price per sample, because that -- the -- the number of reads defines the kind of experiment you wish to do.

Q. So do you know whether price per sample is a significant factor for customers?

A. Yes, price per sample is always a significant factor for customers.

Q. Is it more so for customers who are sequencing a very large number of samples?

A. Yes. It would be higher as the number of samples that you have to sequence increases, I would say.

Q. I'm sorry. What would be higher?

A. The -- the requirement to have a low cost per sample.

Q. Are there any applications for which Illumina NGS platforms are better suited than Thermo NGS platforms?

A. Yes. Anything requiring a large amount of genomic -- a very large amount of genomic footprint, like a human whole genome sequencing or whole exome sequencing, and any application that requires a very large number of samples, even though it has a small genomic footprint, like early cancer detection.

Q. Is early cancer detection best suited for highly centralized sequencing?

MS. RATHBUN: Objection to form. Foundation.

MR. ANDREW: I can rephrase, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. ANDREW:

Q. Dr. Felton, do you know whether early cancer screening would be best suited to a highly centralized environment?

A. Yes, I do.

Q. And is it more suited to a highly centralized environment?

A. Yes. The higher output platforms would be suited to a centralized environment, and early-cancer detection would be suited to a highly centralized environment.

Q. Why is that?

A. The collection of samples from a wide area of the population is inherently easier if it's funneled into a central facility, and the work flows to manage the processing of a higher amount of samples would be much more amenable to standardization in running through a single process in that environment, and then running those samples on a high throughput platform would reduce the amount of labor time involved in the processing of said samples. So we believe -- I believe it's much more suited to a centralized environment.

Q. Okay, thank you.

Your Honor, that concludes the public portion of my examination. At this time, I would ask that we move to an in camera session for the remainder of the examination.

JUDGE CHAPPELL: All right. Do you have any idea how long you're going to need for the in camera portion?

MR. ANDREW: Your Honor, I would estimate about 20 minutes.

JUDGE CHAPPELL: Okay.

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 attorney 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, you are to instruct that person to use the raise hand function on the zoom screen. They will then be moved into a waiting room.

Go ahead.

MS. RATHBUN: Your Honor, it looks good from my perspective.

JUDGE CHAPPELL: Okay.

MR. ANDREW: From mine as well, Your Honor.

JADA: Your Honor, I have muted the public line, and everyone who should be out has been taken out.

JUDGE CHAPPELL: Was anyone moved?

JADA: We moved --

JUDGE CHAPPELL: Did some people move themselves?

JADA: No. I moved Marissa Lee Song with GRAIL and Illumina, Roland Schwillinski, and the public line.

SCOTT: And just so you know, Your Honor, no one can move themselves. We have to move them.

JUDGE CHAPPELL: Oh, but they can volunteer themselves by hitting raise hand?

SCOTT: Yes, that's right.

JUDGE CHAPPELL: Okay, thank you. We are now in in camera session.

(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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THE COURT: Okay. We're in public session. We're getting ready to recess for the day. It is 6:00. According to my notes, our next trial day -- we have some days off for a holiday and some requested days off from the parties. We will reconvene on September 9th, Thursday, at 9:45 a.m.

Anything further before we break?

MS. RATHBUN: No, Your Honor. Thank you.

MR. ANDREW: Thank you, Your Honor.

JUDGE CHAPPELL: All right. We're in recess.

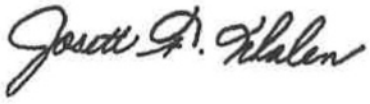
MR. MARRIOTT: Thank you, Your Honor.

Have a good weekend, everyone.

(Whereupon, at 5:58 p.m., trial 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 9, 2021
9:45 a.m.
TRIAL VOLUME 9
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:

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Axinn Veltrop & Harkrider

ON BEHALF OF THE WITNESS LEITE:

Andrew Lacy, Esq.
Goodwin Proctor

I N D E X

P R O C E E D I N G S

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JUDGE CHAPPELL: Okay, we're back on the record. Anything to go over before we continue questioning?

MR. ANDREW: Not from Complaint Counsel, Your Honor.

MR. MARRIOTT: Nothing here, Your Honor.

JUDGE CHAPPELL: Do you want to proceed with questioning?

MS. RATHBUN: I will, Your Honor. I believe we need to proceed in an in camera session.

JUDGE CHAPPELL: So you want to go back into in camera?

MS. RATHBUN: Yes, please, Your Honor.

JUDGE CHAPPELL: Okay. 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 a public session. I need the questioning attorney or lead attorney 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, you are to instruct that person to use the raise hand

function on the Zoom screen. They will then be moved into a waiting room.

Go ahead.

JADA: Your Honor, everyone has been moved, including the public line.

JUDGE CHAPPELL: We are in camera. Proceed.

(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: Any further questions of this witness?

MS. RATHBUN: No, Your Honor.

MR. ANDREW: Nothing from Complaint Counsel.

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

THE WITNESS: Thank you.

JUDGE CHAPPELL: Call your next witness.

MR. ALEXANDER: Thank you, Your Honor.

MS. MUSSER: Your Honor, I would like to introduce my colleague, Wells Harrell, who will be calling our next witness.

MR. HARRELL: Good morning, Your Honor. Wells Harrell for Complaint Counsel.

At this time, Complaint Counsel calls former Illumina employee John Leite.

JUDGE CHAPPELL: You'll need to fix your name on the screen, FTC.

MR. HARRELL: Yes. We will do that right now, Your Honor.

Whereupon--

JOHN LEITE

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

JUDGE CHAPPELL: Proceed.

DIRECT EXAMINATION

BY MR. HARRELL:

Q. Good morning, sir. Could you please state your name and spell it for the record.

A. Sure. John, J-O-H-N, last name is Leite, L-E-I-T-E.

Q. Could you please also share your educational history, including any degrees you've earned?

A. Sure. I have a bachelor's degree in biochemistry from Rutgers University, a Ph.D. in biochemistry and molecular genetics from the University of Pittsburgh, and a post-doctoral fellowship from Cal Tech.

Q. Do you prefer to go by doctor or mister? I am happy either way.

A. Mister is fine.

Q. Mr. Leite, are you represented today by counsel?

A. I am.

Q. Who are your counsel?

A. Mr. Andrew Lacy.

Q. Are you represented by other counsel today?

A. Mr. Richard Stark.

Q. Who is Mr. Stark?

A. He's the Illumina counsel or the counsel assigned by Illumina.

UNIDENTIFIED: Hold on a second. Let me turn down the court case. Hang on.

JUDGE CHAPPELL: It seems like we are interfering with somebody's other trial there. Did anybody else hear that?

MR. STARK: I did, Your Honor, yes.

JUDGE CHAPPELL: Any idea who that is?

JADA: That was (inaudible), but I muted them.

JUDGE CHAPPELL: Thank you.

BY MR. HARRELL:

Q. Sorry about that, Dr. Leite.

Before we proceed any further, I should note that we are in a public session, which means that members of the public are listening in right now. I may have an opportunity later to ask you questions in a closed in camera session, but for the time being, as long as we're in public, I would ask that you please do not disclose any competitively sensitive or confidential information in your answers. Can you do that?

A. Yes, I understand.

Q. Mr. Leite, where are you currently employed?

A. I am currently employed at a company called InterVenn.

Q. What is InterVenn?

A. InterVenn is a company that develops a glycoproteomics platform for other life scientists or for the development of our own diagnostic tests into the clinical market.

Q. When did you join InterVenn?

A. It was November of 2020.

Q. Before you joined InterVenn in November of 2020, where had you been employed?

A. I had been employed for almost six and a half years at Illumina.

Q. When you first joined Illumina, what was your job title?

A. I was VP of clinical business development.

Q. And as the VP of clinical business development, what were your responsibilities?

A. I was responsible for major partnership transactions with either other IVD providers or with pharmaceutical companies across the clinical space.

Q. When you say "partnership transactions," can you please explain what you meant by that?

A. Sure. So these are transactions that stem

outside the normal commercial function and are partnerships, codevelopment agreements, strategic partnerships.

Q. Did you have any responsibilities for marketing when you first joined Illumina?

A. When I first joined, yes. I was responsible for marketing in the Oncology Division.

Q. What sort of work did your responsibilities in the Oncology Division entail?

A. It was primarily the design of new diagnostic products for what was then a fairly nascent division of Illumina, which was the Oncology Business Unit. So we were tasked with developing product specifications and product requirements for a whole new generation of diagnostic tests that relied on the Illumina platform.

Q. What kinds of diagnostic tests specifically were you responsible for?

A. Specifically we developed a test called the TSO -- or the TST-170 and the TSO-500.

Q. Could you please explain what those tests are?

A. Yes. They are tests for the interrogation of tumors from patients who are actively being managed for oncology or cancer care and where physicians have specific questions as to how to treat them. There are a mix of different therapy types, those that are

targeted to specific genetic drivers of the disease, as well as a whole new crop called immunotherapies.

Q. Those two tests that you mentioned, including TSO-500, would it be fair to call them oncology selection tests?

A. It would be, yes.

Q. As part of your work at Illumina, did you come across the term "IVD test" or "in vitro diagnostic test"?

A. Yes.

Q. What is an IVD test?

A. An IVD test is a designation given by the regulatory agencies, whether it be CAP-CLIA or the FDA, for a type of test that is to be used for the diagnosis, prognosis, or therapy selection of patients.

Q. What distinguishes IVD tests from other kinds of tests, including in the oncology space?

A. Yeah, so an IVD test is traditionally associated with an FDA approval, whether that be for a site-specific application or for a distributable application, and that is to distinguish it from what's called research-use-only applications, which are not to be used in the clinical realm unless they are to be included through a validation, through a process of what's called the laboratory-developed test, and in

that case, those tests are managed by CLIA.

Q. As part of your marketing responsibilities early in your tenure at Illumina, which IVD tests were within your portfolio?

A. I was responsible for TST-170, TSO-500, and a test called Praxis.

Q. You've mentioned TSO-500 a couple of times. Could you please explain what TSO-500 is?

A. Sure. It's a TruSight Oncology. 500 is the designation to indicate the number of genes on that panel.

Q. How did TSO-500 relate to your responsibilities at Illumina?

A. So at first, as a -- in charge of marketing for oncology, I was responsible for designing or setting the specifications for the test, securing feedback from physicians who would likely be willing to use our tests, to get a sense for customer requirements, and then to work with the development team to ensure that those requirements were being met, and if any compromises in developments had to be made, how those could be achieved and what impact it would have. I was also responsible for the commercialization strategy.

Q. As part of all of that work as related to TSO-500, what did you need to know about the test?

A. Pretty much everything, including its expected performance, how it differentiates from other similar tests in the market, how it differentiates from the alternative if one were not to use a next-generation sequencing platform, and most importantly, how a physician is likely to make treatment decisions based on the test.

Q. Was TSO-500 based on a sequencing platform?

A. Yes.

Q. Whose platform?

A. Illumina's.

Q. Is TSO-500 a multicancer early detection test?

A. No.

Q. Why not?

A. The genes that are used in TSO-500 are most prevalent in patients that are exhibiting later-stage disease or metastatic disease and are indicated for what's called the adjuvant setting, meaning that in addition to surgery, a physician is considering the use of chemotherapies or targeted therapies.

Q. Has Illumina developed different versions of its TSO-500 test?

A. They have developed a version of the TSO-500 with modified chemistries that make it suitable for interrogation from blood samples, also known as a

liquid biopsy test.

Q. Was there another version of the test that came before the liquid biopsy version?

A. The only one that comes to mind is the TST-170. It's a predecessor to TSO-500, and it was with a smaller set of genes. There was also an older hybridization chemistry being used with that test.

Q. What I'm asking is, was there a version of TSO-500 that relied on tissue samples as opposed to blood samples?

A. Yeah. The original TSO-500 was for tissue.

Q. What types of analysis could the TSO-500 test perform?

A. It could perform detection of pathogenic variants with genes that are known drivers of cancer or are potentially therapeutic targets where those specific mutations make the patient receptive to the use of those therapies.

It is also capable of running something that was called a tumor mutation burden. Tumor mutation burden is a scoring system for determination if a patient is likely to respond to immunotherapies.

Q. Have you heard tumor mutation -- excuse me, let me start that over.

Have you heard tumor mutation burden referred

to as "TMB" for short?

A. Yes. That is its acronym.

Q. Did you consider TMB a selling point for TSO-500?

A. We thought it was a distinguishing feature, yes. Most importantly, up until tumor mutation burden became a general area of interest in the oncology field, it was challenging to continue to expand the number of genes within a panel, and those of us who were interested in precision medicine had long believed that small panels were going to be somewhat short-lived and that the clinical utility of larger panels was greater for the better care of patients.

And it was important to continue to expand that list of genes so that as we are providing care, we are also learning more about that cancer, and tumor mutation burden was a great motivator for physicians to want to adopt broader panels.

Q. Did your position at Illumina change at some point?

A. It did. I moved from the Oncology Division to the Business Development Group.

Q. And when you moved to the Business Development Group, did you have a change in job title?

A. I did. It became -- it went through a couple

of different titles. I think it was strategic partnerships to begin with, and then it ended in clinical business development.

Q. Would that be vice president of strategic partnerships or vice president of clinical business development?

A. That is correct.

Q. When your position changed, to what extent did your responsibilities change, too?

A. Yeah, so I -- my responsibilities shifted from marketing of the Oncology Division products to the securing of collaborations and partnerships with industry partners, including other IVD companies and pharmaceutical companies.

Q. As part of securing those collaborations and partnerships, to what extent did your responsibilities include negotiating agreements on Illumina's behalf?

A. Very -- very often.

Q. What sort of agreements?

A. These could be collaboration agreements, so co -- collaboration on research activities, as well as codevelopment agreements. So with pharma, these would be Illumina taking patient samples secured by pharma during a clinical trial for the purpose of developing what's called a companion diagnostic on our tests,

either Praxis or the TSO-500 test.

Q. A moment ago you mentioned IVD companies. What did you mean by that?

A. So these are companies that are focused also on developing in vitro diagnostics of their own that then they can sell to hospitals and physicians directly.

Q. Would you negotiate agreements with those IVD companies?

A. I would, yes.

Q. What kinds of agreements?

A. Those are also codevelopment agreements or collaboration agreements. In this case, it's more about Illumina providing access to our IVD sequencing instruments and those companies then validating their assays on our instruments, as well as securing quality agreements, as well as securing supply agreements that continue to supply them during their development period.

Q. The agreements that you were just discussing there, did you have a shorthand at Illumina for those?

A. I think we called them IVD agreements.

Q. As part of those IVD agreements, did Illumina grant certain rights to IVD companies?

A. We did, yes.

Q. What kinds of rights?

A. They were rights to use the IVD sequencing instrument platforms; namely, MyCDx, NexCDx, or a future version of an instrument called NovaSeq, which we would have called NovaSeqDx. It was yet to be approved by the FDA, but it was under development. So those were the instruments.

Q. Were any other rights part of the negotiations with IVD customers?

A. There were certain provisions that came with those agreements; namely, a -- what's called a quality agreement, as well as an Illumina development of a software module to include the partner's assay manifest, as well as reporting capability into our instrument.

Q. Why was the software module and related rights part of the negotiations?

A. Yeah, so IVD platforms are by definition what's called a locked box. So to preserve the integrity of the data flow and the audit trail, nothing about the instruments may be changed by the user to ensure the integrity of the clinical data being generated.

So a partner would contract with Illumina to have their assay included as part of that software system and have the report be reported out. This is common practice in the industry.

Q. Why are IVD platforms a locked box, as you say?

A. So the FDA has very strict guidelines for data integrity, and there has to be an audit trail that demonstrates that no one, no unpermitted person may access the instruments and change anything with regards to the software or impact the -- how the results are being reported.

Q. Mr. Leite, we might go into some more detail about these negotiations during the closed session, but while we're in public, I have just a few more questions, but wanted to at least caution you that we are still in a public session.

A. Sure.

Q. Without naming any customers, did you negotiate with any customers who were developing their own oncology selection tests?

A. I did, yes.

JUDGE CHAPPELL: Hold on. Could someone let Illumina know they've got a video on there? It says "Goswami," but there are people walking around joking. Do they know that we can see them?

There you go, all right. Proceed.

MR. HARRELL: Yes, Your Honor.

BY MR. HARRELL:

Q. How many customers involved in negotiations

were developing oncology therapy selection tests during your time at Illumina?

A. There were quite a few developing oncology tests, some of which we did partnerships with. I'm not sure if you're looking for an exact number.

Q. No, there's no number necessary.

The tests that those customers were developing related to oncology therapy selection specifically, to what extent did those tests have anything in common with TSO-500?

A. Quite a few of them overlapped with the performance capabilities of TSO-500.

Q. In what ways?

A. In the sense of the number of genes, in the sense of the output that was created -- namely the variants that it could report -- the fact that it could report tumor mutation burden, microsatellite instability, other features like that.

So in terms of general performance, specificity, sensitivity, these are metrics we use in the industry to assess the performance of an assay.

Q. In negotiating with those customers, did you or any of your Illumina colleagues ever consider whether those customers' oncology therapy selection tests would compete with TSO-500?

A. Yeah. So the ability to maximize penetration into the oncology market was always a consideration. As part of our strategy, we considered the value of inclusion of partners that were developing solutions close to ours. We considered a term called "cannibalization" -- in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners -- to try and decide at least a framework for summing up what the value of that partnership should be.

Q. You mentioned cannibalization. What did you mean by that?

A. Yeah, cannibalization is a term used in marketing forecasting for understanding what is the sum total of loss of placements of direct sales versus that of another partner.

Q. For some of the customers you were negotiating with at Illumina, were any of them developing tests whose successful launch might result in lost sales of TSO-500?

A. Yes, actually by intent, right? So we considered what would be the financial benefit of going -- what we called a go-it-alone or the financial benefit of going with multiple partners. So when we decided to enter into an agreement with a partner, we

did it knowingly that there would be some losses of TSO-500 sales.

Q. Did you do any modeling in connection with deciding whether to, as you say, go it alone or pursue a partnership?

A. Yes. The marketing department, who at that time did not include me, and our finance departments collaborated on a financial model to explain or quantify those circumstances.

Q. Okay. Can you please explain some of the inputs and assumptions into those models?

A. Yeah. So to the best of my recollection, there was a model that described the ramp rate of sales on a year-over-year basis if Illumina was to perform marketing of TSO-500 and there were no other like products in the IVD space.

And we then also modeled what would be the total gain of sales from multiple partners, as well as Illumina. And then we also totaled what is the net loss of TSO-500 sales versus those partners' sales as well.

It's important to point out that in all of those models, we include tests from what's called the LDT providers. So these are providers that offer similar products but not as an IVD product but as an

LDT, which equally serviced the market.

Q. As the modeling would show in certain circumstances a net loss of TSO-500 sales, did you or your colleagues at Illumina ever discuss how to structure the agreements with a customer to compensate for that loss?

A. We certainly took into account what would be the worst case scenario with those models, and let's just say that with every consideration, with every partnership, there's a series of risks that are considered, including that the partnership is not going to work out as conceived.

And so we certainly wanted to quantify from a financial loss perspective what would be the worst case scenario, and we knew that that had to be our floor and that anything that we could gain from a partnership consideration in terms of up-front payments or total deal value should at least look to mitigate some of that risk.

Q. When you say that that risk had to be your floor, could you please explain a bit more what you mean by that?

A. Oh, it's basically we have to quantify what a worst case scenario is to the executive team so that as we're describing what the total value or the potential

value of a partnership is, we also have to consider what is the -- the bottom of that -- of that liability that could be created.

Q. Did the bottom of that liability ever affect the consideration that Illumina sought in connection with IVD agreements?

A. No. It was just something that we considered, and so long as we were gaining some financial consideration up front to help recover our development investment, as well as offset some of that risk, we felt that those partnerships were still meaningful to pursue.

Q. To what extent would up-front payments in certain agreements with customers compensate for the risk of lost sales of TSO-500?

A. It was partially that. It was also that the development of these Dx systems, these IVD systems, is quite costly. They're millions and millions of dollars to develop and secure the documentation and do all the validation work that one has to do to submit with the FDA.

So that had been work or I should say investment that had been sunk by Illumina. So we were looking to these up-fronts to look to offset some of this investment, as well as any potential downside risk

of joining the partnership.

Q. Did anyone at Illumina in your conversations with your colleagues ever express opposition to granting IVD rights to a customer on the ground that the customer's test might compare with TSO-500?

A. Yes. It was an ongoing debate within Illumina.

Q. Could you please identify some of these individuals involved in those debates?

A. Sure. At the time the Oncology Division and eventually the whole clinical group was being headed by someone called Garrett Hampton. Kathy Davy was also in charge of marketing for the Oncology Division. They come from backgrounds that are I would say more traditional diagnostic companies where these types of partnerships are not common.

And, in fact, as I mentioned earlier, because IVD platforms tend to be locked systems, the common practice is to not open these platforms to partners and to seek to control the point of product development, control the point of commercialization, and they were very concerned about the downside risks of opening those platforms to partners and were, let's just say, incredulous as to the potential upside.

MR. HARRELL: Your Honor, the remainder of my questions for Mr. Leite concern documents for which the

Court has granted in camera treatment. I therefore ask that we move into a closed session at this time.

JUDGE CHAPPELL: Okay. At this time, we are going to move 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 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, you are to instruct that person to use the raise hand function on the Zoom screen.

Go ahead.

JADA: Your Honor, the public line has been moved and no one else raised their hand.

JUDGE CHAPPELL: Okay. We are now in in camera session.

(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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BY MR. STARK:

Q. Mr. Leite, Complaint Counsel asked you a number of questions about IVDs generally and IVD agreements generally and I just want to ask you a few follow-up questions about those topics, for starters.

First of all, you testified about IVD tests. Is that right?

A. Yes.

Q. And are IVD tests FDA-approved?

A. Yes.

Q. And you've heard the term "IVD kit." Is that right?

A. That's correct.

Q. What is an IVD kit?

A. It is a specific type of IVD test where a manufacturer assembles an assay for distribution, and it allows for another hospital laboratory or an independent laboratory to run that same test in a distributed fashion. It is intended to differentiate it from a site-specific FDA test, which is one lab filing their work flow but not allowing them to kit and manufacture and distribute IVD-distributed kits.

Q. So is an IVD test the same thing as an IVD kit?

A. Not necessarily. So an IVD test could either be the test that results from a kit or it could be the test that results from a site-specific IVD.

Q. So a site-specific IVD would be one kind of IVD. Is that right?

A. That's correct.

Q. And an IVD kit is another kind of IVD. Is that right?

A. For distribution, correct.

Q. And can you explain a little bit more how an IVD kit would differ from a site-specific IVD?

A. Sure. So in the -- within the context of next-generation sequencing, a kit manufacturer enters into an agreement with Illumina to ensure a few things are happening. There is an agreement for what's called a quality agreement, where both parties work together to devise a quality system for that IVD test kit, and it ensures that the performance of the test from manufacturing run to manufacturing run is as stable as possible. So it's an important step in the process.

There is also the inclusion of the IVD test kit into the system menu. That ensures that the customer running the test in the distributed fashion can see the test lists, select it, and then also gets the result

reported. Both parties work together to file the necessary paperwork to the FDA and secure the approval.

BY MR. STARK:

Q. Now, once approved, IVD kits would be sold to various healthcare institutions. Is that right?

A. That is correct.

Q. And those institutions would then run the kitted tests on their own equipment at their own facilities. Is that right?

A. That is correct.

Q. Do -- do IVD tests generally use next-sequencing -- next-generation sequencing?

A. Not always, and in the total context, only a fraction of IVD tests use NGS.

Q. And in your -- based on your experience working at Illumina, are you familiar with the process for getting an IVD test on -- based on next-generation sequencing to market?

A. I am.

Q. And on direct I believe you testified -- testified about some different routes to getting an IVD test based on NGS to market, and I'd just ask you if you could elaborate on the different routes that are available.

A. Sure. So an alternative to an IVD -- what's

called a lab-developed test, in a lab-developed test, the performing laboratory takes on all the responsibility of development of their quality system. They purchase reagents from Illumina that are research-grade, and then have to take the incoming material as bulk reagent and, in essence, qualify that bulk reagent as appropriate for inclusion into their quality system and, in essence, represents that their laboratory-developed test is now of good standing, and they self-certify with a body call CLIA to register that test.

The site-specific IVD is similar to the LDT in the sense that it's a central lab. They are also wholly responsible for developing of their own quality system. They buy research-grade instruments and reagents from Illumina, but they, in their entirety, develop the documentation and the validation required for FDA filing, and the FDA limits the approval to the use of the test in that one laboratory.

And then there's the ultimate distributed kit, as I have mentioned. That also now has a second route, which is to use the IVD instrument from Illumina, use the IVD kits from Illumina, but not strike a quality agreement with Illumina, use the instrument in what's called the research-use-only mode, which is not a

locked configuration, and, in essence, then ask the customer to do the qualification of any incoming materials and on the quality system.

Q. Are you aware of any oncology screening test that is available as a kit to run on the Illumina NGS platform?

A. No, I am not aware of any.

Q. Now, Complaint Counsel asked you a number of questions on direct about IVD partnership agreements. Do you recall that?

A. Yes.

Q. And sometimes those are called IVD partnerships and sometimes just IVD agreements. Is that right?

A. That is correct.

Q. Are Illumina's IVD agreements related to the development of kitted IVDs?

A. Correct.

Q. Are they related only to the development of kitted IVDs?

A. Only to the development of kitted IVDs. So where a customer does not need an agreement with Illumina to create a site-specific IVD, and they don't need a agreement with Illumina to create an IVD kit, where the customer owns the quality system.

Q. And would a customer need an IVD agreement with

Illumina to develop an LDT test?

A. No.

Q. Now, generally, what are Illumina's obligations under a typical IVD agreement?

A. The obligations mostly are around the co-submission of documentations to the FDA, adhering to the quality agreement, and ensuring that the reagents that it manufactures adhere to the specifications and the performance qualifications under that quality agreement, and also mainly being a responsive supplier and ensuring that the laboratory has adequate supply of instruments and reagents to serve its own needs and meet its own demand.

Q. And on direct you mentioned also that there is a software module that Illumina needs to provide?

A. Yes. Thank you for reminding me.

So under the IVD kit agreement, there's a software module that Illumina provides that is uploaded into the locked configuration of the system that ensures that a customer can see the test item under the menu, and then that a reportable is reported back to the user.

Q. And is it a requirement under FDA regulations that an instrument have that additional software provided by Illumina before it can run an approved

diagnostic?

A. It is. The manufacturer has to be responsible for upgrading or any -- any updates to the instrument.

Q. Is there also something called a right of reference involved in these agreements?

A. I'm not familiar with the right of reference.

Q. Are you familiar with a right of reference to Illumina's file at the FDA?

A. Okay, yes. In that context, yes.

Q. Could you explain what that is?

A. It basically --

MR. HARRELL: Objection. The witness lacks personal knowledge as to Illumina's current practice on agreements.

JUDGE CHAPPELL: Do you want to be more precise in the time period of your questioning?

MR. STARK: Yes, Your Honor.

BY MR. STARK:

Q. Mr. Leite, during the time that you worked at Illumina and you worked on negotiating Illumina's IVD agreements, did those agreements involve a right of reference to Illumina's file at the FDA?

A. It did, yes.

Q. And what is that?

A. So the approved -- the approval of the

instrument itself as an FDA-approved device has certain documents that are -- that have been submitted and filed and approved by the FDA, and those are the documents that an IVD manufacturer would refer to during their own submission.

Q. So does the -- does the IVD developer need to essentially use Illumina's data and Illumina's approval as part of their application?

A. That's essentially it, yes.

Q. And does the -- do the IVD agreements that you worked on provide that right to make use of Illumina's data and approval?

A. Yes.

Q. You've also testified today a bit on direct about quality agreements.

A. Yes.

Q. What's the relevance of a quality agreement to an IVD agreement?

A. Yeah, so the IVD manufacturer or the IVD partner in this case has to develop an assay, and as part of their FDA submission, has to outline the boundaries of the performance of that assay and indicate what would be an acceptable performance level versus a not acceptable performance level.

An important consideration in the development

of those boundary conditions is understanding how Illumina's own reagents and instruments contribute towards that performance variance. So a quality agreement outlines the relationship and the accountability between the two parties in developing both the quality system and the performance boundaries of the assay.

Q. And under the IVD agreements that you worked on, whose responsibility is it to ensure that the requirements of the quality agreement are met?

