our experience, for example, in noninvasive prenatal testing is that when you operate a clinical test as a large service, you will have additional findings. Those could give insights into other types of diseases that GRAIL's technology could be useful for. For example, fatty liver disease or neurodegenerative disease. Those are other applications Illumina would pursue.

In addition, we've found that there's significant cross-pollination between applications, meaning that there's aspects of GRAIL's methylation technology that could be useful for noninvasive prenatal testing or genetic disease testing.

Q. Can you give us a little more specificity around the R&D efficiency you described for fatty liver

disease, as an example?

A. Sure. So GRAIL has some preliminary findings that the methylation technology can be useful for detecting fatty liver disease and, in particular, a very advanced form of that disease. That advanced form of disease can lead to cirrhosis and liver failure.

It's an area of a lot of pharmaceutical development to see if that type of advanced fatty liver disease can be -- can be halted through different therapeutics. So that's an area where Illumina would be interested in further exploring and developing a product.

Q. Can you give us a little more specificity around the R&D efficiency you would expect concerning signals for diabetes and cardiovascular disease?

A. Yeah. So there's evidence of other types of diseases that can be detected using GRAIL's methylation technology. These include metabolic diseases, cardiovascular disease, you know, heart attacks, psychiatric diseases. There's initial evidence that many of these diseases have signals in the blood that could be detected with the GRAIL technology.

Q. Just one last example. Can you give us some specifics around the efficiency you expect concerning neurodegenerative disease?

A. Yes. So I think we're all familiar with the devastating aspects of neurodegenerative diseases, diseases like Alzheimer's, like Parkinson's disease, like, you know, also, multiple sclerosis. You know, the world needs diagnostics for these applications. Today, there are not diagnostics that meet the needs for clinicians and patients.

Given that, there's potential to develop such tests using the Galleri or the GRAIL technology. Illumina would invest in reconfiguring and optimizing the GRAIL technology for these applications, investing in clinical studies, discovery studies, and, if successful, clinical development studies to bring these to market.

Q. And why couldn't GRAIL just pursue projects like that on its own?

A. GRAIL doesn't have --

MR. WIDNELL: Objection. I'm not sure what the foundation is.

MR. MARRIOTT: I'm happy to ask a foundational question.

BY MR. MARRIOTT:

Q. Do you know, Dr. Aravanis, whether GRAIL could pursue the projects of the kind you've described on its own, independent of Illumina?

A. It would be very difficult for GRAIL to pursue these on its own.

Q. And why is that?

MR. WIDNELL: Objection. I still haven't heard an answer about what Dr. Aravanis' foundation is for answering the question.

JUDGE CHAPPELL: First of all, I said go ahead, earlier. My mic was muted. So now I'll deal with this objection, and I'll repeat what I said earlier to Complaint Counsel. When it's your turn to examine the witness, you may test, delve into, or challenge any of these answers that you would like to, and it doesn't end there. We have post-trial briefings and replies as well.

With that, rephrase, lay a foundation, or move on.

BY MR. MARRIOTT:

Q. Dr. Aravanis, as chief scientific officer at GRAIL and as chief technology officer at Illumina, have you made any determination as to the kinds of projects that GRAIL could and could not pursue independent of Illumina?

A. Yes. So I was at GRAIL leading the research and development program there when these signals in fatty liver disease were detected. At the time, we

determined that the company did not have the resources or appropriate expertise to pursue this application, and we stopped that program.

Q. What can you -- withdrawn.

Do you know whether the R&D efforts you've described will lead to cost reductions?

A. Yes. So at Illumina, again, our experience in noninvasive prenatal testing that led to a cost reduction of 90 percent since the acquisition of Verinata, there are many analogous aspects to the GRAIL test; simplification of the work flow, combining steps, new reagents that can perform multiple steps, insourcing of expensive components and manufacturing them at Illumina. We see analogous opportunities in the GRAIL work flow for us to apply those capabilities and reduce the cost much faster.

Q. Do you have any personal experience, Doctor, with generating R&D efficiencies in connection with transactions?

A. I do.

Q. What, specifically?

A. So in noninvasive prenatal testing, being involved in the research and development of future versions of that at Illumina that led to significant cost reductions. Also, in the development of

exome-sequencing products, I oversaw research and development that led to significant decreases in cost, miniaturization, reduced -- much faster testing. There's additional examples I could give.

Q. Does the firewall that Illumina put in place under the open offer impede Illumina from realizing R&D efficiencies?

A. No, I don't believe so.

Q. Do the teams at Illumina who would contribute to the R&D efficiencies you've described also work with Illumina's NGS oncology customers in any capacity?

A. No, they do not.

Q. And do the teams at Illumina who would contribute to R&D efficiencies have access to the information of Illumina's NGS oncology customers?

A. They do not have access.

Q. Now, Illumina has said that the transaction will reduce -- and you've said -- that the transaction will reduce the royalty owed by GRAIL to Illumina. Before the transaction closed, did GRAIL owe Illumina a royalty?