A. It's a combination of the quality team at Illumina and the manufacturing team.

Q. So it's Illumina's responsibility. Is that right?

A. Correct.

Q. Generally, how does the process of a customer entering into an IVD agreement with Illumina typically work?

MR. HARRELL: Objection to the use of the present tense as lacking personal knowledge.

MR. STARK: I'll rephrase, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. STARK:

Q. During your time working at Illumina, Mr. Leite, how did the process of entering into an IVD

agreement with a customer typically work?

A. Yes, so either myself or someone from the -- from my team would proactively approach an IVD provider, or that IVD provider would proactively approach us, and a discussion would ensue. There would be an alignment on the types of assays that would be developed under the agreement, and the time frame and the alignment of the responsibilities. Most of the discussion would usually fall under this quality agreement, and how much responsibility was owned by one party versus the other, and there was always discussion and a debate and ultimately a compromise.

This then results in what's called a -- a deal concept sheet, which is basically a term sheet without the financials where we can put down on paper what we just agreed to verbally. That then leads to discussion of financial considerations and a full term sheet, which then leads to a contract.

Q. In your experience, was Illumina willing to negotiate the terms of IVD agreements with its customers?

A. Once we had the strategy set and the deal framework approved, we were given a range of negotiation terms to agree to. Often, the discussion with the other party would take us into further

compromises which may require that we approach the leadership team yet again for an approval. So, yes, given the framework we were given, within those considerations, there was room to customize and maneuver to accommodate partners' needs.

Q. While you were at Illumina, did Illumina accept proposed modifications from customers when negotiating IVD agreements?

A. We did.

Q. Now, I apologize, you may have already, in effect, answered this, but is an IVD agreement with Illumina necessary for an Illumina customer to obtain FDA approval for an IVD test?

A. It is not strictly necessary. So there is an alternative path where a manufacturer may develop a kit, may ask the customer to run that kit in Illumina's instruments in what's called the research use-only mode, and, in essence, then the customer is responsible for the quality system and ensuring the quality performance of that assay.

Q. And that alternative path you just mentioned refers to IVD kits, particularly, right?

A. Kits, in particular, yes.

Q. Is an IVD agreement with Illumina necessary for an Illumina customer to obtain approval of a

site-specific IVD test?

A. It is not.

Q. And is it necessary for an Illumina customer to develop and commercialize an LDT?

A. It is not.

Q. Now, generally speaking, based on your time at Illumina, why did Illumina engage in IVD partnerships with customers?

A. Ultimately, a strategy was developed that outlined the benefits in creating a network of partners, each contributing investments and their own innovation into developing solutions on the Illumina platform, and the strategy outlined and quantified the potential benefit of such a network of partners.

Q. Now, based on your work at Illumina, was the purpose of Illumina's IVD agreements to raise the prices of kitted oncology assays?

A. No.

Q. And based on your experience at Illumina, was the purpose of Illumina's IVD agreements to diminish innovation in kitted oncology assays?

A. No.

Q. And was it the purpose of Illumina's IVD agreements to restrict competition among kitted oncology assays?

A. No.

Q. And what was the purpose of Illumina's IVD agreements in your experience?

MR. HARRELL: Objection. Asked and answered.

JUDGE CHAPPELL: That objection is overruled.

THE WITNESS: May I go ahead?

JUDGE CHAPPELL: Yes.

BY MR. STARK:

Q. Yes.

A. For the purpose of developed -- of IVD test kits, the purpose of the partnership framework was to ensure that there were multiple participants investing capabilities and their know-how into developing a variety of test solutions, to ensure that we could maximize access -- patient access to this type of testing by maximizing our penetration into the market.

There was an innate recognition coming out of the strategy that a single company could not create sufficient numbers of versions of assays and iterations of assays to meet the entirety of the market's requirements.

Q. And in your time at Illumina, based on your experience there, why did Illumina request up-front payments and other fees from customers to sign IVD agreements?

A. It was a combination of a number of factors. One, there was a recognition and quantification of the value that our own Dx platforms created, and we wanted to participate in that value creation. There was significant monetary investment from Illumina in the developments and the FDA approval of those systems that we wanted to recoup. And there was a potential for downside risk that we needed to offset through some financial consideration.

Q. Based on your experience and work at Illumina, do you have knowledge of the extent to which IVD test developers have invested in developing IVD kits under the terms of Illumina -- IVD agreements?

A. I have some insight based on their spend, but not to the totality of their spend.

Q. And what insight do you have?

A. Well, we know what they spent on buying instruments from Illumina. We know what -- what reagents they have purchased. I mean, they are customers as well as partners.

Q. And to your knowledge, have Illumina's IVD agreements affected the level of customer investment in kitted IVD oncology tests?

A. To the best of my knowledge, yes. We did see increased investments into the liquid biopsy space and

into the diagnostic testing space for oncology using NGS application.

Q. And based on your experience and your work at Illumina, do you have knowledge as to whether Illumina's IVD agreements with its customers have affected innovation in IVD kitted tests?

A. Well, I mean, I'll answer that generally by saying that we've seen more companies participating in the space with their own differentiated solutions, and those companies we've seen grow, and we've seen further investments, and some have even gone into -- to become public companies in their own right.

MR. HARRELL: Objection to that answer as nonresponsive to the question of whether he had knowledge.

JUDGE CHAPPELL: Response?

THE WITNESS: My knowledge is limited --

MR. STARK: Excuse me. I think His Honor's question is probably directed to me.

JUDGE CHAPPELL: It is.

MR. STARK: Your Honor, perhaps I could repose the question.

JUDGE CHAPPELL: All right. The current answer will be disregarded based on the objection. Go ahead.

BY MR. STARK:

Q. Mr. Leite, let me ask you specifically, do you have knowledge, based on your experience, as to the level of innovation in kitted oncology tests used Illumina's platform?

A. Only based on what I see in the public domain.

Q. To your knowledge, have Illumina's IVD agreements affected innovation of kitted IVD oncology tests?

MR. HARRELL: Objection. Improper lay opinion.

JUDGE CHAPPELL: You are going to have to lay a foundation for that or move along.

BY MR. STARK:

Q. Mr. Leite, based on your work at Illumina, did you observe instances of innovation of kitted oncology tests?

A. I did, yes.

Q. And based on those observations, do you have knowledge of the level of innovation with regard to kitted oncology tests?

A. It's difficult to quantify increasing or decreasing levels of innovation versus some other baseline, but I think in general it's fair to say that customers of Illumina have continued to innovate applications on the Illumina platform.

Q. Do you, based on your experience working at

Illumina, have knowledge about the level of competition among test developers for pharmaceutical partners in the IVD kitted oncology space?

A. Yeah. It's not a simple answer. In a sense, a pharma partner will engage often with multiple providers of IVD test kits to ensure maximal penetration and maximal market access, but in general I think it's fair to say that there are multiple customers of Illumina pursuing pharma partnerships.

Q. Based on the time that you worked at Illumina, did the number of customers pursuing those pharma partnerships increase?

A. It did.

Q. I would like to now switch gears, Mr. Leite, to ask you some questions about your current company, InterVenn. You joined InterVenn, I think you testified, earlier in November 2020. Is that right?

A. That's correct.

Q. What's your title at InterVenn?

A. I'm the chief business officer.

Q. And what are your duties as chief business officer?

A. I am responsible for major partnership transactions, as well as responsible for commercial activities.

Q. Do you have responsibility for corporate strategy and corporate developments?

A. I do.

Q. Could you generally describe InterVenn's business?

A. Sure. We are the developers of a platform which combines laboratory work flow and proprietary software to interrogate a layer of biology called the glycoproteome. It's a subspecialization of proteomics. This platform is used for extending our knowledge of biomarker development and discovery, new drug target discovery, and clinical intervention such as diagnostics and potentially new drug and new drug targets. And it can serve the needs of researchers as well as clinicians.

Q. Does InterVenn's businesses that you just described relate to oncology clinical tests?

A. They can, yes.

Q. Could you explain in a little more detail what is glycoproteomics?

A. Certainly. So glycoproteomics is the study of proteins and a post-translational modification is of these proteins called a glycosylation. It's mainly a sugar and a variety of different sugars and a variety of different structures that are attached to these

proteins. Up until recently, the function of these sugars was poorly understood. It's becoming more and more documented and published that these sugars actually do have important functions in metabolism and disease process, and we are leveraging the identification of these sugar molecules for the purposes of diagnostics and clinical intervention.

Q. And, Mr. Leite, I'll just remind you out of caution that we're on the public record. I'm going to ask you questions that I intend only to elicit public information. Please tell me if we run into a problem there. Is that okay?

A. Certainly.

Q. Does glycoproteomics at InterVenn use next-generation sequencing?

A. It does not.

Q. Does InterVenn use next-generation sequencing for any of its products?

A. We do not.

Q. Does InterVenn have a proprietary glycoproteomics platform of its own?

A. We do.

Q. What types of proprietary assays is InterVenn developing on its platform?

A. Certainly. So we are pursuing an ovarian

cancer screening test. This is to screen patients that are symptomatic with pelvic masses and are undergoing an ultrasound examination, and the blood test determines if the pelvic mass is likely to be benign or malignant.

We are developing a predictive test for late-stage cancer patients who are being considered for immunotherapies, and the test determines if they are likely to respond or not likely to respond.

We are also developing an assay for colorectal cancer screening, the idea being these are healthy patients that are being examined or, I'm sorry, considering a colonoscopy procedure. This could be a complementary or alternative to colonoscopy.

Q. Now, does InterVenn have a product called Dawn, D A W N?

A. Yes. Dawn is the amino therapy prediction assay I described.

Q. Is that the test for ovarian cancer?

A. No. That test is called Glori.

Q. How does the Dawn test work?

A. Yeah, so it's a series of proprietary biomarkers that are analyzed for their glyco forms. These are inputted into an algorithm that gives you a score. That score gives you a likelihood or not

likelihood of response to a variety of different immunotherapies and specific cancer types.

Q. Now, does Dawn target late-stage cancers?

A. Yes, late-stage cancers, patients that are being considered for immunotherapies.

Q. And I'm sorry if I -- you may have already mentioned, but which cancers does Dawn identify?

A. We have identified melanoma, non-small cell lung cancer, and pancreatic cancers, as are indicated -- well, are indications.

Q. Has InterVenn conducted any clinical studies for Dawn?

A. We have conducted a number of studies, some retrospective, and we are planning additional studies as well.

Q. What are the study populations that InterVenn has used in its Dawn clinical studies?

A. These are patients that are being actively treated with those therapies, and we do an assessment of blood samples to determine their likelihood to respond versus the actual response.

Q. Do you know when Dawn will be commercially available?

A. We have not publicly disclosed the release date.

Q. Is InterVenn seeking FDA approval for Dawn?
A. We may at some future point, yes.
Q. I'd like to just display a couple of demonstrative slides, which we shared with Complaint Counsel. The first one is RDX 9 for the record, just a demonstrative.
Now, Dr. Leite, this is a PDF from the InterVenn website. Do you recognize this page as being from the InterVenn website?
A. Yes, I do.
Q. And what does this page discuss?
A. It's just a brief introduction to our platform and our goal to create a number of clinical products based on this platform.
Q. And I'd like to move now to the second page of this demonstrative, and if you -- are you familiar with this chart, Mr. Leite?
A. I am, yes.
Q. And what does this chart show?
A. It shows the pipeline of our planned products that we are developing.
Q. And on the left-hand side -- well, withdrawn.
Is InterVenn developing early detection tests as well as late-stage tests?
A. We are. The advanced adenoma, colorectal

cancer, and nasopharyngeal carcinoma tests are early cancer screens.

Q. And on the left side of this chart, you see a column labeled "Indication."

A. Yes.

Q. And what does that show?

A. It shows the specific disease states that we're targeting for our clinical assay.

Q. Okay. And then the first row underneath "Indication," reads, "Ovarian Cancer." I believe you've testified about that, but just for clarity, what's the clinical application for this test?

A. It's in the reference to our Glori test, which is a blood-based test to determine if patients that are showing a pelvic mass by ultrasound are -- if the mass is tumor-benign or if it's malignant in nature.

Q. Is this one an early detection test?

A. It's more of a higher risk population diagnostic.

Q. But what phase of development is this ovarian cancer test in?

A. We've completed our LDT and CLIA validation, and we're in a precommercial state.

Q. And does this test use InterVenn's glycoproteomics platform?

A. It does.

Q. And the second row on this chart is labeled, "Immuno Oncology - Pancreatic, Melanoma." Do you see that?

A. Yes.

Q. What does that line refer to?

A. That is our Dawn assay. It is an immunotherapy response prediction assay.

Q. And is that an early detection test?

A. It is not.

Q. And what phase is the -- what phase of development is the Dawn product in?

A. We're past the point of our classifier validation and entering into our LDT planning stage.

Q. And does that test use the InterVenn glycoproteomics platform?

A. It does.

Q. Now, just going down to the next row, under "Indication," it reads, "Advanced Adenoma." Do you see that?

A. Yes.

Q. What does that row refer to?

A. It is a precancerous state that is often identified under colonoscopy and places the patient at risk for developing colorectal cancer.

Q. Is this an early detection test?
A. It is.
Q. At what -- and -- withdrawn.
Does this test use InterVenn's glycoproteomics platform?
A. It does.
Q. What phase of development is this product in at InterVenn?
A. We are looking to close out classifier validation, so it's in development still.
Q. And then the next line down is labeled "Colorectal Cancer." What does that refer to?
A. It is complementary to the advanced adenoma test, so it can differentially diagnose colorectal from advanced adenoma in the early detection setting.
Q. Is this an early cancer detection test?
A. It is.
Q. Does it use InterVenn's glycoproteomics platform?
A. It does.
Q. What stage of development is this test in?
A. The same. It's in development still.
Q. I would just like to refer to the final row, which is labeled "Nasopharyngeal Carcinoma." What does that row refer to?

A. It's the test to detect polyps in the nasopharyngeal tissue, and it's also as a -- it's -- it's currently in the proof of concept stage.

Q. And is this an early cancer detection test?

A. It is.

Q. And does this test use InterVenn's glycoproteomics platform?

A. It does.

Q. So based on this chart, InterVenn has several early cancer screening tests in development. Is that right?

A. That is correct.

Q. Are these tests based on blood draws?

A. Yes, they are.

Q. And do all these tests use InterVenn's glycoproteomics platform?

A. They do.

Q. And do any of them use Illumina's NGS platform?

A. They do not.

Q. Do any of them use anyone's NGS platform?

A. They do not.

Q. Does InterVenn plan to develop any additional blood-based cancer early screening tests based on its glycoproteomics platform?

A. No further plans beyond what's listed on this

table.

Q. We can take that demonstrative down. Thank you.

Why did InterVenn decide to pursue cancer screening tests using glycoproteomics?

A. There are several advantages to focusing on glycoproteins. One of the few is that we are actually interrogating the host immune response to the presence of the tumor, so we are actually not relying on analytes being shed by the tumor, as is the case with circulating DNA and NGS. Therefore, we're not limited by the size of the tumor or the stage of the cancer.

Q. Are you aware of any other blood-based cancer screening tests outside of InterVenn that use glycoproteomics?

A. No, I'm not aware of them.

Q. Have you heard of a company called Olink?

A. I have, yes.

Q. What does Olink do?

A. Olink has an antibody-based array for interrogating proteins using antibodies and different detection methods, some fluorescent, some actually use next-generation sequencing.

Q. And are you familiar with a company called SomaLogic?

A. I am.

Q. And what does SomaLogic do?

A. It's an array-based technology. I believe they are using aptamers.

Q. In your work at InterVenn, Mr. Leite, have you seen a level of investor interest in InterVenn?

A. We have, yes.

Q. Could you describe that?

A. We have secured a number of financial rounds in the last couple of years, most recently a Series C that we announced on August 3rd.

Q. And was that Series C fundraising successful?

A. It was, yes.

Q. How much did InterVenn raise in its Series C realm?

A. We publicly disclosed a $201 million raise.

Q. And in your -- given your work at InterVenn, are you familiar with the overall landscape of investments in oncology diagnostic companies?

A. Based on what I see on the public domain, yes.

Q. What have you observed, if anything, about investment in oncology diagnostic companies?

A. It appears to be an active area. Investors seem interested in oncology diagnostics.

Q. Now, you mentioned that InterVenn raised $201

million in its last Series C round of fundraising. For what purposes will InterVenn use those funds?

A. We have disclosed that we are planning on accelerating our development efforts to get products, some of the ones you've seen listed, onto the market and as such develop our commercial infrastructure and our operational infrastructure to meet the demands.

MR. STARK: Thank you, Your Honor. That concludes my questioning at this point, subject to the redirect.

JUDGE CHAPPELL: All right. Anything further?

MR. HARRELL: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION

BY MR. HARRELL:

Q. I'd ask to pull up RDX 9, which you were just looking at, Mr. Leite. Let's go to page 2 of that demonstrative.

Mr. Leite, do you recall Illumina's counsel asking you questions about this slide from InterVenn's website?

A. Yes.

Q. Starting with the first row for the indication of ovarian cancer, is that a single cancer test?

A. It is.

Q. Is it a multicancer early detection test?

A. It is not.

Q. The questions that you got from Illumina's counsel about whether something is an early detection test, could you please explain what you meant by "early detection"?

A. Ah, the general consensus definition is a test that is used to screen an otherwise healthy population for a potential cancer.

Q. Is an early detection test, as you used it in your answers before, the same as a test that's primarily designed for asymptomatic patients?

A. Yes. I would say that's accurate.

Q. Let's go to the next test on the list, "Immuno Oncology for Pancreatic and Melanoma." Do you see that?

A. Yes.

Q. Is that a single cancer test?

A. Well, Dawn will be a multiple cancer test. It's an aggregated set of claims, each claim having its own algorithm, but they are all wrapped in the same test.

Q. Is it a therapy selection test or a multicancer early detection test?

A. It is a therapy selection test.

Q. Going to the next one, "Advanced Adenoma." Is that a single cancer test?

A. Yes. It is a single cancer test.

Q. Is it a multicancer early detection test?

A. It is not multicancer.

Q. Going to the next on the list for colorectal cancer, is that a single cancer test?

A. It is a single cancer test.

Q. Is it a multicancer early detection test?

A. It is not a multiple cancer test.

Q. Going to next on the list, "Renal Cell Carcinoma," is that a single cancer test?

A. It is a single cancer test.

Q. Is it a multicancer early detection test?

A. It is not.

Q. And, finally, the last one for nasopharyngeal carcinoma, is that a single cancer test?

A. It is a single cancer test.

Q. Is it an early -- is it a multicancer early detection test?

A. It is not multiple cancer.

Q. Has InterVenn publicly disclosed any plans to develop multicancer early detection tests?

A. We have not publicly disclosed such intent.

Q. Do you recall your counsel asking you

whether -- and we can take this down and I'll start my question over.

Do you recall Illumina's counsel asking you whether FDA approval was necessary for an Illumina customer to develop a kitted test?

A. I did, yes.

Q. Do you remember answering that an IVD agreement -- excuse me. Let me actually ask the question one more time.

Do you recall Illumina's counsel asking you whether an IVD agreement with Illumina was necessary for FDA approval with respect to kitted tests?

A. Yes, I do remember.

Q. Do you remember answering that it wasn't strictly necessary?

A. I do remember.

Q. Could you please explain some of the downsides of not securing an IVD agreement with Illumina where a customer wants to launch an IVD kitted test?

A. Certainly. The effort of qualifying a new batch of Illumina reagents falls to the customer to seek a -- either the -- whether the reagents conform to testing that's been performed by the manufacturer, or they have to run a performance qualification using the protocol that's provided to them by the manufacturer.

Q. Are there any other downsides?

A. Well, there's the overall -- it's just a convenience factor, right? It's the overall additional effort required by the customer.

Q. Based on your experience negotiating these agreements and in Illumina's marketing department, do pharmaceutical companies and healthcare providers tend to want or expect developers of IVD kitted tests to have an IVD agreement with Illumina?

MR. STARK: Objection. Foundation.

JUDGE CHAPPELL: Do you want to respond or rephrase?

MR. HARRELL: I'll rephrase, Your Honor.

JUDGE CHAPPELL: Hold on a second. This is why I like realtime. The question begins with, "Based on your experience negotiating these agreements." The objection is overruled.

Susanne, please read the question, and he may answer.

(The record was read as follows:)

"QUESTION: Based on your experience negotiating these agreements and in Illumina's marketing department, do pharmaceutical companies and healthcare providers tend to want or expect developers of IVD kitted tests to have an IVD agreement with

Illumina?"

THE WITNESS: Yes, I would say that the payers and pharma expect their testing providers to adhere to a strict quality system. I don't know that they have enough sophisticated or understanding of the development of an assay to recognize the benefits or the lack of benefit in being in an agreement with Illumina or not. I think it's -- the table states that the test be of high quality.

BY MR. HARRELL:

Q. For those payers and pharmaceutical companies, and again, based on your experience in Illumina's marketing department and negotiating these agreements, does an IVD agreement with Illumina indicate to them that the test is of a certain quality?

A. I think there's likely to be a -- an enhanced reputation to the -- to the test if there is an agreement with Illumina in place. I think that's generally fair to say.

Q. To what extent would the customers negotiating IVD agreements with Illumina consider that reputational enhancement to be something valuable?

MR. STARK: Objection to foundation.

MR. HARRELL: May I respond, Your Honor?

JUDGE CHAPPELL: Respond or rephrase.

MR. HARRELL: The witness testified on direct examination that as part of his responsibilities at Illumina for negotiating these agreements it was his job to understand and even estimate the value of those agreements to the counterparties.

JUDGE CHAPPELL: Well, based on the objection, why don't you ask the witness that. Let's get it in the record right here.

MR. HARRELL: Yes, Your Honor. Happy to do that.

BY MR. HARRELL:

Q. Mr. Leite, was it your responsibility at Illumina during your time there, as part of negotiating agreements, to understand and estimate the value that Illumina's counterparties placed on IVD agreements?

A. It was, yes.

Q. And consistent with those responsibilities and your understanding, did customers indicate in negotiations with Illumina that they placed value on the reputational signal that an IVD agreement would send to payers and pharmaceutical companies?

A. Yeah. I would say that that response or sentiment was heterogenous. So the smaller companies saw that potentially they could enhance their own brand and reputation by such an agreement. Many companies,

especially those that had been in the industry for some time, did not place a great deal of value on just the brand or the enhancements of their own brand based on that deal.

Q. Well, apart from the brand enhancements, was there also value in your experience in these negotiations the customers indicated they placed on the quality reputational aspect?

A. It was -- it became very difficult to quantify, to be quite honest. The strong labs, the ones that were really experienced and knew how to outline the benefits of their own quality system, independent of whether they had a quality agreement in place with Illumina, as evidence I present to you the number of companies that have submitted and have been successful with site-specific PMAs to the FDA. Those don't require an agreement with Illumina, and they have been very, very successful in securing partners with pharma.

A number of others, like I said, perhaps being less mature in their own quality systems and experience, I think sought some enhancements of their reputational value.

Q. In other words, the smaller the company that's negotiating with Illumina, potentially the more value they might place on that reputational benefit?

A. I think it would be one of the considerations they would take into account. Yes, I think that's fair.

Q. Illumina's counsel also asked you about alternative paths that wouldn't involve Illumina's agreeing to give IVD rights as part of seeking FDA approval. Do you remember that?

A. Yes.

Q. Has any company -- and, again, because we're in a public session, so please, if there is such a company, don't name them -- has any company successfully executed on this strategy without going back to Illumina and asking for an IVD agreement?

A. I'm not aware of any.

Q. And do you recall testifying about a company -- again, unnamed -- that tried to adopt a work-around approach?

A. Yes, I am aware.

Q. And do you recall testifying that that company wasn't successful?

A. I recall testifying that the company was ultimately not commercially successful with that endeavor. They were successful in securing FDA approval.

Q. Were they successful after or before signing an

IVD agreement with Illumina?

A. Well, the FDA approval came with the prior to Illumina timeline.

Q. Illumina's counsel also asked you whether Illumina, during your time there, accepted proposals by customers during negotiations on IVD agreements. Do you remember that?

A. Can I ask you to rephrase the question?

Q. Yes. I'm actually asking for a clarification here, so I am going to try to be as specific as I can.

A. Okay.

Q. Do you recall Illumina's counsel asking whether, in the course of negotiations, Illumina accepted proposals that were made by customers in those negotiations?

A. Yes, I do.

Q. Did you mean to suggest that Illumina accepted every proposal that a customer made in a negotiation?

A. Not every customer.

Q. Is it fair to say that Illumina accepted customer proposals in those negotiations to the extent that it made financial sense for Illumina?

A. I think that's fair, yes. There were other considerations as well.

MR. HARRELL: Thank you, Your Honor. I have

nothing further right now.

JUDGE CHAPPELL: Anything further?

MR. STARK: Yes, Your Honor. I would like to ask to briefly put RDX 9 back on the screen.

RECROSS EXAMINATION

BY MR. STARK:

Q. Mr. Leite, does this exhibit show multiple early cancer tests that all run on InterVenn's glycoproteomics platform?

A. Yes. All these tests run on the same platform.

MR. STARK: Thank you.

No further questions, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. HARRELL: Yes. Just one question, Your Honor.

FURTHER REDIRECT EXAMINATION

BY MR. HARRELL:

Q. Let's pull up RDX 9, page 2, please.

Just to clarify, Mr. Leite, when Illumina's counsel asked you whether this exhibit shows multiple early cancer tests, you didn't mean to imply that there were any multicancer early detection tests on here, did you?

A. So, again, the platform and the work flow are the same. The inclusion of a new reportable indication

requires InterVenn to validate a set of markers that are run in response to the request from the physician. To run multiple indications from the same blood sample would require that we run different, let's call them, in silica or software analytical analyses off the same sample.

So the definition of a multitest becomes a little bit ambiguous in this context. It's not like the next-gen sequencing platform where you're including the genes necessary for a multitest indication in the same run and analysis simultaneously. In the InterVenn example, these would be run in sequence, off the same sample, off the same instance.

MR. HARRELL: Thank you, Your Honor. Nothing further.

JUDGE CHAPPELL: Anything further?

MR. STARK: Nothing further for Respondents, Your Honor. Thank you.

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

Call your next witness. We're going to just take about a five-minute break while you call the witness. We're all going to remain in the courtroom. Go ahead and get everything set up for the next witness.

MR. HARRELL: Yes, Your Honor.

(A brief recess was taken.)

JUDGE CHAPPELL: Call your next witness.

MS. MUSSER: Yes, Your Honor. Complaint Counsel calls Francis deSouza, chief executive officer of Illumina, to the stand.

Whereupon--

FRANCIS deSOUZA

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

DIRECT EXAMINATION

BY MS. MUSSER:

Q. Good afternoon, Mr. deSouza.

A. Good afternoon.

Q. Mr. deSouza, can you please state and spell your name for the record?

A. My name is Francis deSouza, that's F-R-A-N-C-I-S, deSouza, d-e-S-O-U-Z-A.

Q. And, Mr. deSouza, you're the chief executive officer of Illumina, correct?

A. Yes.

Q. And you have been CEO of Illumina since July of 2016. Is that right?

A. That's right.

Q. And as of CEO, you have responsibility over a

number of functions at Illumina. Is that fair?

A. Yes.

Q. And one of those functions is finance?

A. Yes.

Q. Another one of those functions is the human resources or HR function?

A. That's correct, yeah.

Q. You also have responsibility as CEO over the legal function?

A. That's right.

Q. You have responsibility over the corporate development function. Is that correct?

A. Yes.

Q. And, finally, you have responsibility over the strategy function at Illumina. Is that right?

A. I do.

Q. And Susan Tousi reports to you as Illumina's chief commercial officer. Is that right?

A. Yes.

Q. And Dr. Aravanis also reports to you as Illumina's chief technology officer?

A. Yes.

Q. And Sam Samad reports to you as chief financial officer?

A. Yes.

Q. And Chuck Dadswell reports to you as general counsel?

A. Yes.

Q. And does Nicki Berry report to you as general manager responsible for the Americas region?

A. No. She reports to Susan Tousi.

Q. And Ms. Tousi reports to you. Is that right?

A. Yes.

Q. And, finally, Joydeep Goswami reports to you. Is that correct?

A. Yes.

Q. And Mr. Goswami is responsible for corporate development and strategy. Is that right?

A. That's right.

Q. And Illumina is a for-profit company, correct?

A. That's correct.

Q. Illumina is also a public company. Is that correct?

A. That's correct.

Q. And as a public, for-profit company, Illumina's shares are floated on publicly traded --

(Zoom disconnection of court reporter.)

THE REPORTER: I dropped off, Your Honor. Was it only me or --

THE COURT: Yes, we lost you.

THE REPORTER: I can read back where I dropped.

MS. MUSSER: Your Honor, I can re-ask the question.

BY MS. MUSSER:

Q. Mr. deSouza, as a public for-profit company, Illumina's shares are floated on publicly traded exchanges. Is that correct?

A. That's correct.

Q. And as a public company --

A. That's right.

Q. And Illumina also owes a fiduciary duty to those shareholders. Is that right?

A. That's right.

Q. And having a fiduciary duty, things are happening to create long-term value for shareholders. Is that right?

A. That's right.

Q. And this fiduciary duty requires you to try and increase the value of the company. Is that right?

A. That's right.

Q. And part of increasing the value of the company is to try and increase revenue. Is that right?

A. That's part of it, right.

Q. And you get a bonus as CEO, correct?

A. Yes.

Q. And your bonus is tied to meeting certain performance metrics. Is that right?

A. That's right.

Q. And those performance metrics include meeting certain revenue targets. Is that fair?

A. That's right.

Q. And those performance metrics also include meeting certain earnings-per-share targets for the year?

A. That's right.

Q. Is that right?

And, Mr. deSouza, you started at Illumina in 2013?

A. That's right.

Q. Correct?

And from 2013 to 2016, you were the president primarily responsible for products. Is that right?

A. That's right.

Q. And as president of products, you reported to Jay Flatley?

A. That's correct.

Q. And Jay Flatley was CEO from 2013 to 2016. Is that right?

A. Yes.

Q. And GRAIL was created as part of Illumina in

2015. Is that right?

A. The team started working on it a little before 2015. GRAIL, the entity, was created in 2016.

Q. But the team started working on GRAIL a little before 2015. Is that right?

A. That's right.

Q. And I missed your answer, Mr. deSouza. Is that right?

A. That's right. That's right.

Q. Okay. And you also just mentioned that GRAIL, the entity, was created in 2016. Is that right?

A. Yes.

Q. And that was when GRAIL was separately incorporated?

A. That's correct.

Q. Mr. McCullough, can you please pull up what's been marked as PX 2543. This is on JX 2 and has already been admitted into evidence.

Do you see the top of this document, Mr. deSouza?

A. I do now. I do now, yes.

Q. And it says, "GRAIL FAQs, January 11, 2016." Do you see that?

A. I do.

Q. And on the first paragraph, it goes on to say,

"On Sunday, January 10th, Illumina announced the formation of a new company -- GRAIL."

Do you see that?

A. Yes.

Q. And these are FAQs relating to the spinoff or incorporation of GRAIL. Is that right?

A. That's right.

Q. Mr. McCullough, can you please turn to the bottom Q, please.

And one of the questions in this FAQ was why is Illumina starting another company versus expanding its own business to include these new services. Do you see that?

A. I do.

Q. And the first part of the answer is, "This is a major R&D endeavor."

Do you see that?

A. I do.

Q. The answer goes on to say, "requiring trials which will sequence more individuals than any program announced to date, but with the potential for significant returns."

Do you see that?

A. Yes, I do.

Q. The answer goes on to say, "GRAIL is majority

owned by Illumina, but the independent structure will allow us to run as a true start-up."

Do you see that?

A. I do.

Q. And, finally, the answer goes on to say, "The business of GRAIL will be very different from Illumina's core business."

Do you see that?

A. I do.

JUDGE CHAPPELL: Could we see the top of that document, please?

MS. MUSSER: Of course. Mr. McCullough, could you please pull that up?

Is there a particular part you would like to see?

THE WITNESS: I just wanted more info on what this is we're reading from. Could you cover that with the witness?

BY MS. MUSSER:

Q. Of course. These are questions prepared relating to the formation of GRAIL in 2016. Is that correct?

A. That's correct, for a presentation to investors about GRAIL and what we were doing in forming GRAIL.

JUDGE CHAPPELL: Thank you.

MS. MUSSER: Thank you, Your Honor.

BY MS. MUSSER:

Q. Mr. McCullough, you can pull this down.

When GRAIL was first spun off, Illumina still owned over 50 percent of GRAIL. Is that right?

A. That's right.

Q. So post-spinoff, Illumina was still the majority owner of GRAIL. Is that correct?

A. That's right.

Q. But GRAIL remained an Illumina-affiliated entity even after the spinoff. Is that right?

A. That's right, and we owned a majority of it.

Q. And while Illumina was a majority owner, GRAIL had access to deeper discounts on Illumina products than Illumina's other customers. Is that fair?

It received deeper discounts on Illumina's consumables than other customers. Is that right?

A. That's right.

Q. And it also received deeper discounts on Illumina sequencers than other customers. Is that right?

A. That's right. Isn't that what you said two questions ago? Is that the same question?

Q. I believe I asked about consumables.

A. Oh, yeah. So both consumables and sequencers,

that's right.

JUDGE CHAPPELL: I think he attempted an "asked and answered" objection there.

BY MS. MUSSER:

Q. Post-spinoff in 2016, Illumina was also entitled to a royalty payment from GRAIL of future sales. Is that right?

A. That's correct.

Q. And this royalty payment entitled Illumina to receive a certain percentage of future GRAIL sales. Is that correct?

A. That's correct.

THE COURT: Susanne, are you there?

THE REPORTER: Yes, I'm here.

THE COURT: I guess you're sitting there so stoically, I thought you were frozen again.

THE REPORTER: No, I'm here.

THE COURT: Okay, go ahead.

BY MS. MUSSER:

Q. And due to the combination of royalty and Illumina's equity stake, it made financial sense for Illumina to provide a discount to GRAIL, right?

A. That's right.

Q. And if we could pull up that document that we were just looking at.

And another question that was part of these FAQs was, "Why aren't we enabling customers to sequence at the lower cost that we are giving GRAIL"?

Do you see that?

A. I do.

Q. And the answer goes on to say, "We own greater than 50% of GRAIL and we get a significant royalty and our customers wouldn't be able to give those type of economics."

Do you see that?

A. Yes I do.

Q. Basically, the cash GRAIL played for sequencers and consumables, as well as the royalty and the equity of -- and Illumina's equity compensated Illumina for the discount Illumina was providing them. Is that right?

A. That's right.

Q. And for Illumina to provide the same level of discounts to other customers, those customers would also need to have the same combination of sales to Illumina, royalty paid to Illumina, plus equity paid to Illumina. Is that right?

A. That's theoretical, because there were no others in that space. So there was nobody to do that trade with.

Q. Mr. McCullough, could you please pull up PX 7107.

Would you -- you were deposed in this case. Is that right?

A. Yes.

Q. If you could turn to page 196, lines 5 through 16, please.

Okay, you were asked:

"QUESTION: And the amount that you got -- that you could get paid back was more than the amount that you could receive from other companies offering the same cost to those companies?"

Do you see that?

A. Yes.

Q. And you respond:

"ANSWER: They would have to -- SO to get US a discount, GRAIL paid us -- they paid us cash for those sequencers and consumables, plus a royalty on the test, plus equity. And that combination compensated for the discount we were giving them.

"QUESTION: Okay."

And then you go on to say:

"ANSWER: And that's what other customers would have to do."

Do you see that?

A. Yes.

Q. You can pull that down.

And in early 2017, GRAIL initiated their Series B financing to raise over $1 billion. Is that right?

A. That's right.

Q. I'm having a little hard time hearing you, Mr. deSouza.

A. That's correct.

Q. Thank you.

And Illumina made the decision to reduce their ownership in GRAIL during this round of financing. Is that right?

A. That's right.

Q. And post Series B financing, Illumina's ownership interest in GRAIL reduced from a majority ownership interest to less than 20 percent of GRAIL. Is that correct?

A. That's right.

Q. Now, at the time of the Series B financing, other companies were beginning to get interested in developing liquid biopsy tests. Is that right?

A. That's right.

Q. And multiple reasons factored into Illumina's decision to reduce its ownership percentage of GRAIL. Is that fair?

A. That's right.

Q. And one of those reasons was that Illumina felt that it created more shareholder value for Illumina to lower its stake in GRAIL. Is that right?

A. That's right.

Q. And as custodians of shareholder money, Illumina needed to assess what was going to drive returns for shareholders. Is that right?

A. That's right.

Q. Turning to a second reason, at the time of the Series B, companies were trying different approaches to do early cancer detection. Is that right?

A. That's right.

Q. And one input into Illumina's decision to reduce its stake was to give companies as many NGS-based shots on goal for early cancer detection screening as possible. Is that right?

A. I'm sorry. Did you say -- could you repeat that question?

Q. Sure.

And one input into Illumina's decision to reduce its stake was to give companies as many NGS-based shots on goal for early cancer detection screening as possible. Is that correct?

A. No, that's not right.

Q. Do you recall that Illumina investors told -- Illumina representatives told investors that one rationale for spinning off GRAIL was to encourage investment into many different NGS-based companies focused on early cancer detection in order for those companies to have as many shots on goal as possible?

A. Yeah. Our thinking was we wanted to see which approach would work so that we could figure out in the end what was the right way to go, because it wasn't clear to anybody in the market which way to go, and we didn't want to be tied to just one approach. So it gave us the opportunity to assess which way the market was going to go and which technology would work.

Q. And it also gave companies as many NGS-based shots on goal for early cancer detection screening as possible. Is that right?

A. They had -- they had shots on goal whether we reduced our stake in GRAIL or not.

Q. Can you please pull up what's been marked as PX 2561. Can you turn to the top of this email. This is an email from Juliet Cunningham to you, Mr. deSouza.

A. Yes.

Q. Who is Mr. Cunningham?

A. She was the vice president of investor relations at Illumina.

Q. And do you see where it says, "Please see below and attached for Sands call today at 10:30 a.m. PT."

Do you see that?

A. Yes.

Q. And Sands refers to Sands Capital Management. Is that right?

A. That's right.

Q. And Sands is Illumina's eighth largest shareholder. Is that right?

A. That sounds right.

Q. And as part of Sands' stewardship program, Sands likes to engage directly with Illumina. Is that right?

A. That's right.

Q. If you could turn to page 17, Mr. McCullough, and could you turn to point 5, please. Can you pull up the full paragraph, please.

And do you see where it says in this document, "Illumina invented the GRAIL technology, then spun it out in 2016 and is now acquiring it back"?

Do you see that?

A. Yes.

Q. And it goes on to say, "Can you lay out the thinking along this journey?"

Do you see that?

A. I do.

Q. And the second bullet point says, "We spun out GRAIL to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible."

Do you see that?

A. I do.

Q. You can put this document now.

JUDGE CHAPPELL: Ms. Musser, we have heard you refer to "shots on goal" today and in your opening statement. Are we talking hockey or soccer?

MS. MUSSER: Hockey. I'm a hockey fan. Well, I should ask, Your Honor, are you a hockey fan?

JUDGE CHAPPELL: Of course.

Mr. deSouza, and you answered with that phrase, so were you referring to hockey or soccer?

THE WITNESS: You know, soccer.

JUDGE CHAPPELL: See, that's why I asked.

THE WITNESS: And I was referring to shots on goal in soccer even in that note, just to complete my answer.

THE COURT: Do you have some type of special microphone there? You sound like a radio announcer. What brand is that?

THE WITNESS: It is Yeti, Y-E-T-I, and it's

fantastic.

JUDGE CHAPPELL: The same company that makes the coolers?

THE WITNESS: I don't know, but it looks like on it, it says blue. So it's Yeti Blue. I like it.

JUDGE CHAPPELL: Thank you.

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

JUDGE CHAPPELL: Yes.

BY MS. MUSSER:

Q. The Series B financing changed Illumina's relationship with GRAIL from an Illumina affiliate to a customer. Is that right?

A. Yes, that's right.

Q. And you had earlier explained that Illumina provided GRAIL deeper discounts than other customers. Is that right?

A. Initially, until the series -- the next series round, and then it went away.

Q. Okay. And the next series round is Series B, correct?

A. Yes, that's right.

Q. And then you just testified that the deeper discounts went away after the Series B financing round. Is that right?

A. That is correct.

Q. Mr. McCullough, could you please pull up PX 2406. This has been admitted into evidence under JX 2. Could you please pull up the middle email.

This is an email from Eric Endicott to Marc Stapley, Jay Flatley, yourself, and others.

Do you see that?

A. I do.

Q. And this email is dated Sunday, January 1st, at 2017, and the subject is, "Re: GRAIL financing announcement."

And this is initially a draft to Marc, and "Marc" refers to Marc Stapley. Is that right?

A. Marc Stapley, yes.

Q. And who is Marc Stapley?

A. Marc Stapley I believe at the time was our chief administrative officer.

Q. And it's from Eric. That refers to Eric Endicott. Is that right?

A. That's right.

Q. And who is Eric Endicott?

A. He ran public relations for us.

Q. And Eric writes, "Here is an initial Q&A for investors and media."

Do you see that?

A. I do.

Q. And he asks if he can get edits from this team back by midday tomorrow."

Do you see that?

A. Yes.

Q. And can you go to the next email on the top of this chain, please.

And Jay plat will I responds, "May marks," and attaches a document entitled, "GRAIL-Q&A-V2-J mark." Do you see that?

A. I do.

Q. And Jay is Jay Flatley?

A. That's right.

Q. And what was Jay Flatley's role at this time?

A. At the time, he was executive chairman of Illumina.

Q. And at this time he still had responsibilities -- executive responsibilities at Illumina?

A. Yes.

Q. Is that right?

And one of them was relating to the Series B investment in GRAIL?

A. Yes.

Q. Can you turn to the second page, please. I'm sorry, page 5.

Can you turn to the top of the screen.

And here it says, "Illumina/GRAIL Q&A for use with investors and media." These were draft questions and answers relating to the Series B financing. Is that correct?

A. That's right.

Q. And can you turn to the question starting, "By creating and unleashing"?

And one of the questions was, "By creating and unleashing GRAIL have you created a competitor for your customers?"

Do you see that?

A. I do.

Q. And Mr. Flatley writes, "With this change we have actually leveled the playing field."

Do you see that?

A. I see that.

Q. "Previously, GRAIL had access to technology and pricing that was preferential to our customers, albeit just for the asymptomatic screening market."

Do you see that?

A. I see that.

Q. And that preferential pricing and access to technology was referring to those deeper discounts that you testified about earlier. Is that right?

A. That's right.

Q. And after this round of financing, GRAIL was going to have access to technology on the same terms and pricing as other large customers. Is that correct?

A. That's right. It's the same clause we had taken into our open offer letter right now. That's right.

Q. So, yes?

A. That's correct, yes.

Q. And he continues: "As a result, we believe that will accelerate the liquid biopsy market for all."

Do you see that?

A. I see that.

Q. And, Mr. McCullough, if you could pull up PX 2544.

Mr. deSouza, as part of your role and responsibilities at GRAIL, do you speak to investors?

A. I do.

Q. Do you speak to them on a quarterly basis? Is that right?

A. Ah, at least quarterly, and then in between I'll speak to them sort of on an ad hoc basis, maybe once every few weeks.

Q. And this is an email from Tycho Peterson to yourself. Tycho Peterson works at J.P. Morgan. Is

that correct?

A. That's correct.

Q. And this is, "Subject: "Conversation with Illumina CEO Francis deSouza, transcript attached."

Do you see that?

A. I do.

Q. And it attached JPM LST CEO call with ILMN." "ILMN" means Illumina, correct?

A. That's right.

Q. Can you go to the page 3, please. My apologies, Mr. McCullough, one page back.

If you go to the top section of this document, do you see where it says, "JPM Life Sciences CEO Conference Call Series: Illumina, September 3rd, 2019"?

A. I do.

Q. You participated in the JPM Life Sciences CEO Conference Call Series. Is that right?

A. I did.

Q. And you spoke at this conference call series?

A. Yes.

Q. And this is a transcript of that conversation. Is that right?

A. Okay. I haven't seen it, but I -- yes, I believe it is.

Q. Mr. McCullough, you can take that down, and can you go to page 3.

If you could go -- do you see your name there on the second paragraph?

A. Yes.

Q. And do you see where it transcribes or a provides transcription of this call?

A. I do.

Q. Now, you previously told Tycho Peterson on this JPM investor call that, "In liquid biopsy, Illumina was one of the catalysts of this space as a whole and we incubated GRAIL internally and then spun it out."

Do you recall that?

A. I'm sorry, are you reading from somewhere?

Q. We will go ahead and go to that section.

If you could go to PX 2544, page 19, third paragraph from the top, Mr. McCullough.

Do you see where it says, "In liquid biopsy, as you will recall, we were one of the catalysts of that space as a whole when we incubated GRAIL internally and then spun it out."

Do you see that?

A. Yes.

Q. And that's what you told Tycho Peterson during this CEO investment call. Is that right?

A. Yes.

Q. And you continued, "We're continuing to work and I think we're tracking over 70 companies that are doing liquid biopsy in some form or another."

Do you see that?

A. Yes.

Q. "We continue to support them in some cases. It's making sure that they have access to the best of our workflow even on the front end or on the back end."

Is that right?

A. That's right.

Q. And you went on to tell Mr. Peterson that, "In some cases, it's planning with them what their path to a regulated offering could be, cleared offering. And so we're continuing to work with them in a number of different ways to enhance their ability to expand their market because, what's good for them is obviously good for us too."

Do you see that?

A. I do.

Q. And this investor call was dated in September of 2016. Is that correct?

A. Ah, I don't see a date. Where are you looking?

Q. If you can go to the second page, please.

A. I thought it was 2019, not 2016. Yeah, it's

2019, not 2016.

Q. My apologies. I misspoke.

So this took place September 3rd, 2019?

A. That's right.

Q. Thank you.

We can go ahead and put that away, Mr. McCullough.

Now, discussions regarding acquiring GRAIL began in late 2019. Is that right?

A. That's right.

Q. And it began after GRAIL published its data at the ASCO and EMSO conferences. Is that right?

A. That's right.

Q. And ASCO is a medical conference?

A. Yes.

Q. And EMSO is a medical conference as well?

A. That's right.

Q. And Illumina announced its intent to acquire GRAIL on September 21st, 2020. Is that right?

A. That's right.

Q. Illumina agreed to acquire GRAIL for a total cash and stock consideration of $8 billion, correct?

A. That's right.

Q. And as part of that transaction, Illumina agreed to pay GRAIL's shareholders approximately $4

billion in common stock. Is that correct?

A. That's right.

Q. And the last component of the deal included contingent payment rights to GRAIL's shareholders based on GRAIL's related -- GRAIL-related revenues for a 12-year period. Is that correct?

A. That's correct.

Q. You earlier testified that part of your role as CEO is speaking from investors from time to time and at quarterly updates. Did I get that correct?

A. You did.

Q. And when you speak to investors, you provide them with truthful information?

A. Yes.

Q. And you provide them with accurate information?

A. I do.

Q. And after the announcement of Illumina's intent to acquire GRAIL in September of 2020, you spoke with investors. Is that correct?

A. I did.

Q. And you spoke at the Cowen Liquid Biopsy Summit?

A. I did.

Q. What is the Cowen Liquid Biopsy Summit?

A. It was an online call, I guess, that an

investment bank hosted and invited investors to discuss the liquid biopsy market.

Q. Mr. McCullough, could you please pull up PX 2575, which has already been admitted into evidence under JX 2, and turn to page 58.

Do you see the top of this document?

A. I do.

Q. It says, "Edited Transcript, ILMN.OQ, Illumina, Inc. at Cohen Liquid Biopsy Summit (virtual)."

Do you see that?

A. I do.

Q. And it presents the date and time of September 24, 2020. Is that right?

A. Yes.

Q. If you could turn to page 59, I'm looking at the top here. Do you see where it lists corporate participants?

A. Yes, I do.

Q. Now, is your name listed there?

A. Yes.

Q. Do you see where it lists conference call participants?

A. I do.

Q. And do you see where it lists Doug Schenkel?

A. Yes.

Q. Who is Doug Schenkel?
A. He's an analyst at Cowen.
Q. And that's Cowen & Company, LLC?
A. Yes.
Q. Mr. McCullough, if you could turn to the bottom portion of this page.
And Doug Schenkel -- do you see on the top where it says "Questions and Answers"?
A. Yes.
Q. These are questions and answers asked during the course of this call. Is that correct?
A. That's correct.
Q. And Doug Schenkel in this paragraph asks what investors were missing related to this transaction, and what, if anything, you wanted to say that you didn't say on Monday to address some of those concerns.
Do you see that?
A. I do.
Q. If you could turn to the next page.
And do you provide your -- and your response is transcribed in these paragraphs. Is that right?
A. Yes.
Q. And turning to the top portion, you say, "I'd like to -- I'd like to point out --" give me one second.

As part of your answer, you say, "I'd like to point out that after the GRAIL acquisition gives us a leading position in this very large market opportunity. And the early detection cancer market dwarfs the clinical markets we see today, NIPT and therapy selection for oncology combined."

Do you see that?

A. I do.

Q. And when you say I'd like to point out that the GRAIL acquisition gives us a leading position in this very large market opportunity, you're talking about the market opportunity that the GRAIL acquisition provided. Is that right?

A. That's right.

Q. And then you go on to say, "And then, finally, by participating directly in that segment with our own solution, it allows Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider."

Do you see that?

A. I see that.

Q. And those were two -- two of several things that you highlighted for Mr. Schenkel. Is that right?

A. That's right.

Q. If you could turn to page 62, please.

As part of this conference call, you also told investors that you did a financial analysis as part of this deal. Do you see that?

A. I do see that.

Q. And Illumina, in fact, did a financial analysis as part of assessing this deal. Is that correct?

A. That's correct.

Q. And you go on to explain that moving from selling platforms to GRAIL and participating in the revenue stream to owning GRAIL is significantly value-accretive to the Illumina shareholders compared to the previous models.

Do you see that?

A. I do.

Q. And you go on to say, "But in terms of value to Illumina shareholders, owning it creates significantly more value."

So owning GRAIL created significantly more value to Illumina shareholders. Do you see that?

A. That's right. Doing this deal created value for Illumina shareholders. I see it.

Q. And if you would turn to page 80, please.

You also told Illumina's shareholders as part of this deal that, "As Sam pointed out, there is a $60 billion market opportunity. We are able to sort of

capture the value better than the current agreement."

Do you see that?

A. That's right.

Q. And is "Sam" Sam Samad?

A. Sam is Sam Samad.

Q. And he is the CFO of Illumina?

A. Yes.

Q. And when you say, "We are able to sort of capture the value better than the current agreement," you were referring to this acquisition. Is that correct?

A. Yes, that this acquisition creates value for Illumina's shareholders.

Q. And if you could just turn to page 64, please.

If you go to the bottom section and zoom in, Doug Schenkel asked, in part, "But I am curious, how are your customers reacting? I think at the time of the call on Monday, you weren't in a position to have had those conversations." And he asked if you can tell us anything about how the reaction has gone so far.

Do you see that?

A. I see that.

Q. If you could go to the next page, please.

And in answer to Mr. Schenkel's question, you say that "our strategy has always been we want to be a

platform provider to all market segments that we serve. But in a few segments we will also provide a vertical solution that could compete with some of our other -- some of our customers." (As read.)

Do you see that?

A. I do.

Q. You go on in the next paragraph to say that about 20 customers out of the 6,600 have said they have interest in exploring that space, and that's the space of early cancer detection. Is that right?

A. That's right. So none of them are in the space, but about 20 we thought had an interest in exploring that space.

Q. And those 20 customers represent roughly about 2 percent of your revenue. Is that right?

A. That's right. The business those customers did in other segments, in total, represented 2 percent of our revenue.

Q. So those customers collectively represented 2 percent of Illumina's revenue. Is that right?

A. That's right, in segments other than this segment.

Q. And let's talk about who those customers are. Those 20 customers include Guardant, correct?

A. Yeah, Guardant; Roche, for example.

Q. Does it also include Freenome? Is that correct?

A. They do include Freenome.

Q. And Singlera?

A. And Singlera.

Q. And Exact?

A. And Exact.

Q. And GRAIL?

A. And GRAIL.

Q. And you earlier testified that -- and you can put this down, Mr. McCullough.

You earlier testified that as a member of the board of directors, you owe a fiduciary duty to your shareholders. Did I get that right?

A. Yes.

Q. And that fiduciary duty requires you to increase the value of your company, correct?

A. Yeah. We have got to create long-term shareholder value. That's right.

Q. And by -- when making merger and acquisition decisions, you have to abide by that fiduciary duty. Is that right?

A. That's right.

Q. Switching gears a little bit, I wanted to ask you a few questions about another investor conference.

Mr. McCullough, if you could pull up what's been marked as PX 2544, and this is a conference that we had previously looked at portions of, so you should recognize this email, but, again, this is from Tycho Peterson at JP Morgan to you, Francis deSouza, and, again, it attaches the JPM LST CEO call with Illumina.

Do you see that?

A. Just one minute. I see the stuff you highlight. The whole page is in very small font, so it's very hard for me to actually tell what's on the whole page, but I see the part you have popped up, yes.

Q. Okay. We can go ahead and put the callout away, Mr. McCullough, and you can go ahead and blow up the middle portion of this email.

JUDGE CHAPPELL: Mr. deSouza, are you saying that you couldn't read that? Would you like for them to blow it up?

THE WITNESS: I'm good. It's just if she wanted -- other than the callout, I couldn't really tell anything else, but I saw the callout, so I'm good. Thank you, Your Honor.

JUDGE CHAPPELL: All right.

BY MS. MUSSER:

Q. And, Mr. deSouza, just for clarity, I went ahead and pulled up the email that's underneath the top

portion, and this email is an email from Tycho Peterson. Do you see that?

A. I do.

Q. And it says: "Good morning. For those who missed our call with Illumina's CEO, Francis deSouza, and CFO, Sam Samad, on Tuesday, we have attached the transcript."

Do you see that?

A. I do.

Q. If you could to the next page, and this is, in fact, the transcript, right?

A. It looks like it, yes.

Q. Okay. And if we could turn to page 24, please, and if we could go to the last two portions of this, Mr. McCullough.

And Tycho Peterson asks: "Lastly, on BGI, do you have a view of whether they may try to come to the U.S. this year?"

And you respond, "It's obviously the U.S. is a very large and important genomics market."

And you say, "In part, it's also an area where you have very strong IP protection."

Do you see that?

Do you see that, Mr. deSouza?

A. Yes.

Q. Okay. And you say: "So for BGI or anyone else to be successful in the U.S., they have to do so with the technology they have the IP to run."

Do you see that?

A. I do.

Q. And BGI is a genomics company that does next-generation sequencing. Is that right?

A. That's right.

Q. And BGI is a Chinese company. Is that correct?

A. That's right.

Q. And, Mr. McCullough, you can put that down for the moment.

And as CEO, you are generally aware of Illumina's patent position from a business perspective. Is that right?

A. Yes.

Q. And Illumina has filed multiple lawsuits against BGI alleging that it has infringed on Illumina's patent. Is that correct?

A. That's right.

Q. And as a result of those lawsuits, BGI is currently enjoined from selling its products in the United States until at least 2023. Is that right?

A. That's right. It can sell services here and has sequencing customers that use its service, but in

terms of products, it has until 2023 that it can't sell here.

Q. And Illumina has also filed counterclaims against BGI in a Delaware Federal Court alleging patent infringement. Is that right?

A. That's right.

Q. And in that case Illumina has filed counterclaims alleging that BGI infringed on U.S. patent numbers ending in '290, '178, and '055. Is that right?

A. I don't know the specific numbers, but I know we have.

Q. And those patents involved in that countersuit don't expire until 2027. Is that correct?

A. I would have -- I know we have filed against some that have longer time frames. I don't know if that's the exact number and that's the exact date, but it sounds about right.

Q. And if Illumina is successful in its counterclaims, it has sought an order for preliminarily and permanently enjoining BGI from infringing on its patent. Is that correct?

A. That's right.

Q. And you earlier testified that you supervise Dr. Alex Aravanis. Is that right?

JUDGE CHAPPELL: Let's hold that question. Let's go ahead and take our lunch break. We will reconvene at 3:00. We're in recess.

(Whereupon, at 1:52 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(3:04 p.m.)

JUDGE CHAPPELL: Okay. We're back on the record.

Proceed.