A. Yes.

Q. And now that the transaction has closed, does GRAIL owe Illumina a royalty?

A. It does not.

Q. And are you -- are you personally familiar with all the particulars of that royalty?

A. I am not.

Q. Okay. You said that the transaction will also eliminate double-marginalization. Before the transaction closed, did Illumina charge a margin to GRAIL on sales of its NGS products?

A. It did.

Q. And did GRAIL project a margin on its products?

A. Yes, it did.

Q. Are you familiar, Doctor, with the particulars of the extent to which the transaction will eliminate double-marginalization?

A. I am not.

Q. Do you have personal knowledge of Illumina's supply chain?

A. I do.

Q. And you said that the transaction will result in supply chain efficiencies. Why do you say that?

A. Yeah, so during the due diligence process, we identified common suppliers for core components of the Galleri assay. Again, these are common to components that Illumina purchases today at a very large scale, a very large volume.

The cost reductions associated with volume that

Illumina benefits from could be shared with GRAIL as part of an integrated company. Therefore, the cost of goods for the Galleri test would decrease.

Q. As the chief technology officer of Illumina, are you knowledgeable about the company's general operations?

A. Yes.

Q. And do you know what operational efficiencies will result from the re-acquisition by Illumina of GRAIL?

A. Yes. Illumina operates multiple clinical laboratories, has operated genomic testing at a very large scale, you know, millions of tests per year. In doing that, has developed very sophisticated laboratory operations that can be shared with GRAIL to lower their cost of operating labs.

Q. Well, how will Illumina's operational capabilities help GRAIL?

A. So Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories. We believe that will lower the

facilities costs that GRAIL will incur, and those, again, costs can be passed on to people purchasing the test.

Q. Is the lab --

MR. WIDNELL: Objection, Your Honor. Again, the witness is stating what they believe rather than what they're currently planning.

JUDGE CHAPPELL: Sustained.

MR. MARRIOTT: Your Honor, may I try to lay a further foundation for the -- that testimony?

JUDGE CHAPPELL: Go ahead, and I'm going to instruct the witness again, we want to know what you know. This is not about what you believe, what you expect, what you think might happen. Understood?

THE WITNESS: Yes. Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. MARRIOTT:

Q. Dr. Aravanis, do you know whether the reunification of Illumina and GRAIL will result in operational efficiencies?

A. Yes.

Q. Okay. And what efficiencies do you know will come of that reunification?

A. Reduction in the labor costs, reduction in the facilities costs, reductions in automation.

Q. And are the -- the laboratory operation efficiencies you described, are they just cost efficiencies or is there more to it?

A. They're mostly cost efficiencies.

Q. So what role will -- you mentioned international acceleration. So let me ask you a few questions about that, and we're getting close to my being able to wrap it up here.

What role will the international presence and capability play in the success of an MCED test?

A. International expansion of the test will benefit patients in many ways. First, other countries in the world, other than the United States and other than the United Kingdom, will be able to get access to the Galleri test much sooner than they would otherwise. So obviously that's a very large number of people around the world who can potentially then benefit from the Galleri test and find cancers early.

By scaling up the test to much larger volumes through international expansion, there will also be benefits to testing in the United States. By operating at much larger scales, the cost of the components associated with the Galleri test will go down faster, and those cost reductions will benefit testing in a -- in the United States.

In addition, the larger amount of testing that will happen worldwide will generate a significant amount of data on the test performance. That data can be used as clinical utility information in payer discussions, enabling coverage of the test much sooner by payers. That information can also be used in regulatory submissions, for example, with the FDA, to accelerate approval of the test.

Q. Do you know if helping GRAIL to automate its lab operations will impact turnaround time for the Galleri test?

A. Yes.

MR. WIDNELL: Objection. That's a leading question.

JUDGE CHAPPELL: I didn't hear that.

MR. WIDNELL: Objection. The question was leading.

JUDGE CHAPPELL: Do you know if -- it doesn't suggest an answer. I'm going to overrule that. The witness could have said yes or no.

THE WITNESS: The answer is yes.

BY MR. MARRIOTT:

Q. Could you please explain that, Doctor?

A. The GRAIL test today, you know, is a complex work flow taking many days. The laboratory

efficiencies that Illumina can apply to the GRAIL test -- faster automation, better logistics in the laboratory -- will lead to faster turnaround time of processing samples.

Q. How would you describe Illumina's international presence?

A. Yeah, Illumina operates its business in the majority of the companies -- in the majority of the countries in the world, so it has commercial, regulatory, product support, again in -- I don't know the exact number, approximately 100 countries in the world.

Q. And how would you describe Illumina's international capabilities?

A. Illumina can ship and sell products in those many countries, you know, around the globe. It can support those products around the globe. It can also pursue regulatory filings and clearances in those countries around the world.

Q. How would you characterize GRAIL's international presence and capabilities?

A. It has a small presence in the United Kingdom. Other than that, I'm not aware of any other international capabilities.