BY MS. MUSSER:

Q. And before the lunch break, you had just testified that Dr. Aravanis reports to you. Did I get that right, Mr. deSouza?

A. Yes.

MS. MUSSER: If you could pull up PX 2822.

This was admitted into evidence on JX 2.

JADA: Excuse me, Your Honor. I just want to confirm, are we still in not in camera?

JUDGE CHAPPELL: Right. We're in public.

JADA: Okay. Thank you.

BY MS. MUSSER:

Q. And if you could zoom in on the top portion of this document.

Do you see where it says "Baird Non-Deal Roadshow with Alex Aravanis"?

A. Yes.

Q. And that refers to Dr. Aravanis, the chief technology officer of Illumina; is that right?

A. Yes.

Q. And on the left it says "Large Group Investor Meeting."

Do you see that?

A. Yes.

Q. And so this is referencing a large group investor meeting?

I'm sorry, Mr. deSouza. I missed that answer.

A. That's right.

Q. And then on the right it's dated Monday, February 22, 2011 -- or 2021. My apologies.

Do you see that?

A. I do.

Q. And if you could reduce that call-out.

And this is a series of Q&As prepared for this large group investor meeting.

Do you see that?

A. It looks like that. Yes.

Q. If you could turn to page 6, Q17.

And then it says "Audience Questions (to be worked in at the end if there is time)."

An audience question starts, "I'd be really curious to hear about near-term patent expiration. I know there are three or four expiring in the next two to three years. If we could dig into what those patents cover and how Illumina thinks about the impact

of those patents expiring, that would be helpful."

Do you see that?

A. I do see that.

Q. And in the second paragraph, it states (as read): I'd be really curious -- or -- Illumina has also alleged infringement by BGI on a number of other patents in the U.S. and Europe with later expiration dates. These patents direct Illumina's proprietary imaging reagent, modified polymerase and fluorescent dyes, which have expiration dates ranging from 2024 to 2027 depending on the patent and country.

Do you see that?

A. I do see that.

Q. And one of those patent infringement lawsuits is the lawsuit in Delaware that you testified about previously; correct?

A. I expect so.

Q. And going on, it states, "As we learn more about BGI's products, additional patents may become relevant."

Do you see that?

A. I do. Yes, I do.

Q. And Illumina has additional patents touching every aspect of the sequencing workflow, including

nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and development.

Do you agree with that?

A. I agree with that.

Q. And these -- and turning to the second paragraph, the second sentence, that explains, "These patents and pending applications have expiration dates ranging from 2023 to beyond 2030."

Do you see that?

A. I do.

Q. And the last part of this says, "As Illumina continues to innovate, we will continue to broadly file patent applications covering these innovations, providing competitive advantages in our key technology areas."

Do you see that?

A. I do.

Q. You can put this document down, Mr. McCollough.

Now, going back to the deal timeline, I had a few more follow-up questions.

Illumina and GRAIL entered into a merger agreement in September 2020; is that correct?

A. Yes.

Q. And the FTC sued to block the Illumina transaction in this court on March 30, 2021; is that correct?

A. That's right.

Q. And European Union member countries referred a request to the European Commission to investigate the proposed merger of Illumina and GRAIL as well; is that correct?

A. That's right.

Q. And on April 19, 2021, the European Commission accepted its member states' referral request and opened an investigation; is that right?

A. That's right.

Q. And as a result of the European Commission's acceptance of its member states' referral, the European Commission informed Illumina that it was prohibited from implementation of the acquisition while the EC's investigation was pending; is that correct?

A. That's right.

Q. And on July 22, 2021, the European Commission announced they were opening an in-depth investigation into the proposed acquisition of GRAIL by Illumina; is that right?

A. That's right.

Q. And on August 18, 2021, GRAIL merged with Illumina; is that right?

A. That's right.

Q. And as a result of that decision, Illumina filed an 8-K with the Securities and Exchange Commission; is that correct?

A. That's right.

Q. And as chief executive officer, you're familiar with Illumina's filings to the SEC; is that right?

A. That's right.

Q. And Illumina tries to be truthful and accurate in these SEC filings; is that correct?

A. That's right.

Q. Let's take a look at that filing.

If you could pull up PX 0378.

This is not included on JX 2. However, this is an official record filed with the Securities and Exchange Commission, and I move to admit this document into evidence at this time.

JUDGE CHAPPELL: Any objection?

MR. MARRIOTT: No objection, Your Honor.

JUDGE CHAPPELL: So admitted.

(PX Exhibit Number 0378 was admitted into evidence.)

BY MS. MUSSER:

Q. And taking a look at this top page, this is a Form 8-K that was filed with the Securities and Exchange Commission as a result of the August 18, 2021 merger; is that right?

A. Yes.

Q. And James, if you could return -- or turn to the top of page 5, please.

If you can zoom in.

Do you see the sentence starting "As a result of Illumina's decision to proceed with the completion of the Acquisition during the pendency of the European Commission's review, the European Commission will likely seek to impose a fine on Illumina pursuant to Article 14(2)(b) of the EC Merger Regulation of up to 10 percent of Illumina's consolidated annual turnover"? Do you see that?

A. I do see that.

Q. And Illumina decided to close its transaction despite those potential fines; is that correct?

A. That's right.

Q. And Illumina goes on in its SEC filing to say that "In addition, the European Commission, the FTC and/or other governmental or regulatory authorities may seek to impose other fines, penalties, remedies or

restrictions."

Do you see that?

A. I do see that.

Q. And despite those other fines, penalties, remedies or restrictions, Illumina decided to close this transaction; is that correct?

A. Despite other groups seeking to do it, so we don't feel they would be appropriate, and so that's why we're taking this step. They may seek to do it, but as we say in the next sentence, we will vigorously defend against those actions.

Q. Let's go to the following sentence.

But Illumina cannot predict what other adverse consequences could result from this -- from its decision to close its transaction; correct?

A. That's right.

Q. And that's what you told the Securities and Exchange Commission?

A. That's right.

Q. And one of those adverse consequences is potentially adverse consequences to Illumina's reputation.

Do you see that?

A. I see that.

Q. And despite the risk to its reputation,

Illumina closed the transaction; correct?

A. We believe that once people hear what we did, they'll -- there won't be a risk to our reputation or there won't be damage to our reputation, but there is a risk to it.

Q. So, Mr. deSouza, if you could please just answer my question.

Despite the risk that you told the Securities and Exchange Commission to your reputation, you decided to close this transaction; correct?

A. Yes.

Q. Thank you.

Illumina also identifies potential risk to its relationships with governmental or regulatory authorities.

Do you see that?

A. It's not highlighted. Sorry. Where are you looking?

Q. It is highlighted. On the -- one, two, three, four -- seventh line.

A. Yes, I see it. Yes.

Q. And so despite its risk to governmental or regulatory authorities that you disclosed to the SEC, Illumina still closed the transaction; is that correct?

A. Yes.

Q. And Mr. McCollough, if you could turn to page 4, the second paragraph from the bottom.

And if you could highlight the fifth sentence from the top starting "Illumina continues."

Do you see where it says Illumina continues to work with the European Commission on its review and has voluntarily offered to enter into a hold-separate agreement with respect to the European Commission? Do you see that?

A. I do.

Q. And Illumina goes on (as read): As a result of the contemplated hold-separate agreement, Illumina expects that Illumina and GRAIL will continue to operate as independent legal entities that transact at arms' length so that no integration activity will take place day to day -- the day-to-day operation of GRAIL will remain the sole responsibility of GRAIL management and Illumina management will have no involvement or influence over GRAIL.

Do you see that?

A. I do.

Q. And Mr. McCollough, if you could please turn back to page 5 and the first paragraph.

And can you highlight the sentence starting

"Illumina may be required."

And in its SEC filing Illumina says it may be required to hold the asset or equity interests of GRAIL separate for some period of time, and such delay in integration may materially and adversely affect the synergies or other benefits Illumina expects to achieve as a result of this acquisition.

Do you see that?

A. I do.

Q. Now -- you can put this document down, Mr. McCollough.

In the summer of 2020 there were also -- in the summer of 2021, there were also rumors that GRAIL was starting to plan for an IPO; is that right?

A. That's not right. That would be the summer of 2020, not summer of 2021.

Q. And now Illumina has paid GRAIL the eight billion that it owed under the merger agreement; is that right?

A. That's right.

MS. MUSSER: Your Honor, this concludes the portion of my exam covering public material. I expect to have a fair amount to cover in camera, so out of respect for the public, it may make sense for Mr. Marriott to do his public direct or cross, but of

course I defer to you.

JUDGE CHAPPELL: What do you prefer, Mr. Marriott?

MR. MARRIOTT: Your Honor, thank you. I would prefer that we continue with the government's examination and I'll do all mine at the same time. Thank you.

JUDGE CHAPPELL: Okay.

At this time we will go into in camera session. The public who are calling in will be moved into a waiting room and will be brought back into the courtroom when 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, verify that there are no participants in the courtroom who should not be there.

If there is anyone who is not authorized, you are to instruct that person to use the Raise Hand function of the Zoom screen. Let me know after you've done your review.

Go ahead.

JADA: Your Honor, the public line has been moved, and I don't see anyone else.

JUDGE CHAPPELL: All right. Thank you. Let's see what counsel has to say.

MR. MARRIOTT: I think Ms. -- sorry. Go ahead, Ms. Musser.

MS. MUSSER: I was going to say I'm still looking, so if you have an answer, go ahead, Mr. Marriott.

MR. MARRIOTT: It looks to me like Ms. Song needs to be moved, from GRAIL.

MS. MUSSER: Other than Ms. Song, that's the only other person I see.

MR. MARRIOTT: And the same is true for me.

JUDGE CHAPPELL: Okay. Jada, is that done?

JADA: That is done.

(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: Your Honor, the public is connected.

JUDGE CHAPPELL: All right. Go ahead, Mr. Marriott.

MR. MARRIOTT: Thank you, Your Honor.

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CROSS-EXAMINATION (resumed)

BY MR. MARRIOTT:

Q. Good afternoon, Mr. deSouza.

A. Good afternoon.

Q. Would you tell us again, please, sir, how you are employed.

A. I am the CEO of Illumina.

Q. And how would you describe your role as CEO for the court?

A. In my role as CEO, my responsibilities include setting the long-term strategy and vision for the company, you know, managing the operations of the company to execute against that vision, and then I'm the key point person to manage our relationship with key stakeholders, members of our board, investors, key opinion leaders in the industry.

Q. How long have you been CEO of Illumina?

A. I've been CEO of Illumina since July 2016.

Q. Tell His Honor if you would a bit about your educational background, please.

A. I have a bachelor's degree in electrical engineering and computer science from MIT, and then I have a master's degree in electrical engineering and computer science also from MIT.

Q. And how would you characterize the focus of your studies?

A. My focus area was primarily around computer architectures and then algorithms for large-scale parallel processing.

Q. So give us a brief overview if you would of your professional background before you joined Illumina.

A. Yeah.

I started my career and -- in research working at IBM Research, working on computer architectures and parallel processing. They sponsored my master's.

And then after I got my master's, I worked in management consulting, focusing on high-tech companies and telecommunications companies, first in the U.S., then in the U.K., then in South Africa for the government of South Africa, and then in India.

And then after that, I worked for a while in an investment firm.

And then I started and was founder and CEO of an instant messaging company in the mid '90s. That got acquired by Microsoft and became part of their instant messaging offering.

I worked at Microsoft for a few years in Redmond.

And then in 2001, I left to found another company, which did computer security. I was founder and CEO of the company for about five years, and that company got acquired by Symantec, which is a global leader in computer security.

I worked at Symantec for just under eight years, and my last position there was president of products and services.

Q. When did you join Illumina?

A. In November 2013.

Q. And what role did you take upon joining Illumina?

A. I was president and member of the board.

Q. And how would you characterize your duties and responsibilities as president of Illumina?

A. My role was primarily to run the teams that build the products, so it was the product development and engineering teams, the manufacturing teams and quality teams. That's my primary -- that was my

primary role.

Q. And what products in particular did you have responsibility for as president of Illumina?

A. I was responsible for the entire portfolio, so it included our range of sequencers, but it also included our library prep kits. It included our -- actually our IVD at the time, the cystic fibrosis assay. It included our software products as well.

Q. And how long did you serve as president of Illumina?

A. I'm still president of Illumina, so I kept that title throughout my entire time here, but in July of 2016 I also assumed the role of CEO.

Q. And what are your duties and responsibilities as CEO of Illumina?

A. So, in addition to being responsible for building the products, which I kept, I am now responsible for all the other functions, so our commercial teams, our medical teams, which include regulatory affairs, market access, clinical affairs. I'm also responsible for our finance, HR teams. I'm responsible for our legal teams, and so I've got all the functional responsibility now at Illumina.

Q. How would you describe Illumina's mission?

A. Our mission at Illumina is to improve human

health by unlocking the power of the genome.

Q. And what exactly does that mean?

A. What that means is we want to help people -- so it could be researchers, it could be physicians, but it could be consumers as well -- to be able to understand what their DNA says about their health state and their disease state. To do that, specifically, we sell products and services that include sequencing systems.

So, for example, we sell a box like a NovaSeq which is a -- which is a piece of equipment that our customers will buy, and you put in biological samples that could be blood or saliva or plant material, and we'll tell you what the genomic sequence is in that material.

Q. You said you serve on the board of directors of Illumina.

Have you served on the boards of directors of any other companies?

A. Yes.

Q. And identify those companies for us, please.

A. I currently and for the last I think about three years have been on the board -- I am on the board of the Walt Disney Company. And then before that, for a period, I was on the board of Citrix.

Q. Let's have you tell us a little bit about Illumina's business.

When was Illumina founded?

A. Illumina was founded in 1998.

Q. And who founded Illumina?

A. The founders of Illumina were: David Walt, who was at the time a professor at Tufts and is now a professor at Harvard Medical School; Larry Bock; John Stuelpnaegel; Mark Chee; and Anthony Czarnik.

Q. And how many people currently work at Illumina?

A. About 8,000.

Q. How does Illumina compare in size to its peers?

A. So if you look at Thermo Fisher, for example, they also sell tools for genomic analysis, so they sell sequencers. They also sell microarrays like we do, so they compete with us in those two. And then in genomic analysis they also have a very large PCR business which we don't have, so they also sell genomic tools in addition to other products that they sell.

Last year, Illumina did just over $3 billion in revenue, Thermo Fisher did about $32 billion in revenue, so they're about ten times as big as we are.

If you look at -- other players in that space

include BGI, sort of -- and they -- they're based out of China. They are sponsored by the Chinese government or affiliated with the Chinese government, and they sell sequencers and consumables, and they have a service as well, around the world. They -- their market cap is somewhere between six and twelve billion dollars.

Roche, which has a big genomic analysis business around PCR and has bought Genia, a sequencing technology company, is developing its own sequencers. Last year, they did about just over $60 billion in revenue, so they're about twenty times as big as we are in terms of revenue last year.

And then there are other companies like PacBio, which bought Omniome, which is a direct competitor to Illumina, and it's developing a direct competing technology. They are in Menlo Park. They're about maybe six to eight billion dollars in market cap.

And then there are a bunch of start-ups in this space, too.

Q. How would you describe Illumina's core business?

A. Our core business is to sell sequencers and consumables to the -- to our customers that include

researchers, that include, you know, academic medical centers, that include hospitals and healthcare systems. That's our core business.

We have a number of things that we sell in addition to sequencers, like library prep kits and tests, but the vast majority of our revenue comes from sequencers and consumables associated with those sequencers.

Q. Where does Illumina do business?

A. We have products that we sell into 140 countries around the world, just over 140 countries.

Q. And how many customers does Illumina have around the world?

A. We have over 7,000 customers around the world.

Q. Could you describe for us the different types of Illumina customers.

A. Yeah.

So we have customers that span a number of groups.

We have research customers, so a lot of academic institutions, so, for example, the Broad Institute of MIT and Harvard is a big customer of ours, but a lot of -- and, you know, Stanford is, UCSF, a lot of research environments are customers of ours.

They might have genomics departments or biology departments that use our sequencers.

We sell a lot into labs, and so we have big reference lab customers that run our product around the world.

We have customers that build their own tests on our equipment, so they could be across a number of medical areas, so in noninvasive prenatal testing, for example, you know, we have a set of customers that include, you know, Natera and a whole set of other companies in that space.

We sell into the cancer therapy selection space, so a lot of leading cancer hospitals use our products, like MD Anderson or Dana-Farber or -- and Mount Sinai.

And then we also sell into children's hospitals.

So some hospitals use our sequencers to diagnose critically ill children in the NICU, and so they will take a blood sample from a child in the NICU that they can't diagnose any other away and get a whole genome sequence on that baby and get to a -- and hopefully get to a diagnosis.

We also are involved in fighting the pandemic, so we have customers that include CDCs around the

world.

We were, for example, in China in December of 2019, and we helped sequence the first viral genome for SARS-CoV-2 on January 10.

We are used by vaccine and therapy developers, so, for example, Moderna and Pfizer-BioNTech, both of them used data from Illumina sequencers to develop their vaccines. You know, Moderna has never had the virus on-site. It depended on our machines.

So those are some of the customers that we have.

Q. Who are the members of the Illumina board of directors?

A. John Thompson, he's the chair of our board. Until recently he was also the chair of Microsoft. Previously he was the CEO of Symantec, which is a publicly traded company.

Frances -- that's F-R-A-N-C-E-S -- Arnold -- is a -- is on our board. She is a professor at Cal Tech, and she just won the Nobel Prize in chemistry a couple of years ago.

We have Scott Gottlieb. He was -- he is an ex-U.S. FDA commissioner. He is on our board.

We have Gary Guthart. He is currently the CEO of Intuitive Surgical. They provide robotic surgery

tools.

We have Sue Siegel. She used to run GE Ventures most recently.

We have Caroline Dorsa. She was the CFO at a number of companies in regulated industries like pharma and energy.

We have Rob Epstein, who was CEO of Medco.

JUDGE CHAPPELL: Hold there. Hold there.

We're going to take a short break. When I come back, I'd like estimates from both attorneys on whether it's possible to finish this witness today.

We'll reconvene at 4:50, 4-5-0.

We're in recess.

(Recess)

JUDGE CHAPPELL: Okay. We're back on the record.

Let me have your time estimates.

MR. MARRIOTT: Your Honor, my best estimate is about an hour for my public -- to conclude my public examination.

MS. MUSSER: And I would expect about the same, Your Honor. Obviously, a lot of it depends on what Mr. Marriott covers.

JUDGE CHAPPELL: All right. So we're not going to finish today. We'll stop sometime between 5:30 and

6:00.

MS. MUSSER: Thank you, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. MARRIOTT:

Q. Mr. deSouza, before the break, I think you were trying to say that there was one board member you may have omitted from your initial list. Did I -- if I have that right, can you tell us who that is.

A. The last board member is Phil Schiller, who is currently an Apple Fellow and ran worldwide marketing at Apple before that for a long time.

JUDGE CHAPPELL: He was trying to say. Did I cut him off? I thought there was a pause.

THE WITNESS: There was, Your Honor. I was thinking.

JUDGE CHAPPELL: Once that gavel rings out, I'm gone.

MR. MARRIOTT: I think we got it now, Judge. Thank you.

JUDGE CHAPPELL: Okay.

BY MR. MARRIOTT:

Q. Mr. deSouza, how is Illumina's business structured? Give us a little bit of a sense of that, please.

A. Yeah. We are organized functionally, and so,

you know, we have, you know, functional heads that report to me.

As a business, there are a couple of major customer segments that we serve. There's research, there are clinical markets, and then there are applied markets.

And applied markets would be like agriculture -- customers use us to sequence salmon or cows, or actually, dogs is a growing business right now -- but also are the consumer markets, so, you know, ancestry, and so on, so that would all be in the applied segment.

Q. How would you describe competition for NGS products?

A. Yeah. There are a number of categories of competition.

So there are -- let me -- there are sort of the players that exist in the market today.

So, for example, Thermo Fisher has a sequencing business, and it's got good traction in the oncology segment. Their offerings in genomic analysis include next-generation sequencers, and they actually bought the sequencers from a couple of assets they got. One was from Applied Biosystems that had the vast majority of the market share in sequencing initially.

They did the Human Genome Project or the bulk of it.

So they have sequencers. They have microarrays. They bought a company called Affymetrix, which was a leader in the microarray business and is still a strong player there. And they have a very large PCR business. They're one of the leaders globally in selling PCR tools.

So there's Thermo Fisher.

Another existing competitor we have today is BGI, so this is the company based out of China that is affiliated with the Chinese government. They sell their sequencers in many countries around the world. There are a few countries where they are not able to sell and will be -- for example, in the U.S., they sell their services today, and there are customers they have like Nebula, which is Professor Church from Harvard's company. They use BGI as a service offering. They give their samples to BGI who sequences them outside the U.S. and returns their data.

So BGI is another competitor of ours.

We have -- we have other companies that are looking to get into the space.

So, for example, you have PacBio that sells long-read sequencers that announced an acquisition to -- that announced an intent to acquire Omniome, and

that is a company that's going to compete directly with Illumina.

And then we have a large number of start-ups that are looking to enter the space, companies like Element or Singular. Singular has said they'll come out with a product later this year that competes directly with Illumina.

So those are some of the competitors we have to our business.

Q. How would you characterize entry into NGS sequencing?

A. Every -- almost every year, you know, venture capitalists will fund, you know, different companies with different approaches. This is an industry that has been characterized by disruption.

So, for example, we entered the sequencing business in 2007 when we launched our first sequencer, the GA, which we got through an acquisition. You know, for many years before that, the leading player was Applied Biosystems technology. They had the vast majority of the market share in the company [sic]. That was a technology that was acquired by Thermo. But when we came out with a better sequencer, you know, we started to see the market share shift pretty dramatically in the first even couple of years after we

were on the market.

And so this is a market that's very, very early in terms of its ultimate penetration and has been characterized by technology disruptions. And you know, ultimately, customers look for value in the sequencers, and so if there's a sequencer that delivers a better, you know, value proposition to them, you know, they will insert it into their fleet, and they've shown a willingness to do so pretty quickly.

Q. How would you describe Illumina's platform and the data that it generates?

A. Our strategy from the beginning -- and it was different from other players at the time -- was to have an open platform strategy. What that means is, you know, we from the beginning wanted an open ecosystem of players that could build solutions on our sequencer, and so we opened up the ability to build library preparation kits for our sequencers. We sold some, but lots of competitors sold others, and in fact they have the leading share in most segments of library preparation, similarly with sample extraction, similarly with the informatics pipelines. We provide informatics pipelines, but, you know, in most cases customers use either their own or look at any one of the others that are (indiscernible).

So our platforms are open and our data formats are open, so you can take our data and, you know, run it in our own pipeline, you can integrate it with data from other sequencers or other modalities, and we've always been committed to -- you know, to that.

Q. How does the format of Illumina's platform and data impact competition in NGS?

A. We believe that by maintaining, you know, open standards and having the data format that allows our customer to integrate our data with data from other sequencers or other modalities has helped move the industry along. It has made it easy for our customers.

And it's important because our customers have a very wide range of applications that they run on our sequencers. You know, and they range from noninvasive prenatal testing to some of our customers are looking at how you store IT data in DNA. Other customers are looking at developing gene therapies.

And so the only way we felt we could catalyze all those different market segments is to allow people to build their own tests, their own applications, their own software that takes advantage of our technology.

We have people that are using us as the back

end for their proteomics applications, for example.

And so being open we believe has been key to driving the acceleration of the markets we're in and that and just continuing to really just focus on driving the price down to make genomics more accessible to everyone.

Q. What competition does Illumina face from PCR platforms?

A. You know, when you are doing genomic analysis, you have a number of choices. You can use sequencers, and even in sequencers you can choose between long-read, which is a different type of sequencers, or short reads, or you can choose microarrays. And the difference is that microarrays are much cheaper but look an much smaller section of the genome.

So if you know what you're looking for, so, for example, in livestock applications, if you are sequencing cows, for example -- this is a real example -- and you want to know about the marbling of the beef and the milk production genetics of the cows, you would use an array because it's super cheap. You can sequence for under $10 a cow, and you can get at the parts of the genome that you care about, right.

So while some people do do sequencing on animals, it tends to be for things like prized racing

horses, for example, whereas for your routine cows you'd use microarrays.

PCR is also very, very cheap. And what it allows you to do is it allows you to interrogate a much smaller section of the genome, so maybe a couple of points on the genome, so much smaller even than arrays, but it can be very, very cheap to do.

And an example is for COVID testing right now. And that's why (inaudible) does so well and Roche, is for COVID testing you're only looking at a couple of points in the virus to diagnose if somebody has COVID or not, and so PCR allows you to do very fast, very low-cost, but actually very accurate sequencing, only a couple of (inaudible)

THE REPORTER: I'm sorry. There's some sort of interruption that keeps interrupting what the witness is saying, and I am missing some words. I'm not sure what it is.

JUDGE CHAPPELL: It sounds like it could be a squeaky chair.

MR. MARRIOTT: I'm hearing it too, Your Honor. I don't know where it's coming from.

JUDGE CHAPPELL: Maybe let's try answering without the hand gestures. Maybe it's air moving in front of that fancy Yeti microphone.

THE WITNESS: I will try very hard, Your Honor. My hands are under me now.

JUDGE CHAPPELL: Josett, do you want to review some testimony that you might not have heard?

(Discussion off the record with the court reporter.)

THE WITNESS: That's why companies like Roche and Thermo are doing so well in COVID testing with their PCR offerings.

BY MR. MARRIOTT:

Q. What competition does Illumina face from proteomics platforms?

A. Proteomics platforms represent a different set of analysis tools. They don't look at the genome. They look at the proteins present in a sample, so they're not direct replacements for each other at all.

In some applications you can use the presence of proteins to get to the same decision as you would look to get to if you were looking for the presence of, you know, RNA, for example, and so in some cases they may help you address the same biological question, but they are different technologies.

Q. And what competition does Illumina face from microarray platforms?

A. We offer our own microarrays, and we compete

with other companies in the microarray business, and other companies' microarray products compete with sequencers. And the way that works is, microarrays offer a cheap way to look at a subset of the genome.

So, for example, a consumer genomics company may want to look at 800,000 points in the genome to tell you your ancestry, for example, to tell you some, you know, health traits and, you know, physical traits about you. And they only need to look at 800,000 points of the genome, not the whole three billion.

And so in an application like that or for a dog ancestry, which is -- or pedigree -- sorry. Not Ancestry -- for dog pedigree identification, you don't want to look at the whole genome, and so microarrays beat out sequencing in that application.

And so it's application to application, you know, how successful sequencing is against arrays.

Q. And do you know whether NGS will be used for new clinical applications in the future?

A. NGS will absolutely be used for new clinical applications in the future.

Today we still -- even with all the progress we've made in the last, you know, almost two decades since the first human genome, today we still understand

very little of how your genome translates into health and disease states.

We're still trying to connect your genome to chronic diseases like cardiovascular disease or kidney disease. We're also trying to understand how your genome connects to neurological conditions, like autism or Alzheimer's or Parkinson's. There is a lot of research going on in that area, and once the researchers uncover the connections between your genome and those conditions, we'll start to see clinical applications emerge to do the testing based on that finding.

And so as -- we have so much undiscovered in front of us. As we discover that, I have no doubt we will see a lot more clinical applications emerge in the future.

Q. When did Illumina first enter the NGS marketplace?

A. We first entered the NGS marketplace in 2007 when we acquired a company called Solexa.

Q. And how has the cost of sequencing changed since then?

A. When we acquired Solexa and launched the -- our first sequencer, the GA, the cost -- our price to the market to sequence a single human genome was north of

$150,000. That was in 2007. It was $150,000.

Today, the cost to sequence a human genome on our NovaSeq is $600, so we have taken the price of sequencing down by over 99 percent since 2007 when we launched our first sequencer.

Q. And how is it that Illumina has done that?

A. We have done that by focusing on research and development and technology innovation, and so we have teams that work across a number of technology platforms in our company, and each of them looks to drive costs in their area down. And when you bring those together, it allows us to have a lower cost of a sequencer, and we immediately pass those savings on to our customers in the form of lower prices.

Q. What impact has the decrease in the cost of sequencing had on the development of new applications?

A. The -- the lowering of the price of sequencing has vastly expanded the market for sequencing and vastly expanded the number of applications that have emerged on sequencing.

It has also allowed a tremendous amount of biological discovery because what it has allowed researchers to do is to run larger and larger cohorts and understand the difference between people's genomes.