Q. And what impact will international acceleration

of the adoption of the Galleri test have on the United States?

A. Yeah, so --

MR. WIDNELL: Objection. Calls for speculation.

JUDGE CHAPPELL: All right. Based on the objection, let's have a foundation for that.

BY MR. MARRIOTT:

Q. Dr. Aravanis, have you made any determination as to the impact that acceleration of the Galleri test internationally would have on the test in the United States?

A. Yes.

Q. And what is the basis of that determination?

A. The basis of the determination is, number one, our plans for making the Galleri test available in the many countries around the world that we operate, that GRAIL does not operate today, so that's our basis of the determination, that the test will be available worldwide, much faster than GRAIL could given that it has no operations in those countries.

With offering that test in many countries in the world, that will generate a significant amount of testing data. We know that that testing data will be useful in payer discussions around the questions

they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval.

Q. Why couldn't GRAIL just go out and hire a bunch of scientists and sequencing experts to help it achieve the R&D efficiencies that you've described without merging with Illumina?

A. These R&D capabilities take a substantial amount of time to develop, so it's taken, you know, many years for Illumina to hire these individuals, to train them, to develop the programs and teams that can execute on these types of projects. You know, GRAIL doesn't have those today. It will have to build those, and it will take, you know, many years.

Q. And why couldn't --

MR. WIDNELL: Objection. I just want to note, for foundation, it's not clear to me what his basis for saying that GRAIL does not have those capabilities today is, given that he left GRAIL in June of 2020.

MR. MARRIOTT: I'm happy to establish that. I think it's there, but I'm happy to do it again if it would be helpful.

JUDGE CHAPPELL: Well, you can do it now or he

will do it on cross, either way.

MR. MARRIOTT: I will gladly do it now and maybe save us the trouble on cross.

JUDGE CHAPPELL: All right.

BY MR. MARRIOTT:

Q. Dr. Aravanis, you testified that you served as chief scientific officer of GRAIL, correct?

A. Yes.

Q. And since the time that you left GRAIL, have you stayed apprised of the -- of the personnel and capabilities of the company?

A. I have through the due diligence process.

Q. And since you left GRAIL, has GRAIL continually been a customer of Illumina?

A. It has.

Q. And are you aware of the regulatory and payer capabilities that GRAIL has and doesn't have?

A. Yes.

Q. So why can't GRAIL just go out and hire regulatory and payer personnel to achieve the efficiencies you've described?

A. The -- the individuals with these types of capabilities are not available. The -- there are only a small number of individuals in the world who have direct experience doing NGS submissions, working with

the FDA on those types of applications.

Similarly, on the market access, only a limited number of people in the world who have, you know, pioneered approaches to market access for NGS products, who have worked with large payers, who have successfully set up risk-sharing agreements. So, you know, there isn't a -- a significance pool of talent for GRAIL to hire from, nor are there a significant number of consultants. So primarily GRAIL will have to hire and train staff over time to learn these capabilities.

Q. Based on your prior role as chief scientific officer of GRAIL, why couldn't -- withdrawn.

Couldn't Illumina and GRAIL simply achieve the efficiencies you describe by entering into a contract with one another?

A. I don't believe so.

Q. And why not?

A. It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily -- it wouldn't otherwise

share.

Q. And do Illumina's customers share with Illumina the particulars of their assays and their bioinformatics and their proprietary testing information?

A. They do not.

Q. So to wrap it up, Dr. Aravanis, let me just ask you this: What impact do you believe this transaction will have on patients?

A. It will lead to millions of more tests performed, tens of thousands of additional lives saved, reduction in the cost of the Galleri test, much broader access. It will also lead to new discoveries and new diagnostics for Illumina to pursue and to develop.

Q. Thank you.

Your Honor, I have no further questions.

MR. WIDNELL: I apologize, but that last question, I should have objected. I didn't get it in before Dr. Aravanis started speaking, but the question was what he believes.

MR. MARRIOTT: I can rephrase it to say what do you know if that would be preferable.

MR. WIDNELL: Your Honor, if I can respond, I mean, if the -- the witness is giving the same answer to do you know as the question do you believe, it seems

to me that it's equally speculative.

MR. MARRIOTT: Your Honor, I think you're muted, I'm afraid. I can't hear what you're saying.

JUDGE CHAPPELL: All right. Let me check and see what I've said that was missed.

I believe I did a double-tap. I unmuted and muted at the same time.

Just so it's clear on the record, and heartened by what I see as a wrapup, I'm allowing that question and answer. Overruled.

Do you have any further questions?

MR. MARRIOTT: I do not, Your Honor. Thank you.

JUDGE CHAPPELL: I meant Mr. Widnell. I assumed you had passed the witness, Mr. Marriott.

MR. MARRIOTT: I had. Thank you.

MR. WIDNELL: I have a few questions. I don't think that what I have should take more than 15 minutes at most.

JUDGE CHAPPELL: Okay.

REDIRECT EXAMINATION

BY MR. WIDNELL:

Q. Dr. Aravanis, during your testimony, you mentioned your belief that other NGS competitors potentially would be able to meet the needs of MCED

developers. Is that correct?

A. Yes.

Q. And just to be clear, you do not have access to Guardant's confidential business plans regarding commercialization, do you?

A. I do not.

Q. And you do not have access to Guardant's confidential technical requirements for NGS sequencing, do you?

A. I do not.

Q. And you do not have access to Guardant's confidential and proprietary information regarding how its MCED tests work, do you?

A. Well, I don't know if they have an MCED test, but I don't have access to their, you know, confidential information.

Q. And you do not have access to Natera's confidential business plans regarding commercialization, right?

A. I don't.

Q. And you do not have access to Guardant's confidential technical requirements for NGS sequencing, right?

A. I do not.

Q. And you do not have access to Natera's

confidential and proprietary information regarding its plans to develop MCED tests.

A. Again, I don't know if they're developing an MCED test or not, but I don't have access to their confidential information.

Q. Okay. And likewise, you do not have access to Freenome's confidential business plans regarding commercialization. Is that right?

A. Yes.

Q. And you do not have access to Freenome's confidential technical requirements for NGS sequencing. Is that right?

A. Yes.

Q. And you do not have access to Freenome's confidential and proprietary information regarding any MCED test it may be developing to the extent it is developing one.

A. Yes.

Q. And you do not have access to Exact's confidential business plans regarding commercialization, right?

A. Yes.

Q. And you don't have access to Exact's confidential technical requirements for NGS sequencing. Is that right?

A. Yes.

Q. And you don't have access to Exact's confidential and proprietary information regarding how it is developing an MCED test and how that MCED test will work to the extent there is, in fact, an MCED test that it's developing.

A. Yes.

Q. And you also do not have access to Helios' confidential business plans regarding commercialization, right?

A. Yes.

Q. And you don't have access to Helios' confidential technical requirements for NGS sequencing, right?

A. Yes.

Q. And you don't have access to Helios' confidential and proprietary information regarding how it is developing an MCED test and how that MCED test would work to the extent it is, in fact, developing an MCED test.

A. Yes.

Q. Okay. And you do not have access to Singlera's confidential business plans regarding commercialization. Is that right?

A. Yes.

Q. And you don't have access to Singlera's confidential technical requirements for NGS sequencing. Is that right?

A. Yes.

Q. And you don't have access to Singlera's confidential and proprietary information regarding how its MCED tests would work to the extent that it is developing MCED tests. Is that right?

A. Yes.

Q. You also mentioned your understanding about how various NGS competitors could expand their products going forward. Is that correct?

A. Yes.

Q. You don't have access to Thermo Fisher's confidential, proprietary information regarding their product development plans, do you?

A. No.

Q. And you don't have access to Thermo Fisher's confidential proprietary information regarding their sequencers, do you?

A. I do not.

Q. And you don't have access to GenapSys' confidential and proprietary information regarding their development plans. Is that right?

A. Yes.

Q. And you don't have access to GenapSys' confidential, proprietary information regarding its sequencers. Is that right?

A. Yes.

Q. And you also don't have access to Oxford Nanopore's confidential proprietary information regarding their product development plan. Is that right?

A. Yes.

Q. And you don't have access to Oxford Nanopore's confidential, proprietary information regarding its sequencers.

A. I do not.

Q. And you don't have access to PacBio's confidential, proprietary information regarding their product development plans. Is that right?

A. Yes.

Q. And you don't have access to PacBio's confidential proprietary information regarding its sequencers. Is that right?

A. Yes.

Q. And you don't have access to Singular's confidential, proprietary information regarding its product development plans, right?

A. Yes.

Q. And you don't have access to Singular's confidential, proprietary information regarding its sequencers. Is that right?

A. Yes.

MR. WIDNELL: I have no further questions.

JUDGE CHAPPELL: Anything further?

MR. MARRIOTT: Nothing here, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused. You may stand down.

Call your next witness. While you're doing that, it's probably a good time to take a quick break, because this transition always takes a few minutes.

MR. MARRIOTT: Thank you, Your Honor.

JUDGE CHAPPELL: We will take a break and reconvene at 4:20, 4-2-0. We're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: Okay, we're back on the record.

Call your next witness.

MR. ANDREW: Good afternoon, Your Honor. Jordan Andrew on behalf of Complaint Counsel. At this time, Complaint Counsel would like to call Andy Felton, the vice president of product management at Thermo Fisher Scientific.

And, Your Honor, I would also like to introduce

counsel for Dr. Felton attending the hearing today, Mark Alexander of Axinn, Veltrop & Harkrider.

JUDGE CHAPPELL: Okay. Go ahead and swear the witness.