And the reason that's important is, if you are trying to understand what drives a disease like cystic fibrosis that's caused by a single gene change, you don't need a very large cohort. You need a few people with cystic fibrosis and a few people who don't, and you can see that all the people with cystic fibrosis have the one gene change and the others don't.

But for more complicated diseases like cardiovascular or Parkinson's or neurological, the changes across a genome that cause that disease are vast, and so you need very, very, very big cohorts to try and identify those associations. And so by lowering the cost of sequencing, we have allowed researchers to get larger and larger cohorts of genomes and understand the causality associated with more complex diseases rather than just simple monogenic diseases.

In addition to that, by lowering the cost of sequencing, we have been able to make clinical tests affordable to a broader population.

So, for example, you know, noninvasive prenatal testing is now, you know, broadly accessible in the United States, right. There are now over 190 million covered lives for NIPT in the U.S. And

that has a big part to do with the fact that we're lowering the price of sequencing in that market, so the price of that test in the market has kept coming down, and at some point it became affordable and payers sort of jumped on board as well.

So lowering the price of sequencing has a compounding effect. It allows more discoveries by allowing bigger research cohorts. And then by lowering the cost of clinical tests on sequencing, it expands access to those tests.

Q. What do you project to be the future cost of NGS sequencing?

A. I have publicly -- are we on camera or are we public?

Q. We're public.

A. Okay.

I have publicly talked about the fact that we are -- the next step for us is to bring the price of a genome down to a hundred dollars a genome, so that's an over 80 percent reduction from where we are today, so that's the next step we're shooting for.

Q. And what innovations must Illumina undertake in order to accomplish the hundred-dollar genome?

A. I -- there are a number of key technology innovations that are critical to reaching a

hundred-dollar genome.

One, we have to increase the density of our flow cells, and we have teams that are working on that.

Two, we have to continue to reduce the wavelength of the light that we use in our optical assembly, and we have teams that are working on that.

You know, three, we have to speed up our chemistry, and our teams are working on that.

Four, we have to accelerate our algorithms and our data paths, and we have teams working on that.

Each of those -- and there are others, too, but those are some of the big ones. Each of those innovations then compound to give you a lower cost for the next generation of sequencing.

Q. Have any of your competitors announced plans for a $100 genome?

A. Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world, so they've talked about it from -- as of last year.

Q. How, if at all, is expected NGS competition reflected in Illumina's pricing plans and strategy?

A. The -- our expectation of intensifying competition shows up in a number of places. It shows

up in our expectation of the price of sequencing in the market, and it's continuing to decline. It shows up in our expectations of sort of the margin evolution in the industry. It shows up in our expectation of new applications to emerge that rely on a much lower price of sequencing.

So those are some of the ways, you know, the expansion of the market of sequencing is very dependent on us continuing to lower prices for the whole market.

I'll give you an example.

For DNA to ever be credibly used as a store for IT data, which we're working on with Microsoft, the price of sequencing has to go down substantially below the hundred dollars a genome, and so if we make that our goal, which we have, then we have to bring the prices down, you know, dramatically over the next half a decade to a decade.

Q. How frequently does Illumina upgrade its sequencing platforms?

A. For -- it varies very much.

So, you know, a single platform could be upgraded, you know, maybe five plus -- it's unlikely to be less than four years because it takes a while for our sequencers to be absorbed in the market, for

customers to depreciate the equipment, so sometime after five years you can start to think about a potential replacement cycle for us.

Now, the MiSeqDx, for example, though, has been in the market for almost a decade, and we haven't upgraded it.

So it depends on the platform you're talking about. Some will be in the five-year range. Some will be longer than ten years.

Q. And how long typically does it take for clinical customers to adopt an upgrade?

A. It takes several years after we launch a product for clinical customers to put a sequencer in production, so typically they'll wait for a couple of years after a new sequencer is launched, you know, just to see if the product sort of evolves in any way or the chemistry is adjusted once the product is in the market, and then they'll bring in the first sequencers to validate their workflows.

And then after they've validated their workflows, which could take months or quarters, then they'll start to cut over their production samples, and so it could take several years for a clinical customer to cut over, you know, its business.

Q. Did there come a time when Illumina decided to

acquire GRAIL?

A. Yes.

Q. And when was that?

A. We decided to acquire GRAIL in September of 2020.

Q. And what was the relationship between Illumina and GRAIL in September of 2020?

A. Before we announced the -- before we signed the agreement or the intent to acquire them, we were an -- a part-owner, so an equity investor in GRAIL, and they were a customer of ours, and we had an arrangement where we received a royalty on tests they would sell in the future.

Q. What percentage of GRAIL did Illumina own in 2020?

A. A little under 15 percent.

Q. So why did Illumina decide to acquire GRAIL?

A. We decided to acquire GRAIL because we felt we could dramatically accelerate the availability of this lifesaving test around the world and dramatically improve the accessibility of that test to people around the world. And in doing that, we felt we would, you know, not only be doing the right thing and fulfilling our mission, but we could create significant shareholder value as well.

Q. Did Illumina consider purchasing any other MCED test developers?

A. No, we did not.

Q. And why not?

A. We did an exhaustive study of the market, and we had been keeping up with the market since we were the ones who, you know, sort of came up with GRAIL, and we still don't see anybody in the market that has an offering that's like GRAIL's in terms of looking at 50 cancers, identifying the tissue of origin, and so there really isn't anybody else that we felt, you know, was like GRAIL.

Q. Did you identify any companies that you thought would be competitors to GRAIL?

A. We did not.

Q. Did you consider whether Galleri will compete with any single-cancer screening test?

A. We don't believe -- we (inaudible) it won't. And we also talked to a number of doctors as part of our diligence, including I was on the call with a number of doctors myself. And what we feel is that there are very clear parts of the market where single-cancer tests will serve that need well, and there are other parts of the market where Galleri's, you know, 50-cancer test will do very well.

If, for example, you are a GI specialist, then having a test that looks for colorectal cancer makes a lot more sense for you than a test that looks for 50 cancers, and so there are parts of the market where a single-cancer test or a test that looks at a small number of cancers fits perfectly. And I heard that loud and clear from specialists. And then there are other parts of the market where they would prefer a 50-cancer test.

Q. Based on your investigation and discussions with doctors, do you know whether Galleri will compete with tests that screen for fewer than ten cancers?

A. No. They won't compete.

Q. Do you know whether Galleri will compete with tests that do not identify tumor of origin?

A. No.

Q. And just to be clear, no, it will not, or no, you don't know?

A. No, it will not compete.

Q. And why do you say that, sir?

A. It completely --

MS. MUSSER: Objection to the extent it calls for improper expert opinion.

MR. MARRIOTT: I'm happy to clarify the question, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. MARRIOTT:

Q. So based on your due diligence into the marketplace based on your conversations with doctors and your market surveys, why do you say that Galleri will not compete with tests that do not identify tumor of origin?

A. The -- what we heard loud and clear, I heard allow and clear, was that doctors who are looking for 50 cancers and doing a screen would not want a test that did not tell the patient where that cancer was. They felt that that would just -- just not work to -- you know, to raise so much anxiety in a person without telling them what they actually have.

And so for that use case, for doing screening of a healthy person to identify if they have 50 cancers, they felt it was essential that as part of the conversation with the patient you're immediately able to say what to do next, you know, look at this organ, image your pancreas or something or -- or, you know, and so they would not substitute Galleri with another test that identified 50 cancers but didn't tell you what cancer it was and where it was, and so they are not substitutes.

Q. Did there come a time when the FTC raised

concerns about the transaction?

A. Yes.

Q. And did Illumina make any effort to resolve complaint counsel's concerns?

A. We tried to initiate settlement discussions with the FTC based on the concerns they expressed in their decision. We were unsuccessful in that. We asked for a settlement conference, and we haven't got that yet.

And so what we've done is we have gone through what we saw and read were the objections from the FTC. And to deal with those objections, we have put out an open offer letter to oncology customers, saying, you know, we want to make sure that you know that you will have uninterrupted and guaranteed access to our sequencing products and services on the same terms as GRAIL does. We are contractually also committing to making sure that you know we will not raise prices on you.

We're also contractually committing in fact to lower prices for those customers by 43 percent by 2025 with future generations of sequencing. And we chose 43 percent because that's the price we assumed in our business model that GRAIL pays.

We've also made a contractual commitment to

working with anybody who signs that contract on supporting their IVD submissions for -- you know, for IVDs they want to develop.

And so we've made a contractual commitment to address what we heard as some of the objections from the FTC.

Q. Did there come a time when Illumina decided to close the transaction?

A. Yes.

Q. And when was that?

A. That was a couple weeks ago.

Q. And why did Illumina decide to do that?

A. We decided to do that because it became clear to us that given how the timelines in Europe were working that we were not going to receive a response to our challenge in the European court about the validity of the invocation of Article 22 of the European Commission.

We were also not going to receive a decision from the Phase II review in the European Commission before December 20, which is the drop-dead date on the deal.

Given how important this deal is in terms of the thousands of lives that could be saved by accelerating the access to GRAIL, we felt it was very

important that this deal get heard and that we get a decision. And we'll abide by whatever the decision is, but it was important we felt that the deal get its review.

And so to achieve that goal, we closed the transaction and committed to holding GRAIL separate until we get a decision from either the European courts or the European Commission Phase II review.

Q. On direct examination by complaint counsel, you were asked about SEC disclosures of the company concerning risks to Illumina's reputation from closing the transaction. Do you recall that?

A. I do recall that.

Q. Is there anything more you'd like to say about your expectations as to the reputational impact of closing the merger at this time?

A. We have been very transparent with investors, you know, with our customers about, you know, why we -- why we felt we had to do what we did. And we were very clear about what we did and very clear about our intent to hold the company separate until the decision got heard. And you know, we explained how we felt, you know, that given what was at stake here, this was really important. And you know, we've -- you know, so that's we feel an important message that got heard by

the market.

Q. Does Illumina have plans for a unified Illumina-GRAIL to generate efficiencies?

A. We do.

Q. And what plans does Illumina have for the combined companies to generate efficiencies?

A. We believe there are -- (inaudible). Our plan has a number of areas where we will get significant efficiencies.

One is the -- our ability to scale up the GRAIL Galleri test much more quickly than they would be able to scale up their test on their own.

Illumina already has high-throughput genomic testing labs in operation. We have the facilities. We have the equipment. We have the trained personnel. Those tests [sic] have delivered millions of tests a year already.

Today, for example, you know, we are doing a -- you know, thousands of tests a week to do COVID surveillance here in the U.S., and so we will be able to easily scale up the GRAIL test by ramping that test up in our production labs both here in the U.S. and outside the U.S. And that will significantly accelerate the ramp-up, the production ramp-up of the Galleri test.

In addition to that, we feel that by engaging our market access teams with their market access teams we can accelerate the reimbursement of the Galleri test.

Today, the Galleri test is available for $950, and it's a self-pay test primarily. There is a part of the American population that can afford that as a regular test, but there is a lot of this country that cannot afford a thousand-dollar test, and so we feel a sense of urgency to drive reimbursement as quickly as possible.

Our teams at Illumina have helped get reimbursement for one billion people around the world for genomic tests across noninvasive prenatal testing, cancer therapy selection, genetic diagnosis for children, and so we have deep expertise as well as innovative tools and deep relationships that we will bring to bear.

Last week, for example, Michigan became the first state in the country where Medicaid now covers rapid whole genome sequencing for critically ill children in the NICU. That's based on work on a project called Project Baby Deer that we have been working on for a couple of years.

There are similar projects, Baby Dolphin in

Florida, Baby Bear in California, that our teams are working on. We have deep expertise working across the 50 states to get reimbursement in place, as well as working with CMS.

We also have deep expertise working with payers. We have created innovative programs like risk-sharing agreements with insurance companies where we contribute resources and offer a test to a segment of the population to gather the clinical data as well as the economic data to build the case for the insurance company to cover the test.

That has been very successful in noninvasive prenatal testing, for example. When we entered the noninvasive prenatal testing market by acquiring Verinata in 2013, there was almost no reimbursement for NIPT. Today, partly because of the work our teams have done, there are over 190 million covered lives for NIPT in the U.S. And we've done a lot of innovative risk-sharing agreements like that.

We've signed a partnership with UnitedHealthcare. They're not only one of the largest payers in the United States, but they're also -- they also own Optum, one of the largest healthcare systems in the United States. Jointly we're going to commit to a hundred million dollars over the next five years to

drive the evidence to accelerate genomic testing in the clinic.

Now, that's stuff we can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL, so there's a lot of work we can do on market access. And I've just talked about the U.S., but there's a lot of work we can do in countries around the world like we did for those billion people around the world for genomic testing.

We also have deep expertise in working with regulators.

We got the first open platform NGS sequencer cleared by the FDA in 2013 and the head of the NIH, Francis Collins, who wrote about it saying this was a milestone moment in healthcare.

We also in 2013 got the first test, the first NGS test, you know, cleared by the FDA for cystic fibrosis.

And so our teams have deep experience, nearing now a decade, on working with regulators to get cleared tests and to get cleared sequencers. We're working that in oncology now and we're working that for genetic disease now and hope to get the first -- you know, to progress that as well.

Next we believe we can help lower the cost of

the GRAIL test by leveraging our expertise in our supply chain and procurement capability. We are a much bigger buyer of a lot of raw materials than GRAIL is, and so we get much deeper discounts on those materials than GRAIL does, and so by plugging GRAIL into our procurement and supply chain process we'll lower the cost of running the test.

Similarly, when we scale up production, we have deep expertise in optimizing workflows end to end, and so we'll optimize their workflow.

Next, we believe that there are R&D synergies between the two teams, so just like our team discovered the possibility to see cancer in blood because we were processing NIPT samples, we believe that it is going to be possible to develop a diagnostic test, a blood diagnostic test, to look for fatty liver disease, Alzheimer's, Parkinson's. But that requires the capabilities of the two companies to be brought together, and so we believe there are R&D synergies there.

There are also other cost synergies associated with eliminating the royalty that -- that GRAIL has to pay Illumina, as well as the double marginalization of having these two companies as separate companies. And by bringing them together, we believe you can eliminate

those costs, too.

So those are some of the synergies that we're planning for once the deal -- once we're allowed to merge.

Q. Let me see if we can break some of that down, Mr. deSouza.

What role does the FDA -- withdrawn.

What role does FDA approval play in the adoption of an MCED test?

A. The FDA approval allows the MCED test to be run in hospitals and community hospitals and healthcare systems in addition to having a central service that GRAIL would run, and so it allows the test to be run in a much broader set of environments, and that increases access to the test.

Q. And what role does CMS approval play in the adoption of an MCED test?

A. CMS approvals are essential we believe for the success of an MCED test, because what that does is increase accessibility and affordability of this test.

And you know, one of the things, you know, we feel strongly is, you know, the people that benefit the most by the acceleration and synergies we're talking about with CMS are the people today that live in underserved healthcare communities. It's persons of

color. It's, you know -- cancer is the number one cause of death in the Hispanic community and the number two cause of death in the African American community. African American women have a disproportionately higher burden of cancer.

And getting CMS approval, getting Medicaid and Medicare to cover this test broadens access of those tests into those underserved communities.

Q. Would you please describe for us Illumina's experience and expertise in dealing with CMS and FDA.

A. You know, we have again closing in on a decade now of experience working with both of those, both of those organizations.

We started, you know, 2012-ish maybe and maybe a little before on the FDA side getting approval for -- and this was historic. And this is what Francis Collins, the head of the NIH, wrote I believe it was in Nature in December 2013 -- historic approvals for the first NGS-based sequencers, which was the MiSeqDx in 2013 in December, and also the first ever in the world approval for an NGS-based test for cystic fibrosis.

And importantly, our approval for the MiSeqDx was an open systems approval, and so from the very beginning we declared an intent that we wanted to make

sure that anybody could develop tests on our sequencer.

And so we have now, you know, closing in on about ten years' experience working with the FDA. We have since got other sequencers approved. We are now working with the FDA on getting approval for the NovaSeq as a NovaSeqDx. We already have approval for the NextSeqDx.

And on the test side, we're working on getting approval for our TSO 500, we're working on getting approval for our NIPT assay here in the U.S., and we're looking at getting approval for a genetic disease diagnosis workflow as well.

Q. Are you knowledgeable about GRAIL's experience and expertise in dealing with the FDA and CMS?

A. I am familiar with that, with what they have. Yes.

Q. And describe for us GRAIL's experience and expertise in dealing with FDA and CMS.

A. I think the world of Josh, who reports to Hans and is their chief medical officer, but they have a tiny, tiny team on both of those, and so, you know, I think it's a talented team, it's a hardworking team, but it's very tiny.

Q. Do you know how a combined Illumina-GRAIL will

accelerate FDA and CMS approval of Galleri?

A. Yes. We are planning to very quickly start the large-scale evidence generation required for -- for both, actually, for their FDA approvals as well as the -- we want to kick off a number of studies immediately to gather the evidence for accelerating CMS and private payer approval.

And we're going to leverage very much the models that we have used that have been very successful for NIPT, for genetic disease diagnosis, and for cancer therapy selection, so the same people, same tools. We want to immediately plug in the Galleri test into -- into those tools.

We also will leverage the relationships we have. I talked about the fact that we have a signed partnership with UnitedHealthcare, and we are going to be spending with them jointly a hundred million dollars over the next five years for evidence generation to accelerate the adoption of genomic testing.

And so we will immediately look to put the -- both the Galleri test as a multicancer early screening test, to gather the evidence of that and roll it out in a population and get the clinical utility data and the economic data, but also we will put their DAC test, which is their diagnostic aid for cancer test. And

that test helps people who have the symptoms of cancer, but their doctor is unable to find where that cancer is.

And so that's a very significant problem because the patient's cancer is progressing, but because the doctor doesn't know where it is, treatment doesn't begin, and so the prognosis for the patient can continue to get worse.

And so what we'd like to do or what we will do is put both the DAC test and the Galleri test into the studies we're planning with UnitedHealthcare, for example.

Q. Shifting gears a little, what role does payer approval play in the adoption of an MCED test?

A. Payer approval will be absolutely critical in the adoption of an MCED test.

The test as of today costs $950. That means that only a subset of the U.S. population can access it. And the customers, the organizations that GRAIL is targeting, include, you know, the concierge hospitals where people pay a subscription fee to be part of this health system. It includes large payers, so large financial services firms, large tech companies that have, you know, rich benefits programs that they offer their employees.

And so it's only a small subset of the population, and so we need to accelerate, you know, payer reimbursement. We need to accelerate CMS reimbursement. And that's what it will take to make this test broadly available and more importantly broadly accessible.

The other thing is, by making this test more broadly accessible, it improves the test for everyone else, because this is a test that's a learning test, so the more tests you run, the better the accuracy of the test. And so it improves the test for everyone else by making it more accessible.

This is also true globally. If you look at the next five years, GRAIL's plan is to have this test available only in the U.S., Canada, and the U.K., and that's it. We can make it available much more broadly. We just came through a period where we saw what happens when you restrict testing, lifesaving testing, and so we can make it more broadly available and accessible globally as well and drive reimbursement globally.

Q. Would you please describe in a little bit more detail Illumina's experience and expertise in dealing with payers.

A. We have been working with payers in the U.S.

and around the world, again, for almost a decade. We have a very talented team that has expertise in working with payers and is -- and has the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board.

And because of the relationship now we've built up with the payers as we work through one genomic test after another, we're able to more quickly, you know, converge on what evidence would a payer need to get to a place where they can assess whether it makes sense to reimburse a test or not, and so that -- that experience now and again almost a decade of working with them is very deep and very broad.

Q. Are you knowledgeable about GRAIL's experience and expertise in dealing with payers?

A. It's under -- it's under Josh again. It's very nascent.

Q. How will a combined Illumina-GRAIL accelerate payer adoption of the Galleri test?

A. By sharing with them the relationships, the tools, and in some cases they'll be able to recruit people from the Illumina team to go work on the GRAIL team while we sort of backfill that capability, and so we'll be able to dramatically accelerate, you know, their know-how, their bench strength and their

relationship access into the payer community.

Q. Let's talk a little bit about R&D efficiencies.

What role does R&D play in Illumina's business generally?

A. R&D is absolutely critical at Illumina.

Q. Why is that?

A. We believe that innovation is going to be critical to, you know, unlock the future markets for genomics, that to unlock the next set of markets we need to continue to deliver lower prices into the market.

So we've lowered the price by 99 percent since 2007, over 99 percent. We're going to lower it another 80, but there's still more headroom we believe. If you take the prices down for consumers and patients, a lot more opportunity opens up.

In addition, as we deliver -- continue to deliver, you know, tests to the clinic, there is an opportunity to make these tests easier for patients and physicians to understand by delivering end-to-end -- end-to-end workflows with easy-to-understand reports, because increasingly now you need to make this test accessible to people that aren't genomics experts, and so there's more work we need to do to make it easy to understand the output of

a genomic test.

And so there's a lot of innovation still needed to drive the growth of the genomics market, which we think we're at the very beginning of.

Q. How much does Illumina invest in R&D?

A. We spent last year over $600 million in R&D.

Q. And do you track and monitor the level of investment in R&D by your competitors?

A. We do.

Q. How does Illumina's investment in R&D compare to that of its peers?

A. We spend about twice as much as a percentage of our revenue on R&D as our industry average.

Q. What, if any, recognition has Illumina received for its R&D efforts?

A. We've received, you know, numerous recognition over the last few years.

Just a few months ago, we were named, for example, by TIME magazine as one of the most influential companies in the world because of the work we did on COVID, so the work we did to identify the genome of the virus that causes the pandemic in Wuhan, but then, you know, we are now doing surveillance of COVID in over 70 countries around the world. A lot of those countries we donated the sequencers and

consumables. And for some of the countries in Africa it was the first time they've ever had sequencing in their country.

And so for primarily for the work we're doing right now on COVID we've gotten recognized as one of the hundred most influential companies by TIME. MIT Technology Review recognized us as one of the hardest -- hundred smart -- MIT Technology Review recognized us as the number one smartest company in the world a while ago.

So we've received a number of awards over the last few years for our R&D work.

Q. I want to ask you about some of the different kinds of R&D efficiencies involved here, so let me ask you how will the transaction create R&D efficiencies specific to the Galleri test, and then I want to ask you about non-Galleri.

So first, how will the transaction create R&D efficiencies specific to the Galleri test?

A. Our team has deep experience over -- over a decade now in optimizing workflows in the processing of genomic tests. We have been running genomic tests at scale for over a decade now.

What that means is our R&D teams are very good at optimizing, you know, how samples come in, so sample

accessioning, how samples are prepared for sequencing, so both the sample extraction as well as library preparation.

And then our teams are very good at creating high-throughput bioinformatics pipelines to process the data, and so our teams are very good at creating lower-cost, high-throughput workflows to process samples, and that will benefit Galleri.

Q. Give us some examples, if you would, Mr. deSouza, of the kinds of R&D efficiencies that the transaction will create that are independent of the Galleri test.

A. We believe that -- (inaudible) -- once we -- once we're allowed to merge, we will bring our R&D teams together and immediately start the work necessary to identify the genomic biomarkers in blood for other conditions, like fatty liver disease, neurological conditions like Alzheimer's and Parkinson's. We believe -- we will get the teams working on it, and we would love to get a blood test screen for those conditions in addition to this cancer screen.

Q. And why couldn't GRAIL pursue the R&D efficiencies you've described independent of a merger with Illumina?

A. You know, a couple of reasons.

One, it's just a question -- first, it's just a question of focus. That R&D team is running flat-out to get the -- can the Galleri test to scale, then get their DAC test. You know, they have not yet reached a stage that they can even talk about a date for the DAC test, a specific date, so they have work to do there.

Then they have work to do on their MRD test which they -- the minimal residual disease test for cancer patients, which they know they can do, but they haven't had the resources or the focus to do that.

So the R&D team is going to be focused for several years and rightly so on the tests they need to develop and launch associated with the cancer market.

So -- and then two, they just don't have the resources that have the expertise needed, all the expertise needed, to develop these other tests.

To develop the initial insight for the Galleri -- the GRAIL test, it took some R&D folks that are still at Illumina and some R&D folks that are at GRAIL now, and you need to bring those expertise on the sequencing side back with the sequencing on the methylation side together.

Q. Will the R&D advances that you described lead to cost reductions?

A. They absolutely will.

Q. Tell us a little bit about that, please.

A. By optimizing the workflow associated with Galleri, not only will you be able to scale up the number of tests that are being run in a production environment, but the cost per test goes down because it's more efficient, you're eliminating waste, and you're running more samples on the same infrastructure. All of that will combine to lower the cost per test.

Q. I think you said, Mr. deSouza, that the transaction will reduce the royalty owed by GRAIL to Illumina.

Before the transaction, did GRAIL owe Illumina a royalty?

A. Yes.

Q. And now that the transaction has closed, does GRAIL owe Illumina a royalty?

A. No.

Q. Are you familiar with all the particulars of the royalty calculation?

A. I am not.

JUDGE CHAPPELL: Hold on, hold on.

You mean during this period of hold-separate --

THE WITNESS: That's right.

JUDGE CHAPPELL: -- no royalty is owed?

THE WITNESS: Yes. Once the deal closed, no royalty is owed right now.

JUDGE CHAPPELL: Okay.

MR. MARRIOTT: May I proceed, Your Honor?

JUDGE CHAPPELL: Give me an estimate of how much more time you need.

MR. MARRIOTT: Well, I think -- I'm not going to get finished this evening, Your Honor. It turns out it's going a little slower than I anticipated. I have another question and then maybe it's a good break point, but obviously up to Your Honor, but I've got at least another 30 minutes if not longer.

JUDGE CHAPPELL: All right. It has gone 5:45 already. Ask a question or two and let me know when it's a good time to break for the day.

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

BY MR. MARRIOTT:

Q. Mr. deSouza, you said also I believe that the transaction will eliminate double marginalization. Did I hear that right?

A. That's right.

Q. Before the transaction closed, did Illumina charge a margin to GRAIL on sales of its NGS products?

A. Yes.

Q. And did GRAIL project a margin on its products?

A. Yes.

Q. Are you familiar with all the particulars of the extent to which the transaction will eliminate double marginalization?

A. No, I'm not.

MR. MARRIOTT: Your Honor, this is probably a good time to break to be mindful of your admonition.

JUDGE CHAPPELL: All right.

Anything further before we recess?

MS. MUSSER: Your Honor, just a -- complaint counsel just wants to note we have one more witness for tomorrow, but we might be ending a little early depending on how long that goes, so I just wanted to give Your Honor notification of that.

JUDGE CHAPPELL: But you're expecting this witness will fill the day probably?

MS. MUSSER: It might go an hour or two early. It's hard to know depending on how late Mr. deSouza spills over tomorrow. But I'm not -- it just kind of depends. This is running a little bit quicker than we had anticipated, which is why I wanted to give you notice, Your Honor.

JUDGE CHAPPELL: Anyone the respondents can

call tomorrow afternoon?

MR. MARRIOTT: I don't believe so, Your Honor.

JUDGE CHAPPELL: All right. If you're talking an hour or so, that will be fine.

MS. MUSSER: Okay. Thank you, Your Honor.

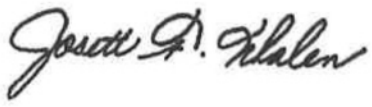
JUDGE CHAPPELL: All right. So we'll reconvene tomorrow at 0945.

We're in recess.

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

CERTIFICATE OF REPORTERS

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
Friday, September 10, 2021
9:45 a.m.
TRIAL VOLUME 10
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

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

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I N D E X

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: All right. Thank you.

We're back on the record.

Anything to take up before we proceed with questioning?

MS. MUSSER: Not from Complaint Counsel.

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

JUDGE CHAPPELL: All right. Go ahead and continue with your examination of Mr. deSouza.

Whereupon --

FRANCIS DESOUZA

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

CROSS EXAMINATION (cont.)

BY MR. MARRIOTT:

Q. Good morning, Dr. deSouza.

A. Good morning.

Q. Do you have personal knowledge of Illumina's supply chain?

A. I do.

Q. And what supply chain efficiencies will arise from the merger?

A. We have supply contracts with a large number of suppliers, and we purchase a number of raw materials in -- that GRAIL also uses in much higher quantities than GRAIL does. So what that means is we are able to get deeper discounts for those raw materials than GRAIL is able to do. And so by consolidating purchasing for these materials between GRAIL and Illumina, GRAIL would enjoy bigger discounts than it gets today for a lot of the materials that it has.