Whereupon--

MARK FELTON

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ANDREW:

Q. Good afternoon, Dr. Felton.

A. Good afternoon.

Q. Would you please spell your first and last name for the record?

A. A-N-D-Y, F-E-L-T-O-N.

Q. And before we proceed further, I want to remind you that we are in a public session. So I will do my best to stick to questions that relate to information that is not confidential; however, if I ask you a question for which your response would touch on confidential information, just let me know and I will try to rephrase it or save it for a closed session, okay?

A. Yes.

Q. Dr. Felton, who is your current employer?

A. Thermo Fisher Scientific.

Q. What is your current position at Thermo Fisher Scientific?

A. Vice president, product management, platform research, and applied markets.

Q. And for the remainder of my examination, I will refer to Thermo Fisher Scientific as Thermo, if that's all right with you.

A. Yes, that's fine.

Q. How long have you been in your current position?

A. I've been in my current position for approximately seven years and with the legacy business for ten years.

Q. What are your responsibilities in your current position?

A. In my current position, I'm responsible for the platforms and the reagents that run upon them and for the software, as well as applications in research and applied markets.

Q. And are the platforms that you're responsible for specifically next-generation sequencing platforms?

A. Correct, the next-generation sequencing platforms from the Ion Torrent group of Thermo Fisher, also known as the Clinical Sequencing Division.

Q. As part of your responsibilities, do you monitor Thermo's competitors?

A. Yes, I do.

Q. And do your responsibilities include understanding the technology of Thermo's competitors?

A. Yes, they do.

Q. Do your responsibilities also include understanding the requirements of Thermo's customers?

A. Yes, they do.

Q. What was your role immediately prior to your current position?

A. Senior director, product management, for Thermo Fisher Scientific's Next-Gen Sequencing Division.

Q. And during what time did you have -- time frame did you have that role?

A. From 2010 to approximately 2014 or so.

Q. What were your responsibilities in that role?

A. Very similar to what I have now, primarily the -- the platforms, as well as the core reagents that run on it, but it excluded the software at that point.

Q. And what was your role prior -- prior to that position?

A. I was director of product management for the capillary electrophoresis sequencing business at

Applied Biosystems.

Q. Describe your responsibilities at Applied Biosystems.

A. Responsible for platforms and the core reagents for the capillary sequencing business, which was the, if you will, the precursor technology to next-generation sequencing for obtaining sequencing data from all kinds of samples.

Q. Did you have any other roles during your time at Applied Biosystems?

A. Yes. I was in product management for the realtime PCR business, the sample preparation business, and DNA synthesis business.

Q. And during what time frame were you at Applied Biosystems?

A. From 1994.

Q. And briefly describe your educational background.

A. My undergraduate degree was in chemistry from John Moores University. I have a Ph.D. in peptide protein chemistry from Oxford Brooks University.

Q. Okay. Now I'd like to turn to some questions about Thermo's business. At a high level, describe Thermo's next-generation sequencing business.

A. At a high level, the business comprises of two

groups of platforms today, primarily focused on our GeneStudio sequencing and Ion Chef platforms, our new Genexus integrated sequencing platform. It addresses primarily three markets: oncology market, research/inherited disease, and reproductive health markets. Those combine both research, pharma/biotech environments, and routine testing facilities of various kinds.

Q. I believe you just named some of them, but what are the NGS platforms that Thermo sells?

A. Yes. So we sell currently two major platforms that I described in the previous answer, the gene -- Ion GeneStudio sequencing platform and its adjacent instrument, the Ion Chef, the Genexus integrated sequencer. We also sell variants of our earlier generation platforms, the proton instrument, and we still sell our current PGM Dx platform, which is the FDA- and EU-approved version of the original PGM sequencing platform.

Q. And collectively, does Thermo refer to these as their Ion Torrent instruments?

A. Correct. They go to market under the brand Ion Torrent.

Q. In what ways are the instruments that you just named different from one another?

A. The primary differences are both in the output pro run in terms of the number of reads or gigabases of output they are able to generate, and the amount of work flow time that the user has to invest in running the system. So they vary from, you know, quite complex work flows from our earlier generation instruments to very hands-free work flows for our latest generation sequencing platforms. So it's a difference of throughput and work flow are the primary differences.

Q. How do these platforms compare to each other in terms of throughput?

A. We characterize throughput at Ion Torrent primarily in the number of reads, sequencing reads that are generated, and those are generated from our Ion Torrent chips. The PGM has a maximum output of 5 million reads per run; the proton, a maximum of 60 to 80 million reads.

The GeneStudio S5 series has a range of about 5 million to 130 million reads per run. And our Genexus platform has a maximum of 40 to 60 million reads per run.

Q. So, then, what is the maximum number of DNA fragments that a Thermo sequencing platform is capable of reading in a single run?

A. That's typically -- that would be the Ion

GeneStudio platform, and that would be 130 million sequencing fragments.

Q. Is there a particular chip that's used on the GeneStudio to be able to read up to 130 million fragments per run?

A. Yes. That's called the 550 chip.

Q. And for the GeneStudio S5, what is the run time or how many times can a customer run it in one day?

A. The run time for the sequencing platform itself is approximately 2 1/2 hours, depending on the complexity of the run itself, but around that time. So typically twice in an eight-hour shift, if you can accommodate making the up-front part of the work flow twice in that time. If you have the ability to run multiple shifts, you could run it up to maybe six times.

Q. Is there more to the entire work flow of a sequencer than just the sequencing portion?

A. Yes. So the -- in the case of the GeneStudio, that also performs the sequencer. The Ion Chef platform can perform the second of the first two parts of the work flow that we term library prep and template prep. The library prep portion would take about six to eight hours on the Ion Chef platform, and that would need to be followed by the template prep process, which

takes about 14 hours.

Q. And so, all in, how long would it take for a given run of a GeneStudio with the proper work flow to read the maximum amount of reads that you described earlier?

A. It would take at least 24 hours to probably something like 36 hours, depending on whether you could get the library run finished and kick off the templating reaction to run overnight. Otherwise, it would take two days, two complete work days.

Q. Other than Illumina sequencers, are you aware of any NGS instrument available in the United States that can read more than 130 million DNA fragments per run?

A. Not at this time, no.

Q. You mentioned the PGM Dx platform. What does the "Dx" mean in the context of the platform name?

A. The Dx means -- for us that is an FDA-approved platform or a European Union-approved CEID-marked platform. So those are platforms that have had approvals either via the FDA in the U.S. or by the European Union in Europe.

Q. And what type of approval did that instrument receive from the FDA?

A. That has had -- that is currently a Class III

premarket approval as a companion diagnostic, along with a -- it's a system approval along with an assay called the oncomine Dx target test.

Q. Does Thermo currently have any other FDA-approved NGS sequencing platforms?

A. No, we do not.

Q. Does Thermo typically recommend different NGS platforms to its customers depending on the application?

A. Yes, and it will depend on both the application and the throughput required in a particular application. So currently we would most likely recommend either the GeneStudio or the Genexus, unless the user requires a fully FDA-approved system, in which case we would recommend the PGM Dx platform. So it would depend on both the scale of the experiment or the testing required and the application.

Q. For applications requiring high throughput sequencing, which instrument would Thermo generally recommend?

A. Generally, we would recommend the GeneStudio platform.

Q. Are any of Thermo's NGS platforms currently used in oncology applications?

A. Yes. All of them are used to some extent in

oncology applications.

Q. Describe the different oncology applications for which Thermo NGS sequencing platforms are currently used.

A. The primary one for us is routine testing in a pathology setting for detection of mutations in patient samples for therapy decisions. So that would be directly related to patients who have most predominantly later-stage cancers and need to be put on either chemo or targeted therapy. So the targeted therapy result would be provided to them from the assessment mutations from our assays.

We have some research markets in oncology, and we also have both for solid tumor and hematological sample therapy decision at some level of recurrence monitoring, testing, but that's very small currently.

Q. Is Thermo currently being used for early-stage cancer detection tests?

A. Not that we are aware of.

Q. And do you know why Thermo is not being used for early-stage cancer detection tests?

MS. RATHBUN: Objection. Foundation. Calls for speculation.

MR. ANDREW: And, Your Honor, I've asked the witness just does he know why.

THE WITNESS: Yes, we --

JUDGE CHAPPELL: Hang on. Hang on. I have to rule on the motion -- I mean the objection.

As currently phrased, I'll allow the question. Overruled.

THE WITNESS: Yes, we have our opinions on why it's not used in that modality.

BY MR. ANDREW:

Q. And what are those?

A. That the -- that environment would require most likely in a heavy centralized setting, so what we mean by that is a large number of samples would be coming in to a single environment, and, therefore, a platform with considerably more output per run than 130 million reads would be the preferred environment. In general, the system isn't well suited to a kind of test that needs a very large number of samples through it -- running through it very quickly.

MS. RATHBUN: Your Honor, I'm sorry. I am going to move to strike that answer. The question was if he knows, and he answered with his opinion.

MR. ANDREW: And, Your Honor, Dr. Felton said that he does know this. It's based on his business. He has said that his responsibilities include understanding the requirements of his customers. These

are part of the requirements of a customer who would have an early-stage cancer screening assay.

JUDGE CHAPPELL: I am going to allow the answer. I am allowing the answer. Overruled.

BY MR. ANDREW:

Q. In your answer, Dr. Felton, you said in general the system isn't well suited to a kind of test that needs a very large number of samples through it. What system were you referring to?

A. I was referring to the GeneStudio platform.

Q. Dr. Felton, do you know what attributes are necessary in an NGS instrument to be useful for early-stage cancer detection tests?

MS. RATHBUN: Your Honor, I'm sorry. I am going to renew my objection. Mr. Felton testified earlier that he -- Thermo Fisher does not have any customers that he's aware of in the MCED space, so I continue to believe there has not been adequate foundation laid.

JUDGE CHAPPELL: Response?