In addition, we have conducted -- just because we have a lot more experience and a bigger team, we have been able to identify vendors that provide superior cost performance points across the products that we buy, and because we have been able to do that, you know, more extensively than GRAIL has so far, there are areas where we've identified vendors that offer superior cost performance than the vendors that GRAIL would use, and so they're able to take advantage of those capabilities as well.

And then as a global company, we're able to enjoy the benefits of leveraging a supply chain that is global, and so, again, that gives us access to a superior cost performance supply chain than GRAIL would have on its own.

And so those are the efficiencies, some of the

efficiencies that GRAIL would be able to enjoy as a result of being part of Illumina.

Q. What will that mean in terms of prices for -- lower prices for customers?

A. It means -- it would mean the savings that we get as a result of being able to buy products more cheaply are savings that would be passed on to customers, resulting in a lower price of the product to customers.

In addition, it would mean a higher quality, potentially, set of products, as well as a more resilient supply chain.

Q. As CEO of Illumina, are you knowledgeable about the company's general operations?

A. I am.

Q. And do you know what operational efficiencies will result from Illumina's acquisition of GRAIL?

A. I do.

Q. And what are they?

A. Some of them include leveraging our production labs to run the GRAIL test. So, today, for example, GRAIL runs its test out of its small development lab in Menlo Park, which is where they developed the product initially. To scale up, they will need a set of production-scale labs that are able to do, you know,

millions of tests in the geographies that matter.

We have been doing that for well over a decade now. We have labs in the U.S. but also outside the U.S. So, for example, we run genomic tests for the government of England as a result of the genomic tests they offer their population for cancer therapy selection, for genetic disease diagnosis, and we have been doing that for a number of years.

Our labs have already been delivering tests in the millions of tests a year to consumers and have been doing that for a while. What that means is we already have the lab facilities, the real estate facilities. We already have the equipment in the labs. We already have the personnel that are trained to run genomics, and it requires a certain level of sophistication to run a genomics pipeline.

In addition to that, we have optimized the work flows associated with running a genomics lab, things like that sample accessioning, how do you bring in, you know, from a logistics perspective but then also, on the facility itself, how do you unpack a lot of samples? How do you maintain a chain of custody with integrity as a sample comes in to your position all the way, you know, until you return data?

We have also been able to optimize the work

flow end to end from a safety perspective, from a supply chain -- sorry, chain of custody perspective, and from a cost perspective. We've also developed the custom automation tools it takes to run a highly automated lab. We've also developed the software pipeline it takes to analyze the data in a very high throughput way coming off those samples.

So, you know, all of those operational capabilities are benefits that GRAIL will enjoy, and it will take GRAIL years to develop that capability themselves.

Q. What role will international presence and capability play in the success of an MCED test?

A. The international presence will be very important in the success of an MCED test in a number of ways. One, the market for an MCED test is obviously global. Cancer is a global disease. It kills 10 million people a year, of which 600,000 die in the U.S. every year, but 9.4 million die outside the U.S. every year.

And so there's a global need for an MCED test, and it's important to meet that need, and it will be an important source of potential revenue in terms of accessing the market. The vast majority of that need is outside the market.

But in addition to meeting that need and getting the revenue associated with serving the -- delivering the test outside the U.S., there's another important dimension to this. This MCED test is -- are based on algorithms that have been developed from running large studies. What that means is this test gets better as you run more samples.

And so by accessing a bigger market, you get a better test because the algorithms continue to get refined, and you get better and better accuracy in the test the more samples you run. This is especially true if the samples are genomically diverse.

And so the -- the benefit you get from running this test globally is not just driven by the fact that you are running more tests and that gives you more accurate performance. Running more tests in regions where there's high genomic biodiversity, you know, in Africa, for example, in Asia, for example, or even just extending from the UK into the rest of the European Union, or going into Latin America, gives you a more diverse set of genomes. That gives you a better test.

And so long term, global expansion is important to the success of the MCED test in at least those two dimensions.

Q. How would you describe Illumina's international

presence?

A. We have a strong international presence. In fact, more than half of Illumina's revenue today comes from outside the U.S., and so the countries outside the U.S. represent the majority of Illumina's business today, and that wasn't always true, but as we grew, we were able to access more of the international markets.

Today, we've placed products in over 140 countries around the world. We have cleared products in dozens of countries around the world. And to -- what that means is we have presence in those countries. We have partners, we have sales teams, we have in-market surveillance teams to make sure that we are quick to recognize if there's any issue our customers are having and be able to respond.

We're able to market into those countries. We have medical affairs teams that are connected to the medical communities in those countries, the standards bodies. We have regulatory teams that are in connection with the regulatory bodies in the countries that we operate. So we have a substantial presence that supports this global capacity.

Q. What do you know about GRAIL's international presence and capability?

I think we have some background noise.

JUDGE CHAPPELL: Any idea who that was?

JADA: I think Illumina's room. I'm sorry, if everyone can please remember to keep yourself muted while you're not speaking, that would be great.

BY MR. MARRIOTT:

Q. Let me repeat -- thank you, Judge.

Let me repeat the question, Mr. deSouza. What do you know about GRAIL's international presence and capabilities?

A. They're very minimal. The GRAIL plan is targeting the GRAIL test being available in only three countries over the next five years, and the three countries are the U.S., Canada, and the UK. They just hired in the last year their first person in the UK, and so they are starting to build up a small presence in the UK, but they really have no presence in the European Union, in Africa, in Asia, in Latin America, or anywhere outside those three countries.

Q. And do you know what impact international acceleration of Galleri will have on the adoption of the test in the United States?

MS. MUSSER: Objection. Calls for speculation.

JUDGE CHAPPELL: Do you know what impact? As phrased, it does not call for speculation. Overruled.

THE WITNESS: I do know what impact

international expansion will have on the GRAIL test. By accessing larger sample sets, by accessing the genomes from more patients or more consumers around the world, the GRAIL test will become more and more accurate, and this is a test that's based on a learning algorithm, and so accessing larger sample sets will improve the GRAIL test for people here in the U.S.

In addition, accessing more diverse genomes than are available in the U.S., which you will get access to as you enter, you know, continents like Africa or Asia or Latin America, or even in the European Union, accessing the more diverse -- the bigger biodiversity associated with those genomes will improve the test for people here in the U.S.

This is a special issue in genomics because the cohorts that are used here in the U.S. to develop genomic tests are predominantly Caucasian cohorts. What that means is if you are an African-American person in the U.S. or a number of other minorities, the genomic tests just simply aren't as good for you as they are for Caucasians, and that's just a health inequity we're dealing with in the U.S. that we will be able to address more fully as we expand the cohorts to include cohorts from Africa and from Asia.

BY MR. MARRIOTT:

Q. Why couldn't GRAIL go out and hire third-party experts to achieve the efficiencies you've described without merging with Illumina?

A. It would not be possible for GRAIL to do that. To achieve all the efficiencies we're talking about, GRAIL would need to access the expertise Illumina has across all of the different functions I talked about. There's no group in the world, arguably, that has as deep an expertise in market access for genomic tests as Illumina. There's no other consulting firm. There's no other, you know, group.

Illumina's teams have helped deliver reimbursement for over 1 billion people around the world for genomic tests across a number of domains; non-innovative prenatal testing, tests to match cancer patients with the right therapies, tests to attract COVID and the mutations associated with this virus, tests to diagnose children in the NICU that have undiagnosed genetic diseases but are experiencing seizures and other undiagnosed symptoms.

There is no group you could go to that would have the depth and breadth of expertise and just the long experience that the Illumina team has and the set of tools and innovations that we've developed. I used market access as an example, but similarly, you can go

function by function; clinical affairs, commercial teams, our footprint on the ground.

No other company, for example, has cleared regulatory products associated with genomics in as many countries as we do, and so those are capabilities that are not accessible outside of Illumina, and we at Illumina aren't set up to be a consulting firm and make those services available to everybody on a fee basis. So that's why, absent us being integrated, these efficiencies would not be available to GRAIL.

Q. In your experience, do Illumina customers share their proprietary information with Illumina?

A. No.

Q. Does Illumina have any incentive to raise prices to any GRAIL rival or potential GRAIL rival?

A. Absolutely not.

Q. And why not?

A. Our core business is to sell sequencers and consumables. That's how we make the vast majority of our revenue. And so our strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve.

Even in the markets where we have our own test, so noninvasive prenatal testing, for example, or cancer therapy selection, even in -- or genetic disease

diagnosis -- even in those markets, we make significantly more money by selling sequencers and consumables to companies that compete with our test than we do from our own test.

For example, in noninnovative prenatal testing, we make eight times as much revenue selling sequencers and consumables to companies that compete with our test than we do from our own test.

In cancer therapy selection, we make 14 times as much money selling sequencers and consumables to companies that compete with our test than we do from our own test.

Our strategy has been consistently to open up a market and then enable lots of players to serve that market, each with their own different approach, because we believe that maximizes the opportunity in the market.

Also, it's very important for us that our customers -- and we have 7000 customers across 140 countries -- recognize that we are the company that drives the cost of sequencing down at high quality and makes sequencing more accessible. We would not want to change that dynamic or cause customers to be concerned that we wouldn't continue to do that.

Now, if we did that, we would lose their

business. They would move on to, you know, a BGI or a Thermo, send their services, their genomes even in the U.S. They can. They can send their genomes to be serviced by BGI. So from our perspective it's very important that we don't raise prices, and we wouldn't raise prices certainly on GRAIL's rivals because it's inconsistent with our strategy.

It's also inconsistent with our history. You know, what we have shown is that we are the company that drives prices down. We are the company that encourages an ecosystem even in markets where we have a test.

Q. Couldn't you make up for lost NGS sales by diverting test sales from GRAIL rivals to GRAIL?

A. No, we couldn't.

Q. And why not?

A. Because -- a couple of reasons. One, the GRAIL test and the other tests that will come up on the market are not substitutes, and so, you know, if they don't buy rival tests, it's not clear that they would move the business to GRAIL or vice versa.

So, for example, if you are a GI specialist, you want a test that's a single cancer test. You don't want a test that tells you about the potential 49 other cancers that you're not qualified to deal with, and we

have heard that loudly and clearly -- and I did, too -- when I was talking to these specialists. They're saying, look, for my specialty, I want a colorectal test. They don't want the 50 cancer tests.

Those aren't -- if they don't do a colorectal blood test, they will do other colorectal tests. You know, there's Cologuard out there, there is colonoscopy, for example. Those are the substitutes in terms of detecting colorectal cancer.

And so the first reason is they aren't clear substitutes. If we lose the business -- if our customers lose the business associated with a blood test, an NGS blood test for colorectal cancer, we lose the business completely because it's likely to go to another test that doesn't use NGS at all. And so that's the more likely scenario. So we are better off if that GI specialist uses that colorectal blood test from a company that creates it, an NGS-based specific colorectal blood test.

Secondly, if we were to raise prices on GRAIL, we would lose a lot more in sequencing business from the other markets, right? The rest of our customers, whether they are in cancer detection or cancer at all, would look at what we did here and would be concerned about us doing that in the other markets that they're

in.

And so there would be a knock-on effect where we would lose sequencing business across our 7000 other customers who would be concerned about that kind of behavior. And so we wouldn't do that because, again, the much bigger part of our business is the sequencer business. So losses there really are much more impactful than you'd see.

Q. Does the projected size of the profit pool for clinical testing services give Illumina an incentive to advantage GRAIL vis-à-vis potential rivals?

A. It does not.

Q. Why not?

A. Because the way the profit pools will play out over the next decade are that, you know, we -- for the first few years, we incur very significant losses. There are no profit pools until 2026 associated with GRAIL. We will incur losses that are closing in on $2 1/2 billion associated with launching the GRAIL test. All of that will be funded by our sequencing business.

Then, after 2026, we get our first dollar of profit, but it's not until 2030 where we've recouped the losses we've made in GRAIL. And so if you think about the next decade even, we really need and are

really fueled by the profit pools associated with our sequencers.

JUDGE CHAPPELL: Do Illumina's sequencers -- say the NovaSeq, do they have a life span, X number of years and you've got to replace them?

THE WITNESS: They don't. We have customers that are running our sequencers even ten years later. Now, at some point, if we've released a new version, then we'll set a date in the future for an end of life of that product. In this market, though, we have made a commitment that if any customers are using our products, we will not obsolete the product as long as they're using it.

JUDGE CHAPPELL: How often do you have a software download or update to, say, NovaSeq?

THE WITNESS: In -- from time to time, but in the clinical markets, if a customer has locked a work flow, then they very rarely upgrade the software. So they don't take any software. They lock a work flow, and then it's very occasionally that there's an upgrade associated with that locked work flow.

JUDGE CHAPPELL: Does a sequencer like the NovaSeq, does it have an airgap or is it connected to the Internet at all times?

THE WITNESS: Customers run it in both ways.

Some customers completely just run it on their own and don't have any connection to the internet at all. Some customers connect it and they can connect it in two ways. They can connect it to us to monitor the health of the instrument and proactively let them know if something is looking off, for example, or if they need trouble shooting, they can call us. So that's one way, just to monitor the health.

But the second way some customers connect to the internet is they may store their data in a cloud-based service. We allow you to -- NovaSeq can connect to our cloud-based service or anyone else's. Some people use Amazon or Azure or a company-specific cloud-based service, but some others run it completely airgapped.

JUDGE CHAPPELL: Let's talk about that first way you described. A customer connects to you, Illumina. What data or information do you have access to?

THE WITNESS: So there's -- they can -- they can choose. They can send, if they want, just the instrumentation metrics, so how the instrument is performing, without any of the genomic data associated with the run. So that's one option they have.

The second option they have is they can store

the genomic data in a cloud-based service that we offer which is built on AWS. They can choose to do it on us. They can choose it to do it on AWS or other options. We have in our license agreements that we will not -- we are stewards of that data. We will not mine that data for drug discoveries or anything like that.

JUDGE CHAPPELL: So under no circumstances do you access or look at or review any customer's genomic data?

THE WITNESS: We don't. That's very -- that's an important bright line for us.

JUDGE CHAPPELL: All right, thank you.

BY MR. MARRIOTT:

Q. Mr. deSouza, you -- we spoke a little earlier about profit pools. Why do you project that profit pools may eventually shift downstream?

A. We believe that we will continue to see profit pools in the sequencer business, but we believe that because of the competition in this business, the profit pools will -- the operating margin will decline over the years. And so I think you guys saw that the -- our projections, that because of the competition, we expect a decline in the profit pools associated with sequencers, although it will continue to be a profitable business.

Now, the -- on the other side, the testing business for many, many years will not have a profit, will lose business, and that's very typical in clinical testing businesses, is they scale up and get to a scale that they need to drive profitability, and at that point you will start to see profits. And so the testing business will go from a negative margin business to a profitable business.

Having said that, you know, the -- I think you guys saw the numbers, that both -- it's not that the testing business becomes more profitable from a margin perspective than the sequencer business.

Q. You said yesterday that Illumina has an open platform. How, if at all, does that bear on Illumina's incentive to foreclose a potential GRAIL rival?

A. Yeah, the open platform means it's very -- it's very easy for customers to run a mixed environment today, where they run our instruments and other -- and other companies' instruments. Because, again, the data formats are open, they can -- they can manipulate data from our instruments with data from other instruments.

Because we have an open platform, customers can use library preparation kits that are from other companies, not Illumina. Although we offer our own, we let you use whatever library preparation kits you want,

and so you're not tied in to either the front-end preparation from Illumina or the back-end. You could run both in completely Illumina-independent environments.

And so what that means from an incentive perspective is we have to continually earn the sequencing business from our customers, because they have options, and we have made it such that, you know, if they have -- if they want to switch out of an Illumina sequencer, they can keep the back end that they have if they were using AWS or Azure or any of the other data services or even their on-premise data. A lot of customers store their data on their own site. They can keep that.

The library preparation may not be Illumina either. In fact, the majority market share in library preparation for Illumina sequencers is by non-Illumina companies, and so more likely than not they already have a library preparation work flow that is not from Illumina. And so that means we have to be continually earning their business because they have options on the sequencer side.

Q. How would raising prices to or imposing costs on potential GRAIL rivals affect Illumina's business?

A. It would have a very significant negative

effect on Illumina's business, because if people heard that we were raising costs in a market, I mean, that would cause us to have a ripple effect of losses in our sequencer business, not just in the cancer screening market, not just in the oncology market, but across our customer base as a whole.

In addition, in the screening market specifically, if we were to raise prices there, those customers have choices, too. And so, you know, at some point it becomes possible for -- you know, for us to see a ripple effect not just in that market, but across our whole customer base.

Q. Today, what fraction of Galleri's price is attributable to sequencing?

A. Today sequencing costs represent about 10 percent of the price of Galleri.

Q. And what fraction of Galleri's price will be attributable to sequencing by 2025?

A. By 2025, we project that sequencing costs will be less than 4 percent of the price of GRAIL's Galleri test.

Q. And does Illumina have any plans to raise prices to or impose costs on potential GRAIL rivals?

A. No.

Q. What, if anything, has Illumina done to

eliminate the possibility that it will raise prices or impose costs on potential GRAIL rivals?

A. In addition to the fact that raising prices would be counter to our mission as a company, counter to our strategy, counter to our entire history, counter to our stated path to the market and to investors, just to make sure that it was very clear to the market that we wouldn't raise prices on GRAIL's rivals, we have put together an open offer. That is a contractual commitment signed by Illumina that highlights a few things.

First, it commits us contractually to making sure that anybody who signed that open offer letter continues to have access to Illumina's products and services on the same terms as GRAIL does.

We have also contractually committed in that letter to not raising prices on anybody who signed that offer letter.

In addition, we have contractually committed in that letter to lowering sequencing prices by at least 43 percent by 2025.

In addition, we're committing we won't obsolete products that our customers are using.

In addition, we're committing to support any IVD work that those customers want to do.

So those are some of the commitments we're making contractually to any customers that would sign that offer letter.

Q. Does Illumina have an incentive to disadvantage or not cooperate with any potential GRAIL rival?

A. No.

Q. And why not?

A. Because what we want to do is expand the market as a whole, because that's how we make our revenue, by selling sequencers. So what we want to do is make sure that we're creating as many options for our customers that -- that we can then sell sequencers into those options.

In addition, if -- if it became -- if it became a fact that we started to advantage some customers or -- and not others or advantage our own test and not anybody else's test, that would, again, have a ripple effect across the rest of our customer base and cause them to start to think about using alternatives to Illumina.

Q. Does Illumina have any plan to disadvantage or not cooperate with potential GRAIL rivals in any way?

A. Absolutely not.

Q. Won't Illumina's incentives change as the downstream market expands?

A. No, it won't.

Q. Okay. Independent of the open offer, does Illumina have a contractual obligation to customers to provide technical support and service?

A. Yes, we do.

Q. And what, if anything, has Illumina done to eliminate the possibility that a combined Illumina/GRAIL could disadvantage any GRAIL rival in terms of access or cooperation?

A. We are contractually committing in both the license purchase agreements -- when you buy an instrument from us, there are commitments there around our support of you and that instrument -- and in addition, we have maintenance contracts that customers have signed that contractually commit us to a higher level of on-site support and other things that customers will get from us.

And then in the open offer letter, we are committing to do a few things. One, to make sure that any customer has access to the same services that GRAIL has access to, so any of the same support services that GRAIL has access to, our customers will have access to on substantially the same terms, economic terms, for the level of service.

We are also committing to publish publicly what

GRAIL is buying from Illumina, not only what products by SKU GRAIL is buying but also what services, so what maintenance contracts are they on, and that will be publicly visible to everyone else, and we will be publishing the pricing grid that's being used to determine the prices for GRAIL. So it will be very transparent to everybody what products, what services GRAIL is using, and what price they're getting for those products and services.

Q. Does Illumina monitor investment in MCED testing?

A. We do.

Q. What can you tell the Court about investment activity in MCED testing since the announcement of the Illumina/GRAIL transaction?

A. The -- as we expected, the investment in the MCED market significantly ramped up after Illumina entered the MCED market. A few -- a little while after we acquired GRAIL or we announced our intent to acquire GRAIL, another startup in this space that had no product, no revenue, Thrive, was acquired by Exact for over $2 billion.

Companies like Caris, for example, experienced large investment rounds after we invested, and so we saw a significant increase in investment in the MCED

space after we got in, and that was very consistent with what we saw in the noninvasive prenatal testing space when we entered in 2013. Investment there jumped, too, after we got in.

And that was also consistent with what we saw in the cancer therapy selection space after we announced our products. Investment in alternatives significantly went up after we announced.

Q. Are you knowledgeable about the NIPT space, Mr. deSouza?

A. Yes.

Q. And are you knowledgeable about Illumina's acquisition of Verinata?

A. Yes.

Q. Following Illumina's acquisition of Verinata, did Illumina take any steps to foreclose Natera?

A. No.

Q. And what can you tell the Court about Verinata's market share since Illumina's acquisition of Verinata?

A. After we acquired Verinata, our share with Verinata in the NIPT market went down.

Q. And how, if at all, has the annual number of tests ordered changed since 2013?

A. The number of tests ordered by expectant

mothers has significantly increased since 2013.

Q. And how have Illumina's prices to its NIPT customers who compete with it changed since 2013?

A. The price we charge to customers that compete with NIPT has dropped by over a half since we entered the NIPT space.

Q. And how has the reimbursement status of NIPT tests changed since 2013?

A. Reimbursement for NIPT tests has dramatically expanded since 2013. In 2013, there was almost no reimbursement for NIPT. It was primarily a self-pay market. Our teams have done a lot of work since 2013, and today, in the United States, there are over 119 million covered lives for NIPT tests in the United States, including --

JUDGE CHAPPELL: I'm sorry, but I want to ask you about the NIPT test. Does the profitability change for you whether the test is covered by insurance or not?

For example, you're selling the test, say like Galleri right now. The public pays, what, 950 or so and you make or lose X amount of dollars. With NIPT, I don't know if you do that or not, but can you tell me whether or not in a situation where there's a test being offered, once it's being covered by insurance,

say one goes in and they just pay a copay, does your profitability change from your end?

THE WITNESS: Great question. What -- the answer is we -- no, we allow our customers to keep the benefit associated with, you know, private payers reimbursing at a higher level. So we charge for the sequencing and consumables, and we take those prices down over time, and so our customers can benefit in a couple of ways.

One, you know, no matter what, their profitability continues to improve as we take our sequencing prices down. And then two, to your point, as reimbursement comes in -- and that comes in from a private perspective, it comes in higher than, you know, maybe Medicaid would, for example -- our customers benefit from, you know, any higher reimbursement that comes in. They also obviously benefit from just more people being reimbursed.

JUDGE CHAPPELL: Have you done projections on Galleri, any profit margin or markup today versus two years from now if it's totally reimbursable by Medicare and Medicaid and insurance?

THE WITNESS: We have --

JUDGE CHAPPELL: Again, we're in public session, if this is something you can discuss in

public.

THE WITNESS: Sure. What we are expecting in the -- in the Galleri marketplace is that the -- we will continue to drive the cost of sequencing down for the Galleri test. So that alone will drive up -- will expand the profitability of the Galleri test because the cost of sequencing, as we bring it down -- now, sequencing is a small part of the overall cost of Galleri, and so it will help incrementally in terms of driving its profitability.

The other thing we have modeled is the price of the test going down. So what we believe is today, the Galleri test costs about $950, and it's a self-pay test. Our intent is to significantly lower the price of that test to the market to make it more accessible, and so we've said it will go down towards $600 and then hopefully, over time, even below that.

And so we've modeled that and we've modeled an expansion in reimbursement to say -- and even that $600 for the majority of people should not be a self-pay, and so we will do the work with CMS, with Medicare, Medicaid, at the state levels, as well as federally, and we will do the work with the payers so that the $600 becomes primarily covered by insurance companies or CMS, and there's a small, if any, copay associated.

So those are things we've modeled in Galleri's ramp.

JUDGE CHAPPELL: You referred to driving down the cost of sequencing. What are the major factors involved in doing that?

THE WITNESS: There are a number of technology innovations that we're pushing on to drive the cost of sequencing down. So, for example, we do sequencing on a flow cell. So you load the sample up on a flow cell, and one of the important ways to drive the cost of sequencing down is to have a more dense flow cell, so to have the -- the wells closer and closer to each other so that when you scan the flow cell, you are reading more and more samples at a single time. What that means is the cost gets divided by a larger number of samples, and so that drives the cost of sequencing down.

Another thing that we're working on is continuing to push -- and here we are running into a little bit of the boundaries -- but we're using techniques to use shorter and shorter wavelength light to shine on the flow cell. What that, again, allows you to do is put the clusters in the flow cell closer and closer together to drive the density of a flow cell up so you can have more samples on the flow cell.

We're also improving the chemistry we use so

that you can run our entire work flow faster on the sequencers and so you can do more samples for a given period of time. We're also looking to continually improve the data path, because you're reading a lot of data very quickly, and you need to process it very quickly, and you don't want the processing time to be a bottleneck. And so there's a lot of work we're doing in how do you accelerate the processing associated with the data coming off the flow cell.

So what we have then is we've created these technical teams that work on each of those components, and then when you bring them together, they each have a compounding effect, and that's how we -- and we showed this year some of those technology components -- and that's how we have confidence we will lower the price of sequencing.

Today it's $600 a genome. We have publicly said we are going to take it down by another 80 percent, $100 a genome, and we were able to show this year some of the technology breakthroughs we've had on each of those fronts, the density, the wavelength, and that's how we get the price or cost down, and then we pass it on to consumers as a lower price.

JUDGE CHAPPELL: Okay. You talked a lot about changing flow cells. If I have a NovaSeq today and I'm

using a flow cell and then you modify, change, or improve a flow control, do I need a new NovaSeq sequencer? How does that work?

THE WITNESS: No, you do not. So, you know, we have the NovaSeq we launched in 2017. You can use the exact same machine you had in 2017 even though we launched new generations of sequencing. So we launch different flow cells that give you different outputs, as an S1, S2, S3, S4. You can still run the S1, but the S4 gives you much higher output, and so what you should think about is you're buying the platform, the machine, and you should expect from Illumina that we will give you options on flow cells, and depending on how many samples you want to run, depending on the application you want to do, you will get the option to start to pick which flow cell you want to run for -- you know, for that application.

JUDGE CHAPPELL: If I have an Illumina sequencer, am I required to use a flow cell provided by Illumina?

THE WITNESS: You are, because the two are connected in terms of the things we put on the flow cell. We have -- we've put -- because we know how to read the things on the flow cell, so those two are very connected.

JUDGE CHAPPELL: So this improvement of flow cells you've been discussing, that's being done or driven by Illumina, not by the customer or the lab.

THE WITNESS: That's right, and that's how all sequencers in the market work. So BGI, you use BGI flow cells. Thermo, you use Thermo flow cells. So you're right.

JUDGE CHAPPELL: Thank you.

BY MR. MARRIOTT:

Q. Mr. deSouza, do you know whether there have been any new entrants in NIPT since 2013?

A. Yes. The number of entrants -- the number of players in the NIPT space has significantly expanded since 2013.

Q. You have made mention several times of Illumina's offer or Illumina's open offer, so let me ask you some more specific questions about that. What exactly is Illumina's open offer?

A. It's a contract that we're making available to anyone. It's on our website, signed by us, that any customer can sign, and contractually commits to making sure that whoever signs that contract has confidence that they have contractually guaranteed access to Illumina products and services at the same terms as GRAIL or anyone else.

And to do -- so it's a 12-year term, and to do that, we've put specifics in place around, you know, you will -- you know, you will have access to products and services on the same terms, you -- as GRAIL does. You -- we will not raise prices on you. In fact, another term is that we will lower prices of sequencing by at least 43 percent in future generations, you know, of our sequencer technology. So there's a set of contractual terms we're providing in that open offer.

Q. We'll come back to some of those terms.

Why did Illumina make the open offer?

A. We made the open offer based on feedback we were hearing from the FTC around concerns that we would raise prices in a market. Frankly, we were surprised to hear that because our entire history and our entire ethos as a company has been to very significantly lower costs and expand the market for sequencing, and we've publicly stated our plans to continue to do that into the future.

But based on what we heard from the FTC's comments, we put the open offer letter out to really highlight our commitment to providing equal access and to continue to lower costs.

Q. And to whom was the open offer made?

A. It was made to oncology customers, and it's

open on our website.