MR. ANDREW: Yes, Your Honor. Again, Dr. Felton has testified that part of his responsibilities are understanding the needs of his customers. He has also testified that he has -- part of his responsibilities are understanding the

technology of his competitors. Here, we're going to talk about later on competitors that may, indeed, offer products in this space, and so I think Dr. Felton would be well positioned to be able to answer this question.

JUDGE CHAPPELL: The current question is "do you know." I'm going to allow that. Overruled.

MS. RATHBUN: Thank you, Your Honor.

BY MR. ANDREW:

Q. Dr. Felton, do you need the question again?

A. Yes, please. I'm sorry.

MR. ANDREW: Susanne, would you mind reading back the question for Dr. Felton.

(The record was read as follows:)

"QUESTION: Dr. Felton, do you know what attributes are necessary in an NGS instrument to be useful for early-stage cancer detection tests?"

THE WITNESS: Yes. So, in our opinion -- in my opinion, we would believe that the system would have to have --

JUDGE CHAPPELL: I am going to have to instruct you, tell us what you know, not your opinion.

THE WITNESS: Okay. Apologies.

JUDGE CHAPPELL: You're here as a fact witness.

THE WITNESS: The system would have to have a large number of reads to cope with the number of

samples and also the accuracy to provide a result that was sufficiently useful for the intended purpose of the test itself.

BY MR. ANDREW:

Q. And, again, why would there have to be a large number of reads?

A. There would be expected to be a very high number of samples in that kind of test environment, because you're screening a large population of people within a geography or a country. Most of them are relatively healthy, so there's a -- we would expect there to be a high number of samples, and, therefore, a system with a high throughput capability would be much preferable to one with a small output that you would have to run multiple times.

Q. Does Thermo also have a microarray business?

A. Yes, it does.

Q. Now, are you familiar with that business?

A. I am familiar with the general technology behind microarrays. I am not familiar with the specifics of the business.

Q. You said, though, that you're familiar with the microarray technology?

A. Yes, correct.

Q. Describe Thermo's microarray technology at a

high level.

A. The -- the Thermo technology uses a microarray system that deposits fragments of nucleic acid onto a surface. Many hundreds of thousands or up to millions of those fragments can be placed, and you hybridize nucleic acid to that surface to generate a result if the particular fragment matches one in the sample that you are trying to analyze.

Q. In what ways does Thermo's NGS technology differ from its microarray technology?

A. The microarray technology is what's termed a hypothesis-based system in that the fragments of DNA that are placed onto the microarray surface are, a priori, known and, therefore, you can only expect to get answers for the fragments that you place onto the surface.

Sequencing, by contrast, is what we term hypothesis-free, where you sequence whatever is in the sample, and that will give you an answer, because you're detecting reads whatever is in the sample and reading through those sequences.

Q. Do you know how the throughput of Thermo's microarray technology compares to the throughput of its NGS technology?

A. Not well, no.

Q. Do you know whether microarray technology is generally lower throughput than NGS?

A. Generally, it would -- I would say it would be lower throughput than NGS.

Q. Are there certain applications for which Thermo's NGS platform instruments are better suited than for microarrays?

A. Yes, in general, for more things like oncology testing, inherited disease testing, where you have to -- where you're looking to detect a relatively reasonable number of mutations, but across a large genomic footprint. That would tend to be the space that they would have an advantage over a microarray platform.

Q. And to be clear, you're saying that is where NGS would have an advantage?

A. NGS would have an advantage, yes.

Q. Does Thermo also have a PCR business?

A. Yes, we do.

Q. And you testified earlier that you have some experience in your career working with PCR technology. Is that right?

A. Correct.

Q. At a high level, can you describe PCR technology?

A. PCR technology comes in two forms. There is standard polymerase chain reaction, where you are simply making copies of a particular region of the DNA that you are interested in by heating and cooling, along with an enzyme that generates those copies.

And there is quantitative PCR in which you make copies of those particular regions, but you also probe it with a fluorescent target, and that gives you information -- quantitative information about how many copies are present in that target.

Q. In what ways does Thermo's NGS technology differ from PCR technology?

A. PCR technology only allows you to interrogate a very small number of genomic regions at a time, and that's limited by the number of what are called PCR amplicons, so the region's defined by oligonucleotide primers that interrogate parts of the genome.

It's also limited in the case of qPCR by the ability to distinguish closely related fluorescent molecules by the wavelengths, and, therefore, you cannot interrogate a large number of mutations simultaneously with either PCR or qPCR very efficiently, which is where NGS has a huge advantage.

Q. And do you know how the throughput of PCR compares to the throughput of NGS?

A. In terms of samples, in terms of genomic regions, it's very much lower, because you can -- each well is essentially only interrogating one or two small regions or mutations at a time in a qPCR plate. So although you may have 96 well plates or 384 well plates, that's a very small number of mutations.

NGS is interrogating thousands to tens of thousands to potentially millions or the whole human genome at a time. So on a mutation level, the scale is massive in NGS compared to qPCR.