Q. And what's the term length of the open offer supply agreement?

A. Twelve years.

Q. What options does a customer have to exit the 12-year supply agreement?

A. They can exit the agreement at any time for any reason they want.

Q. And what options does Illumina have to exit the 12-year supply agreement?

A. We cannot exit the agreement.

Q. What does the open offer do to ensure that Illumina cannot offer disadvantaged pricing to any potential GRAIL rival?

A. There are -- we are contractually committing that they will get access to the same prices. We are committing that we will publish the products and services that GRAIL is using. We are committing that we will publish the pricing sheet that we have given to GRAIL and that everybody will have access to that exact same pricing sheet, which is what we use.

We are committing that customers have an ability to audit us twice a year to make sure that what we are sharing is -- you know, is what we said and that we're committing to abiding by binding arbitration in

the event that there is a discrepancy.

Q. Does the open offer make any guarantees as to price decreases?

A. Yes, it does.

Q. And what's the guarantee?

A. We are guaranteeing that we will lower prices of sequencing by at least 43 percent by 2025.

Q. Does the open offer include a universal pricing grid?

A. Yes, it does.

Q. And what's the purpose of the universal pricing grid?

A. The purpose is to be very transparent around the prices that GRAIL is getting for the products and services that it buys from Illumina.

Q. And what, if any, impact does the universal pricing grid have on predictability of pricing?

A. It's -- it should be very helpful to customers as they plan, you know, their multiyear business plans, because they will be able to know with certainty what prices they will have access to.

They will also be able to know with certainty that they are not disadvantaged vis-à-vis GRAIL or anybody else in the market because everybody is going to be on that same pricing sheet. That was why it was

very important that we don't give any one customer a very large discount off the pricing sheet. And so, you know, it was an -- we need to make sure that everybody knows it's an even playing field.

Q. What does the open offer do to ensure that any GRAIL rival has the same access as GRAIL to Illumina's products and services?

A. It provides a contractual guarantee that we will provide it, and it also allows customers to be able to audit that they're getting that, as well as provide for a remediation plan if they are not getting it for any reason.

Q. Does the open offer make any commitments regarding obsolescence or situations of short supply?

A. Yes, it does.

Q. And has Illumina made any commitments to customers about entering into IVD agreements?

A. Yes. We've committed that we will support them and we will enter into IVD agreements if they want to create an IVD in a space that they're in.

Q. And what commitments has Illumina made to ensure that Illumina cannot share a customer's confidential information with anyone at Illumina or GRAIL who works on the GRAIL business?

A. We are committing that we will firewall

customers' information from GRAIL and, frankly, from anyone else that they compete with that uses our products.

Q. And what commitments has Illumina made to ensure that intellectual property does not create a barrier to customer supply agreements?

A. We are committing in the contract that if we license any technology to GRAIL for use in their test, or any other third party for use in their test, we will make sure that that technology is -- that IP is available to everyone on the same terms as we made that technology available either to GRAIL or someone else.

Q. And what, if anything, does the open offer do to ensure that Illumina is abiding by all of its provisions?

A. It provides a mechanism for customers to be able to audit the -- you know, audit Illumina, to make sure that we are living up to those commitments, and it provides mechanisms for binding arbitration, that we commit to living with, to resolve any disputes that emerge.

Q. Has Illumina recently amended the open offer?

A. Yes, we have.

Q. And why don't we take a look, please, at RX 3935. Tell us, if you would, Mr. deSouza, what is

RX 3935?

A. This represents the amendments that we made. We found a number of ways that we could make the open offer -- the open offer even slightly better, and so we wanted to share that with our customers right away, and so these are the amendments that reflect, you know, those enhancements.

Q. And to whom is this addressed?

A. It's going to be part of the publicly available open offer letter.

Q. So it says at the top in brackets, "Name, title, company." Why does it say that versus specifically identify a customer?

A. It's open to everyone. It's not to specific customers. Any customer who wants to take advantage of it can get this off our website, and we will execute the contract with them.

Q. And who signed this document?

A. I did.

Q. And when is the document dated?

A. Yesterday, September 8th.

Q. So I think yesterday may have been September 9, so -- is that --

A. September -- I'm sorry, you're right. September 9th, I'm sorry. These days are flying buy.

MR. MARRIOTT: Your Honor, we move the admission of RX 3935 into evidence.

JUDGE CHAPPELL: Any objection?

MS. MUSSER: No, Your Honor.

JUDGE CHAPPELL: So admitted.

(RX Exhibit Number 3935 was admitted into evidence.)

BY MR. MARRIOTT:

Q. Mr. deSouza, if you would, please, if you can go to the next page, would you just describe for the Court the changes that Illumina has made to the open offer?

A. Sure. There are a number of changes. First, we specifically lay out that customers will have access to the same services that GRAIL uses at the equivalent level of service. So they will have access both to the pricing as well as the level of service that GRAIL has access to.

Second, we lay out that customers will have access to any products that GRAIL has access to within five days of GRAIL having access to that product. So I believe simultaneously, but no later than five days after GRAIL has access to it.

Next, we are committing that customers will have access to the same information about final product

specifications of any new product within five days of GRAIL having that information. Again, we are going to shoot for simultaneous, but no later than five days of GRAIL having that information.

Next, we commit to publishing the products and services by SKU that GRAIL is purchasing, as well as the pricing grid for those products and services that GRAIL is purchasing.

Next, we talk about the pricing of any materially improved product. We commit that that pricing must be commercially reasonable and reflect the value of that product to customers. If there is any question about whether the new -- the price of the new version, you know, is inappropriate, then we commit to an arbitration where the arbitrator is empowered to determine the reasonableness -- the reasonable -- reasonableness of the price we put out, valuing the improvement we've put into the product and performance or capability, and if there's any refund necessary to customers, we will make those refunds available.

Next, we provide -- we increase the number of audits that a customer can do. In the initial offer letter, they could do one audit a year. We're expanding that to having them be able to do two audits a year, so once every six months.

And then we are also committing to -- so that if an arbiter determines that we have breached the supply agreement in any way, the arbiter is empowered to order any relief necessary to address the concern.

And then we want to -- we are also stating here that the arbiter should know that the purpose of this supply agreement is to address concerns about a customer being disadvantaged to GRAIL, so that they have that lens when they're determining whatever remedy they think is appropriate to make sure that the customer is not disadvantaged relative to GRAIL.

Q. Thank you, Mr. deSouza.

You can take that down, please.

Understanding that you've made commitments in the open offer about providing information concerning GRAIL, how important is it as a general matter for a customer to have advance notice of a new offer?

A. In general, customers like to know when we've launched a new offering, but in terms of the real world, what happens with customers, especially clinical customers, is once we launch a product, they wait for a period to see how that product is performing in the market.

Now, research customers may look to move more quickly, but for clinical customers, which is what

these markets would be, they wait, and they could wait for a year or two, for the product to be on the market, to see if there are any modifications that get made, to look at the performance characteristics of the product, and get, you know, some sense of how the product performs in the real market.

After that, what they'll do then is they'll typically bring in a single sequencer and start to validate the work flows that they have, as well as train their people on the new sequencer. This validation process takes months or quarters, depending on the size of the clinical customer, and it's only then that they start to roll out their production tests on the new sequencer.

So it's not uncommon for clinical customers to adopt a new sequencer years after -- it could be three-plus years after a new sequencer comes out. For example, NovaSeq was launched on -- in 2017, first half of 2017, and we still have a substantial portion of our NovaSeq customers that are new to high throughput or new to Illumina, and they are only now bringing the NovaSeq into their environment.

And so adoption cycles for new sequencers are -- in clinical markets are measured in months and more likely years, and so while we are -- we want to

make sure that customers have access to the product immediately, they have access to information immediately about the new products, the reality is the adoption cycle will take -- or even the cycle when they first start looking at the product in substantial detail -- is going to be months or years later.

Q. To wrap up, Mr. deSouza, let me just ask you this: What impact will this transaction have on patients?

A. This transaction has the potential to fundamentally dent the mortality curve in cancer and save many, many thousands of lives around the world. Illumina can accelerate global access to this life-saving test by making this test more available.

Illumina can accelerate real world access to this test by making it more affordable and by making sure there is reimbursement in place so that the rest of the market, both in the U.S. and around the world, truly has access to it, and this test gets into the hands of the underserved healthcare communities that, again, are disproportionately, you know, dominated by minorities and persons of color.

This -- you know, our modeling estimates that if we can accelerate -- which we think is very, very doable -- if we accelerate reimbursement in the U.S. by

one year beyond what GRAIL can do, then our acquiring GRAIL will have saved over 10,000 lives in the U.S. over the next nine years. That's just in the U.S.

GRAIL, over the next five years, only has plans to launch this product in the U.S., the UK, and Canada. We just went through a period where we saw the tragedy that happens when we restrict life-saving technologies to a small set of wealthier markets. We will make this test available globally much faster than Illumina could, and so those 10,000 lives that could be saved will be a much bigger number when you think about us making this test available to people around the world.

This has personal resonance and urgency for me because I have family in Africa, I have family in India. On its own, GRAIL will not get the test to Africa and India even over the next decade, and so we feel a sense of urgency, given what we know this test can do, to get this test out into the market. And so that's what -- you know, that's what this transaction represents.

Q. Just to clarify, Mr. deSouza, you said that you'll make this technology available faster than Illumina would. Did you mean GRAIL?

A. Than GRAIL would, sorry. Good. Illumina will make this technology available globally and more

accessible globally than GRAIL could on its own.

Q. Thank you.

Your Honor, I have no further questions at this time.

JUDGE CHAPPELL: Anything further, Ms. Musser?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION

BY MS. MUSSER:

Q. Good morning, Dr. deSouza.

A. Good morning.

Q. Yesterday you spoke with Mr. Marriott about FDA approval. Do you recall that?

A. Yes.

Q. And FDA approval impacts whether federal CMS or Centers for Medicaid Service will approve a product for coverage. Is that correct?

A. That's not necessary. In genomic testing, that's now how it's played out.

Q. But it can impact how federal Centers for Medicaid Services will improve a product, correct?

A. It could be an input, but in genomic testing, we have not needed FDA approval as an industry. LDTs have gotten approval from CMS.

So, for example, when I talked about the state

of Michigan became the first state in the country last week to cover a rapid whole genome sequencing for critically ill children in the NICU, that does not depend on an FDA-cleared test at all. That's an LDT.

Q. And, Mr. deSouza, I'm focusing on federal CMS coverage. For federal CMS coverage, FDA approval is an input. Is that fair?

A. It's an input.

Q. And the FDA submission process differs depending on the type of product a company is seeking FDA approval for, correct?

A. The process doesn't change. It's the FDA process. The specific information they want from you in the process that they have is dependent on the test. So they would want data on your test, you know, when they're approving your test, but the process they have is their FDA process.

Q. Mr. McCullough, can you please pull up PX 7072.

You testified at an investigational hearing in this matter, correct?

A. I did.

Q. And if you look at the date, you testified on March 24th, correct?

A. That's right.

Q. In the middle of the cover page.

A. That's right.

Q. And you were under oath during this testimony?

A. Yes.

Q. Could you please go to page 195, lines 2 through 17, and looking at the top, you were asked:

"QUESTION: Is the FDA submission process different depending on what type of product that you're offering?"

And you respond, "Yes." Do you see that?

A. I do. I'm talking about the submissions, not the process, yes.

Q. And following that logic -- you can put that down, Mr. McCullough.

Following that logic, an MCED submission process would be different than a single origin cancer test, correct?

A. The -- the submission itself would be different. The submission process is similar.

Q. But the submissions are very specific to your test in terms of the clinical claims. Is that correct?

A. That's correct. The specific submission is dependent on the test. That's correct.

Q. And Illumina has not received FDA approval for an MCED test before, correct?

A. Nobody in the world has received FDA approval,

that's correct, for an MCED test.

Q. And Illumina has actually never received approval for any type of clinical oncology test in the FDA. Is that correct?

A. We have received approval for a cystic fibrosis test and are in process for our cancer therapy selection test with the FDA.

Q. But you have not received approval for the cancer therapy selection test with the FDA, correct?

A. That's correct. We're in process with the FDA for our cancer therapy selection test.

Q. Got it. So it hasn't been approved yet.

A. That's right.

Q. And whoever is writing submissions for MCED has to understand a little about sequencing. Is that fair?

A. I'd say a little about sequencing. That's fair.

Q. And post-integration, Illumina would be able to accelerate GRAIL's FDA approval process by providing additional information about its sequencers to GRAIL as part of the FDA approval process, correct?

A. No. That's not how we'd accelerate it. We'd accelerate it because we know the FDA submission process, having done with the -- I think we're one of the only companies in the world that's got a cleared

test from the FDA. And so we understand the process for the submission and what the submissions need to look like. That's -- that's how we will accelerate the GRAIL test, not by giving them more information on the sequencers. The information on the sequencers is publicly available.

Q. Mr. McCullough, could you pull up PX 7072 again and go to page 201.

Going to line 15 -- I'm sorry, line 2, and you were asked:

"QUESTION: And how does Illumina's expertise in sequencing assist GRAIL after the regulatory process?

"ANSWER: Well, whoever they hire will have to come up to speed on sequencing because it's a sequencing-based test, and this is a complicated technology, and there's a steep learning curve that whoever they bring on will have to go through.

"All of that goes away if it's an Illumina person because our team really understands sequencing..."

Do you see that?

A. Yeah. They will have to learn about sequencing. It's publicly available information, but they would have to learn about sequencing, and it's a

complicated technology.

Q. And you rarely get involved in strategy discussions relating to FDA approval, correct?

A. I -- yeah, I sometimes do. I don't get involved in the details of the FDA submissions.

Q. And Karen Gutekunst is the person responsible for Illumina's regulatory team. Is that correct?

A. She runs the group that does regulatory work, yes.

Q. And other than the regulatory affairs team, the clinical affairs team and government team would also be involved in GRAIL's FDA approval process. Is that correct?

A. That's correct.

Q. And Janice is in charge of your clinical affairs team, correct?

A. That's correct.

Q. And at the time of your deposition in June of last year, you weren't sure if her name was "Lem" or "Tam." Is that correct?

A. That's what I said, yes, at the deposition.

Q. And she's only been at Illumina a little over a year. Is that right?

A. We got her from Gilead, where she's been working in the space for a long time.

Q. And what type of company is Gilead?

A. It's a pharmaceutical company.

Q. And at the time of your deposition in June, you were still recruiting someone to be in charge of your government affairs team. Is that right?

A. That's correct.

Q. And at the time of your deposition, you testified that you haven't looked through the résumés of the people at GRAIL, so you don't know what their expertise was, correct?

A. That's correct.

Q. And you earlier spoke with Mr. Marriott about your work with Project Baby Deer and Baby Dolphin. Is that correct?

A. That's right.

Q. And Project Baby Deer relates to whole genome sequencing. Is that correct?

A. That's correct.

Q. And Project Baby Deer relates to state coverage in Michigan regarding whole genome sequencing. Is that correct?

A. That's right. Rapid whole genome sequencing, but yes.

Q. And the Project Dolphin also relates to rapid whole genome sequencing?

A. Yes.

Q. And Project Dolphin relates to rapid whole genome sequencing for CMS coverage in the state of Florida. Is that correct?

A. That's correct.

Q. And you're familiar with project Baby Bear, correct?

A. That's right, yes.

Q. Project Baby Bear also relates to rapid whole genome sequencing. Is that correct?

A. That's correct.

Q. And Project Baby Bear relates to CMS coverage for the state of California and rapid whole genome sequencing, correct?

A. That's right.

Q. And you spoke with Mr. Marriott that we believe there are R&D synergies between the GRAIL team and the Illumina team. Is that correct?

A. Yes.

Q. And you also talk -- spoke about NIPT. Is that -- do you recall those discussions?

A. I do.

Q. And you acquired Verinata in January of 2013. Is that correct?

A. Yes.

Q. And Illumina closed the acquisition in February of 2013. Is that correct?

A. Yes.

Q. And Dennis -- Dr. Dennis Lowe is a GRAIL board member. Is that right?

A. No, he's not a GRAIL board member.

Q. But you're familiar with Dr. Dennis Lowe?

A. I know of him. I don't know him personally.

Q. And do you recall that Dr. Lowe was instrumental in the development of noninvasive prenatal testing?

A. Yeah. He developed some of the technology associated with NIPT, yes.

Q. And Dr. Lowe published a study in late 2012 showing how cancer-associated genetic aberrations and variants could be detected in plasma taken from patients. Is that right?

A. I'm personally not familiar with the study.

Q. Have you heard of the study?

A. Not that specific study, no.

Q. And Mr. -- Dr. Lowe works at the Chinese University of Hong Kong. Is that right?

A. I believe he does, yes.

Q. And GRAIL pays a royalty to the Chinese University of Hong Kong?

A. I'm not familiar with all of GRAIL's royalties.

Q. And you did not start at Illumina until late 2013. Is that right?

A. I started in November 2013.

Q. And from 2013 to 2015, the research team did not report to you?

A. They did not report to me.

Q. And you were not involved with the scientific team regarding discussions around cell-free DNA?

A. I was involved in some of the discussions, because we would have tech reviews that happened every few weeks that I would be part of.

Q. But you didn't do all of the scientific outreach yourself. Is that correct?

A. I'm sorry. I'm not sure what you mean by "all of the scientific outreach." I spoke to some of our scientists. I spoke to some of our customers that are scientists. What specifically --

Q. But you didn't re --

A. I'm sorry. What part are you asking about?

Q. I'm asking whether you were involved in all the scientific discussions related to NIPT during that time.

A. I certainly did not do all the scientific outreach associated with NIPT.

Q. Fair enough, Mr. deSouza.

And we just spoke about CMS coverage for Project Baby Bear, Dolphin, and Deer, correct?

A. That's right.

Q. And just so the record 's clear, that's CMS coverage for the states of Florida, Michigan, and California, correct?

A. Correct.

Q. And going back to R&D efficiencies, I believe you mentioned that this merger could facilitate R&D efficiencies regarding research for other diseases, such as fatty liver disease and Parkinson's. Do you recall that discussion?

A. I do.

Q. And you haven't formed the research teams for fatty liver disease and Parkinson's at this time, correct?

A. We have not yet.

Q. And those teams would be speculative research teams. Is that right?

A. What do you mean, sorry, by "speculative research"?

Q. If we can pull up PX 7107, page 155, lines 1 through 7. If we could go to the page -- the previous page so we can get the complete question and answer.

And you were asked at your deposition about collaboration with GRAIL on projects absent the merger. Do you see that?

A. I do.

Q. And you testified, in part, that -- "You know, this is where GRAIL was in 2014, '15, when we came up with the idea in lab and thought, okay, but because we're a big company, we can dedicate a research team to say, look, you know, this may not pan out. We did it. That's what research is. GRAIL wouldn't do that because they can't have a speculative team on Alzheimer's, a speculative team on Parkinson's, and a speculative team on fatty liver disease."

Do you see that?

A. I see that.

Q. And these speculative teams might not pan out, correct?

A. That's right. That's exactly what I mean by "speculative." All research by nature is speculative. You don't know what the outcome may be. It may work and it may not work.

Q. And you haven't started clinical trials for any of these speculative teams?

And you can put that down, Mr. McCullough.

Correct?

A. No, we have not.

Q. You haven't developed a commercial plan for any of these speculative teams, correct?

A. No, we have not.

Q. And as you just explained, that's part of what research is, that these speculative teams may not pan out, correct?

A. Yeah. Research is doing the work to identify if something can work or not, yes.

Q. And you currently have or Illumina currently has collaborations with pharmaceutical companies. Is that correct?

A. That's correct.

Q. And Illumina also currently has collaborations with research organizations, such as Memorial Sloan Kettering. Is that correct?

A. That's correct.

Q. And I believe you also spoke with Mr. Marriott about being able to optimize its work flow on Illumina's -- strike that.

I believe you also spoke with Mr. Marriott that, post-merger, Illumina would be able to work with GRAIL to optimize its work flow on Illumina's sequencers. Do you recall that?

A. I recall saying we would optimize the

end-to-end work flow. So part of it is on Illumina sequencers, part of it involves things like that sample accessioning where there's no Illumina technology at all, but we have the experience in running high-production end-to-end work flows. So, yes, we will optimize on Illumina, but we will also optimize the end-to-end work flow.

Q. And you testified yesterday that you told investors in September 2019 that Illumina supports liquid biopsy companies, making sure they have access to the best of Illumina's work flows, even on the front end or back end. Is that right?

A. Yes. We would provide the best of Illumina work flows, so things that we sell into the market, that's right.

Q. And you also spoke with Mr. Marriott about certain synergies as a result of this deal. Do you recall those discussions?

A. Yes, I do.

Q. And do you recall that at the time of your investigational hearing on March 24th of this year, you were not aware of any synergies?

A. That's not correct. We spoke a lot in that hearing about synergies, and then there was one section of the investigational hearing where we were talking

about a specific page that had work streams, and then that's when I said I wasn't aware of the synergies associated with that work stream, but we talked in that investigational hearing a lot about the synergies before that -- before that part and after that part, too, and then we talked a lot about the synergies in the deposition, too.

So the part of the investigational hearing where we talked about -- where I said I was not aware of the synergies, I was talking about the output from that specific, you know, work team that you were showing me on that page.

Q. And if you could pull up PX 2072, 211, 12-16, please.

And you were asked:

"QUESTION: Do you know whether Illumina has identified specific -- specific contracts where it could potentially get cost savings as a result of combining its supply purchases?"

And as of March 24th, 2021, you said:

"ANSWER: I'm not aware yet."

Do you see that?

A. I see that.

Q. And can you please pull up what's been -- or the same exhibit, page 12 -- 212, line 25, through

213:3.

And you were asked:

"QUESTION: So sitting here today, you have not at this point developed a total synergy projection for this deal; is that correct?"

A. Yes.

Q. And you recalled -- and you said:

"ANSWER: As of March 24th, 2021, I don't recall seeing anything like that."

A. I see that.

Q. You can put that down.

You also spoke with Mr. Marriott yesterday about the elimination of double marginalization. Do you recall that?

A. I do.

Q. And at the time of your investigational hearing, do you recall testifying that you were not sure whether Illumina had calculated margin that could be eliminated as part of this deal?

A. I'm sorry. Can you repeat the question?

Q. Of course.

At the time of your investigational hearing, that transcript that we just looked at, do you recall testifying that you were not sure whether Illumina had calculated margin that could be eliminated as part of

this deal?

A. Yeah, that's right. This isn't my area of expertise.

Q. And at that investigational hearing, you said you would go to Chuck Dadswell, your general counsel, for information on that, correct?

A. I would ask him, yes.

Q. And you told Mr. Marriott yesterday that you don't have any details surrounding the elimination of double marginalization. Is that right?

A. That's right. This is not my expertise area.

Q. And you were asked some questions about the open offer. Do you recall that discussion?

A. Yeah.

Q. And post-announcement of the acquisition, Illumina reached out to several companies, including Guardant, Freenome, and Foundation Medicine. Is that right?

A. That's right.

Q. And in determining what companies to reach out to, Illumina considered what companies were interested in early detection. Is that right?

A. What companies we believed might be interested in early detection.

Q. And what companies some day may have a product

that competes with a GRAIL product, correct?

A. That may be interested in developing a product or in that space in general.

JUDGE CHAPPELL: Hold on for a second. I need to have a sidebar with just the lead attorneys.

Jada, let me know when you have removed us and muted the public line.

BRIA: Jada has stepped away. This is Bria.

MS. SULLIVAN: Good morning, Your Honor. This is Marguerite Sullivan on behalf of GRAIL. May I join as well?

JUDGE CHAPPELL: Are you the lead attorney for GRAIL?

MS. SULLIVAN: Today I am, Your Honor.

JUDGE CHAPPELL: All right.

Bria, are you there?

BRIA: Yes, and Jada's back.

JUDGE CHAPPELL: You can move them all into Judge's Chambers, if that will work, including Ms. Sullivan.

(Pause in the proceedings.)

JUDGE CHAPPELL: For the record, we just had a very brief discussion offline about any pending or possible settlement offer to the Commission. That's it.

Go ahead with your questions.

BY MS. MUSSER:

Q. Mr. deSouza, before that sidebar, we were discussing the recent amendment to the open offer. Do you recall those discussions?

A. Yes, I do.

Q. And this -- these amendments were posted on September 8th. Is that correct?

A. That is correct.

Q. And these reflect additional changes to Illumina's March 29th, 2021, letter. Is that right?

A. Yes. They represent enhancements to that letter. That's correct.

Q. So the March 29th, 2021, offer did not include every term that Illumina felt necessary to alleviate customer concerns, correct?

A. It did include every term we felt necessary to alleviate customer concerns. Subsequently, we've found ways to make it even better.

Q. So you provided additional changes to that letter, correct?

A. That's correct. We provided those enhancements.

Q. And in your view, those changes improved that March 29th, 2021, letter, correct?

A. We believe it marginally improves it, that's correct.

Q. I'm looking at -- if we could pull up the open offer, which is RX 3935, and can you go to page 2, number 3. Looking at number 3, Section 4 of Exhibit A, it was amended by adding the following Section F -- 4F at the end thereof. Do you see that?

A. I do.

Q. And this relates to access to information. Do you see that?

A. I do.

Q. And it reads, "The customer shall have access to the same information about final product specifications of any new Supplied Product, any new version of a Supplied Product, or any Pre-Release Sequencing Product within 5 days of when GRAIL is provided such information."

Do you see that?

A. I do.

Q. Illumina does not have final product specifications until its new product design is finalized. Is that right?

A. Yeah, until we're able to know what the final product specs are going to be.

Q. And so when Illumina first decides to develop a

product, it doesn't have those final specifications yet, correct?

A. That's right. When we begin, we don't have the final product specs.

Q. And when you first start development of a new product, you do not have the final product specifications, correct?

A. That's correct. We start with a target, but we don't have the final product specs yet.

Q. And the board learns about Illumina's new product development efforts before Illumina has a final product specification for its new products. Is that right?

A. Yeah. We ask -- we talk to the board early so we can get approval for the spend it will take to start development on a new product.

Q. And nothing in the open offer prevents Illumina from designing products specifically to optimize GRAIL's tests, correct?

A. We -- we commit that any product we give GRAIL, everyone will have access to it, so it won't be a product specifically for GRAIL. It will be a product for everyone. That's what's in here.

Q. But that product could be tailored to GRAIL, correct?

A. It's technically available to everyone, so it won't be -- it could take -- it could improve GRAIL's work flow, but it's a publicly available product to all our 7000 customers.

Q. But it could be designed to specifically improve GRAIL's work flow, correct?

A. We're not a consulting firm, so we don't design products for one customer. If we are going to embark on a substantial undertaking from an engineering team perspective, we want a product that can meet the needs more broadly of a customer. So we don't do -- we are not a consulting firm, so we don't do custom development for -- like that.

Q. But nothing in the open offer would prevent Illumina from designing a product tailored to GRAIL's specific work flow and processes, correct?

A. We could design a product and make it available to everyone. There's nothing -- we are not allowed to make a product just available for GRAIL, but it could take into account modifications that will improve GRAIL's work flow.

JUDGE CHAPPELL: Hang on a second.

Regarding that answer, the question was, "Nothing in the open offer will prevent Illumina from designing a product tailored to GRAIL's specific work

flow," and then part of your answer, "We are not allowed to make a product just available for GRAIL." How is it you're not allowed?

THE WITNESS: So in this offer letter we're saying that any product that's available for GRAIL will be available for everyone. So we're not allowed to make a product only for GRAIL.

JUDGE CHAPPELL: And you're referring to you're not allowed by this agreement?

THE WITNESS: That's correct.

JUDGE CHAPPELL: All right, thank you.

And I think you told me earlier, do you make specific products with your sequencers today? Do you make specific products for your customers?

THE WITNESS: No, we do not. We sell to everyone the same portfolio.

JUDGE CHAPPELL: Okay.

BY MS. MUSSER:

Q. So a couple followups on Judge Chappell's questions.

First, I believe you just testified that you don't make product -- you have to make products available to everyone. Do you agree with that?

A. In this context, we're saying that any product that GRAIL has will be available to everyone. Any IP

that GRAIL licenses, we will make available to everyone.

Q. And my question was whether you would -- whether anything in the open offer prevents you from designing or tailoring a product to GRAIL.

A. If we -- I'm not sure what you mean by "tailoring." We're not -- we don't tailor products. We launch products, and everybody has access to the products.