If you -- conversely, if you want to generate a very small amount of information on a lot of samples, qPCR can be quite efficient. So it depends on the kind of experiment that you need to do.

Q. And so are there applications for which Thermo's NGS instruments are better suited than for PCR?

A. Yes. Again, you know, for things like oncology, inherited disease testing, reproductive health testing, they are generally better. For things like infectious disease testing where you need to just test for a single target of interest and detect its presence or absence across many thousands of samples, qPCR and PCR tend to be a better solution.

Q. And going back to the -- your description of

the GeneStudio for just a moment, what is the maximum read length of each fragment that the instrument supports?

A. On the GeneStudio we can support up to about 600 base pairs for certain applications on that platform.

Q. Okay. Now, I just wanted to move on to a few questions about the NGS market generally. Do you know which companies, besides Thermo, currently offer NGS platforms for sale in the United States?

A. Yes, we do.

Q. Which are those?

A. Illumina, Pacific Biosciences, Oxford Nanopore.

Q. Of the companies that you just named, which ones currently offer short-read sequencing platforms?

A. Illumina.

Q. And which companies offer long-read sequencing platforms?

A. Pacific Biosciences and Oxford Nanopore.

Q. And do you know the difference between a short-read platform and a long-read platform?

A. Yes, I do.

Q. What is it?

A. It's kind of in the name. The long-read technology platforms tend to generate sequencing reads

of more than 1000 bases or 1 kb or kilobase, up to 10, 20, or 30 kilobases in length in the case of certain platforms, whereas the short-read technologies are typically limited to 300 to 600 base pairs in length.

Q. Do you know how the throughput of long-read platforms compares to the throughput of short-read platforms?

A. Yes, I do.

Q. And how does it compare?

A. In general it's much lower, because there are lower numbers of reads generated per long-read platform. For example, the Pacific Biosystems platform has -- Sequel II platform has a maximum 8 million long reads. So generally much lower than the short-read platforms in terms of the number of reads generated.

Q. Do you know whether long-read platforms are typically used in oncology applications?

A. Not -- certainly not -- I do, yes. Sorry, let me answer the question. Yes, I do.

Q. And are they?

A. To some extent in research applications, but relatively rarely in routine testing applications.

Q. And do you know why they're used rarely in testing applications?

A. For the majority of current routine testing

applications, the sample source is what is termed formalin-fixed, paraffin-embedded tissue from -- for example, from solid tumor material that's been biopsied from a patient. The nucleic acid isolated from that material is already highly fragmented and has a maximum read length of about 175 to 200 base pairs in read length.

So it's highly inefficient to use a platform that can generate and has to generate very long reads compared to a platform that's, you know, primary utility is in 200 to 600 base pair read length space.

Q. Then for which applications does Thermo compete with Pacific Biosciences?

A. To some extent in the inherited disease testing space and the infectious disease testing and research spaces.

Q. Do you know whether -- whether Pacific Biosciences competes in the early cancer screening space?

A. I don't know for sure, but I believe the answer is no.

Q. Does -- does Thermo compete with Pacific Biosciences in the early-cancer screening space?

A. No.

Q. And for which applications does Thermo

currently compete with Oxford Nanopore?

A. Primarily the infectious disease testing space and somewhat in the inherited disease testing.

Q. And do you know whether Oxford Nanopore competes in the early cancer screening space?

A. The same answer as for Pacific Biosciences. I am not 100 percent sure, but I believe the answer is no.

Q. Does Thermo compete with Oxford Nanopore in the early cancer screening space?

A. No, we do not.

Q. Does Thermo currently compete with BGI in the United States?

A. No. We don't -- BGI does not sell its sequencers in the United States that we are aware of. We would be competing with them if they offered any service business within the U.S., and they offer genomic sequencing services where the samples are shipped from the user laboratory to a centralized setting for BGI.

Q. And do you know where they're shipped?

A. Both Europe and into other regions like the Middle East and in some cases into China.

Q. Is Illumina also a competitor of Thermo?

A. Yes, they are.

Q. How do -- how do Thermo's NGS instruments compare with Illumina's NGS instruments in terms of throughput?

A. There is some overlap on the low-end instrumentation that Illumina offers, particularly the iSeq, MiSeq, and some applications on the NextSeq platform. The NextSeq platform offers up to one to two billion reads currently. Beyond that, the two platforms that Illumina has on market, called the HiSeq and NovaSeq, are much higher in output than any of our platforms.

Q. Do you know what the throughput for a NovaSeq is?

A. Up to 10 billion reads per run, single-ended reads.

Q. How does the cost per read on the NovaSeq compare to the cost per read on the GeneStudio?

A. It would be more expensive by what amount -- sorry, the NovaSeq would be less expensive than the GeneStudio by a reasonable amount, although I -- off the top of my head, I can't give you an answer as to exactly what that number is.

Q. And for oncology applications, does cost per read drive price per sample?

A. Yes. So cost per read is directly linked to