Q. Can you tell me what specific provision in the open offer prevents you from designing or tailoring a product for GRAIL?

MR. MARRIOTT: May I just assert -- I have no necessary objection to the question, but it seems to me that that question would require the witness being shown the actual open offer itself as opposed to simply the amendment that's in front of the witness.

JUDGE CHAPPELL: Well, I think the way the question is worded, "can you tell me what provision," I am going to allow that. It's a yes or no right there.

THE WITNESS: So we talk about the fact in this given amendment that all customers who have access to any product that GRAIL has access to within five days. So if we design a product for -- even in your hypothetical, if we designed the product for GRAIL, it

wouldn't -- within five days, it definitely would not be for GRAIL, because in this -- in this amendment, we have a contractual commitment to making sure that that's available for everyone.

BY MS. MUSSER:

Q. But just so the record's clear, that's a no, correct?

A. No to what? Sorry.

Q. To my question as to whether there was a specific provision in the open offer that prevents Illumina from designing a product for GRAIL.

JUDGE CHAPPELL: To be fair, that wasn't the question.

The question was, can he show you or point to it, as far as I know, or can he tell you what specific provision. So let's be fair.

THE WITNESS: Thank you.

Can I just see -- actually can you drop the callout so I can actually see the agreement so I can point to something?

BY MS. MUSSER:

Q. Sure.

A. Okay.

Q. Let me know if you would like to see a different page.

A. Can you pop up 2(b), please, on this page.

Okay. If you look at 2(b), it says that customer shall have access to Supplied Products for GRAIL -- that GRAIL or any For-Profit Entity has access, within 5 days of when GRAIL is offered access. So any product that GRAIL gets, everybody will get within five days. So that's the provision I would point you to.

Q. So if a product were designed specifically for GRAIL, other companies would have access to that product, correct?

A. Everybody -- yes, that's right.

Q. And I believe you spoke with Mr. Marriott about the audit provision, correct?

A. Yes.

Q. And that audit provision -- can you turn to that, Mr. McCullough? And that's Number 6.

And this audit provision, 12A, was amended on September 8th to change the audit from an annual audit to a biannual audit. Is that correct?

A. That is correct.

Q. And Illumina selects the auditor, right?

A. Ah, I'd have to look at the agreement to see who selects the auditor.

Q. And do you know whether customers have input

into the selection of the auditor?

A. I would have to look at the agreement to see about it.

Q. And unless a customer has a good faith basis for alleging Illumina is in breach of the open offer, the customers will only learn of a potential breach from the biannual audit. Is that fair?

A. I'm sorry. So the question is, unless they have a reason to believe there's a breach, they can learn about it through the biannual audit? Yes, that's right.

Q. And that's the only way that they can learn about it, correct?

A. They can learn about it through conversations. I mean, I'm not sure how else they would learn about it, but however they hear about it, that's how they could learn about it, right?

Q. And customers do not know the prices Illumina's other oncology customers pay, correct?

A. They do know the pricing grid we use. So what they don't know is -- unless, actually, some customers are publicly traded, so they share how much business they do, but otherwise customers don't know how much business everyone else does, and so they don't know where on the volume grid a customer may be, but they do

know the discount structure, and, again, that's why it was so important for us not to give one-off exceptions to Exact, because we want people to stay within the grid.

Q. And do customers have access to the discretionary discounts other -- Illumina's other oncology customers pay?

A. I'm sorry. What do you mean by "discretionary discount"? We're showing them the public discount grid.

Q. And Illumina can -- are you aware that Nicki Berry testified that Illumina can offer discretionary discounts off the public discount grid?

A. Yes. We do have for specific projects or -- so if there is something that's for the greater good or something like that. It's not a -- it's generally for specific projects. It's not a permanent production, you know, discount.

Q. But Illumina's customers wouldn't have access to other oncology customers' discretionary discounts, correct?

A. We don't -- so, for example, we are involved in a project cataloging seeds in Africa for sustenance farmers. That would be a one-off project, and we don't publish the pricing, or we donated sequencing into

Mumbai, for example, or Mozambique. Those are one-off projects. We don't publish the pricing for those -- that those customers may get.

Q. And Illumina customers do not know the products Illumina's other oncology customers buy from Illumina. Is that right?

A. There -- no, you're right, because we will only publish what GRAIL is using. We won't share what other customers are using.

Q. And customers do not know how quickly Illumina repairs instruments for other oncology customers, correct?

A. They know what they can sign up for with the different tiers of service, and each of them has service level agreements. What they don't know is what other customers have signed up for and, therefore, what turnaround time they're signing up for. So that's correct, unless they share with each other.

JUDGE CHAPPELL: Regarding that, repairing instruments, how often, in general, does a NovaSeq go down or need repairs?

THE WITNESS: Not that frequently. The intent is to keep them -- I mean, a lot of customers keep them up and running in some cases, you know, 24 hours a day, and so the -- you know, the intent is to make sure they

continue to be up and running. So a downed instrument is an unusual event.

JUDGE CHAPPELL: What is the most frequent issue that would need repair on a NovaSeq?

THE WITNESS: What is the most frequent issue? You know, I'm not aware right now what it could be. I know we help a lot of customers on the install sometimes, so that's something that will -- if I look at why we get called, sometimes customers ask us for help with the install, but I'm not sure.

JUDGE CHAPPELL: Are you aware of any repairs that have been needed on a NovaSeq?

THE WITNESS: I would say not specifically, no.

MS. MUSSER: Anything else, Your Honor?

JUDGE CHAPPELL: That's all.

BY MS. MUSSER:

Q. And you -- we spoke just moment a ago about discretionary discounts. Illumina also offers discretionary discounts when customers upgrade sequencers, correct?

A. We can offer upgrade programs and trade-in programs.

Q. And you also offer discretionary discounts as well?

A. I'm not aware of us doing -- I'm aware of

trade-in programs, and that's mostly around capital costs. So if you give us, you know, your old instrument, we will -- we will give you a credit against -- we do that especially when there's a new purchase, and we do that especially when we launch a new product, and especially if a customer has bought a product recently, and then we launch a new product, we give them credit as a part of a trade-in program. So I'm familiar with that.

Q. And Illumina offers discretionary discounts when customers have quality issues with Illumina reagents. Is that right?

A. What we do is if a -- I know we have this, but if a customer calls us and says that they have had a problem with the run, we will give them generally a new -- you know, a new flow cell or some kind of credit, you know, and trust that they did have a problem, and we'll make it right.

JUDGE CHAPPELL: I have a question. I have a question. Assuming that Illumina wanted to drive or change design of a sequencer in a way to benefit any customer, let's say GRAIL, how could you do that and what would you do?

THE WITNESS: Honestly, it's hard for me to imagine, Your Honor, what that could look like. Their

work flows aren't that different. In the end, you're putting in a library, and we read the DNA in it. So it's hard for me to visualize at this point what we would do in that that would just be specifically a benefit for one customer or another.

Typically, customers will ask us for the same things. They'll say, you know, drive performance, which means give us lower costs over time, continue to drive quality up, continue to shrink turnaround time. I mean, if you look at how we design products and the things we list as our goals, these are those kinds of things, and they benefit everybody.

A faster sequencer benefits everybody. Higher accuracy benefits everybody. So I don't know that -- I'm trying to visualize even what a single variable -- technical variable would be that would benefit just one use -- it's -- I don't think there are any that I can think of.

JUDGE CHAPPELL: What are the improvements that customers seek to the sequencer? More throughput? Faster throughput?

THE WITNESS: Exactly. It's faster, so they're saying keep driving the turnaround time. I'll give you an example. Clinical customers are saying, you know, in certain use cases, like children in the NICU, hours

actually matter. So they're saying drive the -- the turnaround time, you know, much shorter. So, you know, we have just set a world record with Dr. Kingsmore at Rady's Children's Hospital for going from taking the blood draw from the baby to having a sequencing result in well less than 24 hours, and that really matters because in some cases you can do an intervention that can -- that can stop further development delay, or you can prevent other medical interventions on the baby, and so one thing in clinical customer cases, they say make it go faster.

Now, 24 hours is great, but now some clinical customers are saying, look, our shifts for our staff is eight hours, so the next goal would be can we get to a place where if we start a test at the beginning of a shift, we can actually get a result at the end of a shift?

So, you know, what you'll hear from customers as sort of a goal for us would be, can you make that faster and get it even down to within a shift? So that's one thing they ask for.

Another thing they ask for is, again, just keep driving prices down, where they say, you know, I want to do bigger experiments, and so, you know, if I want to discover the genetics behind autism, for example, or

Alzheimer's, you have to do experiments that have very, very, very high numbers of people.

And so they're saying that only becomes viable -- everybody was excited about setting us on the goal for the $1,000 genome, and then we hit that, and then everybody wanted a $100 genome, and we're working on that, and I'm pretty sure in the data storage arena, for example, they're saying can you get it down to under $10, you know, so we can store a lot of data?

So turnaround time, price is another one, and then just continued accuracy, because there are emerging -- there continue to be emerging areas where you're looking for very events, and so people are saying, look, if you can give me more and more accuracy, that opens up new clinical applications for genomics. So those are probably the biggest, you know, by orders of magnitude, asks we get, and they benefit everybody.

JUDGE CHAPPELL: And if -- I guess another way to ask my previous question, if you made one of these improvements to time, throughput, or reducing cost, is there any way to limit that to one particular user or customer?

THE WITNESS: No, there isn't. There isn't any number of ways. There isn't technically a way to do

that. Honestly, also, we don't want to do that, because we have competitors, and so any advantage we put out there, we want to make sure everybody has, so that we continue to be the product they want to use.

So, technically, I can't imagine how we would give it to just one patient, and then finally it's contractually we're committing, for GRAIL specifically, say, and absolutely it won't happen for GRAIL. Anything that GRAIL gets, the entire market will get.

JUDGE CHAPPELL: Okay, and this question is -- I don't want you to speculate, so what I'm getting at is, did Illumina ever consider, I guess, or wargame this scenario: You've never, ever spun off GRAIL and kept GRAIL within Illumina the whole time. Is there anything you would have or could have done to assist GRAIL if they had been part of Illumina the whole time that would not have also benefited other customers?

THE WITNESS: Your Honor, we did not -- we did not wargame that scenario, so I could speculate, but given that you said not to, we did not wargame that scenario.

THE COURT: If I asked you to speculate, is there any way Illumina -- any way GRAIL would have benefited by being in-house the entire time?

A. So technically, what could we have done if we

had kept GRAIL in-house the entire time? I'm not -- nothing obvious comes to mind. Obviously, we wouldn't be going through this process if we had kept them the whole time, but technically, they would have done the same studies, because they did the big studies.

They approached it hypothesis-free, which was good, and I would have done the same thing, which means they didn't prejudge that it was going to be genomics. They also looked at proteomics, and also in genomics, they didn't prejudge that it was mutations. They looked at methylation. So we would have done that, too.

So I don't -- Your Honor, I'm not sure I can come up with something that would be different if they had done it, you know, in the research phase, if they had just done it in-house, but -- and that's probably also -- maybe an Alix or one of our more deeper technical people may be able to think about it harder.

JUDGE CHAPPELL: Let me ask this: If Illumina invented or created, let's say, NovaSeq-3, is there any way you provide that to GRAIL ahead of competitors?

THE WITNESS: No. We would not do that, and we're contractually committing here that we will make sure everybody, you know, gets it, certainly within five days of GRAIL getting it.

And, Your Honor, strategically I will say the way we would launch a NovaSeq-3 is the first customers to get it candidly are not going to be our clinical customers. GRAIL is not going to be the one that first gets our brand new sequencer, because clinical customers don't do that, because they have to validate a clinical work flow. That takes quarters.

So three, four -- you know, it could be nine months, it could be -- so it's -- clinical customers are not the first customers used. Usually they come in a couple of years later. The first customers you would get -- and we have done that with every sequencer that we've launched, if you look at NovaSeq, if you look at the HiSeq X -- the first customers you always get on a new high throughput sequencer are the research customers.

They are the ones who will adopt a new sequencer immediately because they have deep genomics expertise on their staffs, and they are looking to do, you know, new research cohorts and big, brand new studies, and for them it doesn't matter what the last study was done on, because it's a new research endeavor, and so whenever we launch a brand new instrument, if you look at who our launch partners are, every high-throughput sequencer we have ever launched,

for example, the Broad Institute, one of the leading institutes in genomics research is a large customer of ours. They are very quick to adopt new technology and they do research. They don't do any, you know, sort of clinical return of results. They are a research institution.

So those are the kinds of institutions that adopt immediately. Clinical customers will take years. They'll wait. They also know that the first year to two of an instrument coming out, we will upgrade the chemistry, for example, typically, because you don't know how it's going to perform in the real world until you've seen it perform for the first year or two, and so we will upgrade the chemistry, and we'll issue updates. It could be chemistry update, software update. And so clinical customers will wait for a couple years until they know it's -- it's -- this is what we're going to go with.

Then they'll bring it in-house, and then they'll do the nine months of validation that they want to do, and then maybe, 2 1/2 or three years after we launch is when they will ramp up on the new instrument. And so the NovaSeq-3, GRAIL is not going to be the leading -- the first adopter or even in the first two months of its launch, it's not going to be a leading

adopter because it's a clinical customer.

JUDGE CHAPPELL: All right, and I know you're no lawyer, and I haven't read all the evidence yet, but answer my this:

If this goes forward and the open offer is accepted by customers, how is that policed? Are you offering independent audits or what? How was that policed? How do the customers know that there's no cheating on that agreement?

THE WITNESS: Absolutely. We're offering independent audits that they can request twice a year to make sure that everything we say is happening is happening, and then we are committing to independent binding arbitration, to say -- and if --we don't get to say whether the audit was right or wrong, and you get to ask for, you know, what you need with the arbitrator, through arbitration, and then in this amendment we're saying, and we're giving the -- the person who has the arbitration very broad leeway on how to remediate it, and is that person has to take into account that we want to make sure that there is an even playing field between GRAIL and anyone else.

And they should take that as the -- how to make a decision on what the right remediation is, and we will abide by it whatever it is. So independent

auditor, binding arbitration, and very broad powers around what the mechanism of arbitration could be.

JUDGE CHAPPELL: So as Illumina's CEO, your position is you don't have a problem opening up, raising the hood, and inspecting what's going on under there.

THE WITNESS: That's absolutely my position. I want to make sure that it is always an even playing field. That's very important to us in the market, to say, you know, we want a vibrant -- this market needs to expand a lot, and it will take a lot of innovation -- some of it done by us, a lot of it done by our customers -- and they have to know that we are going to do everything we can to make sure that there's a completely even playing field.

JUDGE CHAPPELL: All right.

Go ahead, Ms. Musser. I wanted to get my questions out in case you have any followups.

MS. MUSSER: Thank you, Your Honor. I do have a few followups.

BY MS. MUSSER:

Q. Can you pull up PX 2541, please. This document is called "Interim Review, K2-GRAIL," and it's dated February 2nd, 2017. Do you see that?

A. I do.

Q. If you could turn to page 4, please. The justification of interim review was, in part, a reduction of GRAIL shareholding, the Illumina reduction to less than 20 percent shareholding in GRAIL once funding is complete, approximately 1Q17, and that's referring to the Series B financing that reduced GRAIL's ownership from a majority shareholder to less than 20, correct?

A. That's correct.

Q. If you could turn to slide 8, please. Slide 8 summarizes the changes that will result from the changing business dynamic and Illumina functioning as a supplier compared to product development partner. Do you see that?

A. That's right. I do.

Q. And the first row says that Pre Series B, the service and support plan was a collaborator; and post Series B, GRAIL would be a customer, correct?

A. That's right.

Q. And for product -- project development process, or PAC approval, it says, "PDP co-development, Pre Series B," and Post Series B, it says, "Non-PDP reagent sustaining."

Do you see that?

A. I do.

Q. On the third row, it says, "Assay development workflow. Pre Series B, Illumina and GRAIL were collaborators, and Post Series B, it was limited -- after transfer, so the relationship was limited to library conversion."

Do you see that?

A. I do.

Q. And on the fourth row, software and data analysis, Pre Series B, they were collaborators. Do you see that?

A. I do.

Q. And Post Series B, the relationship was limited to access to MSK and 2K Atlas samples. Do you see that?

A. I do.

Q. And finally, for kit design, Pre Series B, it was purpose-built for GRAIL with possibility for changes. Do you see that?

A. I do.

Q. And Post Series B required Illumina review and approval before those changes were executed. Do you see that?

A. I do.

Q. And you agree these were all changes in response to the dynamics of -- the change in dynamics

Pre Series B to Post Series B?

A. That, and, you know, when we launched with GRAIL, they didn't really have any capabilities, and so they were dependent on Illumina. I mean, we took 40 scientists and said, you are now a separate company, you know, and so they were very dependent on Illumina in that first, you know, what is it, year, ten months, 11 months?

And so this also reflects that, you know, there are not 40 scientists now in just a different building. They are now standing up their own capabilities, you know, to operate on their own, and so they don't need to depend on us for a PDP process. They don't -- so -- so that -- you know, and that coincides with and we're moving them to a Series B, they're able to be more stand-alone, and then they will be -- you know, they will going through a Series B soon.

Q. And so these changes did result, in part, from the changing business dynamic as described on this slide, correct?

A. A changing business dynamic and a maturation of GRAIL.

Q. And can you turn to page 10, please, of this PowerPoint, and this slide says, "Illumina-GRAIL relationship change."

Do you see that?

A. I do.

Q. And on the third bullet point in the top arrow, it says, "Illumina and GRAIL no longer collaborating on development of LP and sequencing kits."

Do you see that?

A. Yes.

Q. And Post Series B, Illumina and GRAIL were no longer collaborating on the development of library prep and sequencing kits, correct?

A. That's -- we weren't going to, yes, that's right.

Q. You can set that down.

If you could pull up the amendment to the open offer, RX 3935, please. I just had a few followup questions on some of the conversation you were having with Judge Chappell around arbitration, and there are costs associated with arbitration, correct?

A. Yes.

Q. And can arbitration take time?

A. Yes.

Q. And the arbitration provision in the open offer provides for 120-day arbitration process?

A. Okay.

Q. Is that a yes?

A. I'd love to look at it, but I believe you were reading from it, yes.

Q. And GRAIL is part of Illumina, correct?

JUDGE CHAPPELL: Hang on. If he wants to look at it, let's let him look at it so the record's clear.

MS. MUSSER: Okay.

BY MS. MUSSER:

Q. If you could pull up PX 0064, please. Do you recognize this document?

A. I do.

So where is the arbitration, the 120 days you're talking about?

Q. Just give me one second, Mr. deSouza. I'm trying to find it myself.

Can you go to page 10, please. Do you see the arbitration provision there?

A. Yes.

Q. And if you can take a minute to look at it and let me know how long -- how long the arbitration process will take.

A. (Document review.)

Q. And let me know when you want to go to the next page.

A. (Document review.) Okay. So it says we will mutually agree a place, we will designate a contact to

be able to resolve disputes in a final and binding fashion, that we will meet with -- for a period of 30 days with each other, and -- in an attempt to resolve the dispute --

JUDGE CHAPPELL: Sir, why don't you read to yourself. We're on the record.

THE WITNESS: All right. Okay.

JUDGE CHAPPELL: Is that the entire arbitration provision?

MS. MUSSER: It goes on to the next page.

Let me know when you would like me to move to the next page, Mr. deSouza.

THE WITNESS: Okay.

MS. MUSSER: If you could turn to the next page, Mr. McCullough, and I believe you may have to zoom in as much as you can.

JUDGE CHAPPELL: Why don't we go to the end of the arbitration provision.

Ms. Musser, I suspect the answer to your question is one of these provisions. How about you highlight it so we can move on?

MS. MUSSER: Of course.

BY MS. MUSSER:

Q. If we could turn to B-1, please.

And unfortunately, Your Honor, we will have to

do a bit of math here, so please bear with me.

JUDGE CHAPPELL: All right.

BY MS. MUSSER:

Q. If you look at B-1, it provides for -- that the parties shall meet in person by telephone for a period of 30 days. Do you see that?

A. I do.

Q. Okay. And, Mr. McCullough, if you could go to the next page, please, and then it says, "Within 5 business days of the commencement of an arbitration, customer and Illumina shall each furnish a legally binding writing to the other committing to maintain the confidentiality of the arbitration and any written statements."

Do you see that?

A. I do see that.

Q. And on the next page, paragraph V, it says, "Upon written request by either party to the other party, the parties shall promptly negotiate in good faith to appoint an appropriate Arbitrator. If the parties are unable to agree within (10) days after the receipt by a party of the written request, in the immediately preceding sentence, the AAA shall be responsible for selecting an Arbitrator with relevant experience related to the dispute of at least ten (10)

years and to do so within fifteen (15) days of being approached by the parties."

So this could -- 10 plus 15 is 25. Is that correct?

A. Ten plus 15 is 25.

Q. If you could go to Section 12-3-V, do you see that? I'm sorry, oh, B-vi. And it says, "Within twenty (20) days after an arbitrator is designated, each party shall simultaneously submit a written statement of their respective positions."

Do you see that?

A. I do see that.

Q. So if we add up the 30 days we just saw, the 20 -- the five days on top of that, the 25 days and the 10 days there, I believe that math is 75, but you can correct me if I'm wrong, Mr. deSouza.

A. But, Susan, I don't know that they all were sequential. In listening -- in reading them, it seemed like a number of them start in a parallel way. Some are sequential. So I don't -- I'm not sure I follow the math, then. If some are parallel and some are sequential, I don't think it gets you to 75.

I guess my overall point is, look, we want to get through arbitration as fast as possible and use as accelerated a process as available. So if there is any

feedback on this or there is a way to make this better, we are completely open to it. Believe me, we don't want to spend extra time in litigation or arbitration. So if there is a way to make this better, just let us know. We are committed to making this as expeditious as possible.

Q. But regardless, you agree that currently this arbitration provision and the time frame applied herein is what would control the timing of the arbitration. Can we agree on that, Mr. deSouza?

A. I think what you said was we are laying out the process here, and then that will tell you how long -- you know, what the boundaries are on the arbitration timing, right?

Q. Yes.

A. Okay, yes.

Q. Great.

Can we turn back to the amendment to the open offer, please, which is RX 3935. Before we do that, we spoke a little bit about discretionary discounts on sequencers. There are also discretionary discounts on reagents, correct?

A. Yes, there are, for the -- exactly the projects I talked about.

Q. And if we could go to number 4 of the amendment

to the open offer, Mr. McCullough. Can you zoom in on that provision, please.

And this provision provides that Illumina shall publish the SKUs -- or SKUs -- of the supplied products GRAIL's purchasing, correct?

A. That's right.

Q. And Illumina will also publish the price grid under which Illumina is purchasing products, correct?

A. That's correct.

Q. And Illumina will publish the price grid under which GRAIL's purchasing service agreements, correct?

A. That's correct.

Q. And Illumina owns GRAIL now, correct?

A. That's correct.

Q. And when GRAIL purchases products from Illumina, that transaction is now between two Illumina entities, correct?

A. That's correct.

JUDGE CHAPPELL: Is that correct under the current hold-separate agreement?

THE WITNESS: The GRAIL entity is now a separate unit, but its ownership reverts to GRAIL, so we own -- you know, we own that GRAIL unit, and so now the -- the -- any supply agreement would be between that organization and Illumina.

JUDGE CHAPPELL: I haven't seen any hold-separate agreement. Are you familiar with the terms of it?

THE WITNESS: I'm sorry. Are you asking me or Susan?

JUDGE CHAPPELL: I am asking you. You're the witness.

THE WITNESS: Yes, I am. Sorry. Yes, I am.

JUDGE CHAPPELL: Then what does it guarantee, the hold-separate agreement? And that's public? I don't know why it wouldn't be.

THE WITNESS: Yeah, and we have taken it off -- you know, the European Commission has publicly available what a hold-separate agreement would look like, and so we took it from there. The intent is that, you know, there will be no integration between our companies during this period while we're holding it separate, that it will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis. So they would buy product, but, you know, they're buying product off standard terms and agreements with Illumina, you know, those kinds of provisions.

JUDGE CHAPPELL: But some things aren't being held separate. Like we heard yesterday, the royalty

from GRAIL is now gone, correct?

THE WITNESS: They have moved to a standard purchasing agreement like everyone else. So no other customer gives us royalty on their sales, and so now GRAIL has moved to look like any other customer, where they just buy products from us, and we don't get a royalty from their sales.

JUDGE CHAPPELL: Right. And the reason I went into this, this provision we're looking at, is that being done now? Is this being published now, the terms of deals with GRAIL and Illumina?

THE WITNESS: We just came up with it a couple of days ago, so we're putting it into place right now. So we will do it shortly. I don't know if that's tomorrow or in a few days, but, yes, we agree that this is something we want to do right away.

JUDGE CHAPPELL: All right, thank you.

BY MS. MUSSER:

Q. And so the price at which GRAIL purchases products from Illumina represents the price at which one Illumina entity purchases products from another Illumina entity. Is that correct?

A. That's correct.

Q. So it's the price from which Illumina purchases products from itself, correct?

A. From one Illumina entity buying from another Illumina entity, that's right.

Q. And no matter what price that is, it will not have any effect on Illumina's bottom line, correct?

A. Ah, that's -- so we will report the P&L for GRAIL. So it will have an impact on the numbers we put to Wall Street, and those aggregate up into the parent company as well. So we will show a P&L for GRAIL that talks about, you know, revenue and what it's earning.

So it will impact that P&L, and it will also impact the other P&L, because, you know, we will show what we're selling in terms of sequencers and consumables, so the price we sell it at matters.

Q. And as a separate company, do you know if GRAIL advertises the SKU of the products it purchases from Illumina on its website?

A. It did not before we bought it. It will now or we will now.

Q. And does Illumina -- and does Illumina post the inputs it buys for its own products on its website?

A. We do not post all the -- all the things we buy to make our products on our website.

Q. Do you know if GRAIL advertises the prices it pays for Illumina products and services on its website?

A. It does not.

Q. Does Illumina post the prices it pays for its inputs to its own products on its website?

A. We do not.

Q. And Illumina will be responsible for posting GRAIL's purchases and prices on its website, correct?

A. That's right. We will purchase -- we will publish those, yes.

Q. And Illumina will be responsible for updating GRAIL's purchases and prices on its website, correct?

A. That's correct.

Q. And the amendment mentions Illumina will publish the pricing grid for products and services that GRAIL --

JUDGE CHAPPELL: Hold that question. We have been going well over two hours. Let's take a short break. We will -- we will reconvene at 12:10. We're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: Okay. We're back on the record.

Go ahead.

BY MS. MUSSER:

Q. And Illumina owns GRAIL today. Is that correct, Mr. deSouza?

A. That's correct.

Q. And the company does not need to enter into a supply agreement with itself. Is that right?

A. The company doesn't need to enter into a supply agreement with itself.

Q. And the company doesn't need to enter into a service agreement with itself either, correct?

A. It doesn't need to. We could, but it doesn't need to.

Q. And, Mr. deSouza, we talked earlier before the break about the price that Illumina charges GRAIL. Do you recall that discussion?

A. Sorry. I'm still thinking about the last question. In this case we would do an agreement between GRAIL and Illumina. So, in general, I guess your question was do companies need to -- in general, they don't need, but in this case we will do agreements between GRAIL and Illumina, supply agreements and service agreements.

Q. And before the break, we were talking a little bit about the price between Illumina and GRAIL. Do you recall that conversation?

A. I do.

Q. And the price that Illumina charges its GRAIL subsidiary for NGS consumables will have no net impact on the combined entity's net P&L. Is that correct?

A. On -- it will have an impact on the P&Ls we report to Wall Street for the GRAIL entity, for the Illumina entity, and then they will be combined into the overall P&L for the company.

Q. And the combined entity will net out those -- the entries on the GRAIL P&L and the Illumina P&L, correct?

A. That's correct.

JUDGE CHAPPELL: How will the financial transactions work with the GRAIL separate entity? Does GRAIL have its own budget? Is there a line allocation? Is there a debit to Illumina or is there -- you know, what happens when GRAIL, for example, purchases a NovaSeq?

THE WITNESS: Yeah, you're right. So GRAIL is a separate organization. I believe it's an LLC. They will have their own budget, and they do, and then they will spend against that budget. And so if they purchase a NovaSeq, it will be against that budget, and they would have to pay the other Illumina entity for those transactions.

JUDGE CHAPPELL: So GRAIL will be making a payment to Illumina for items that are purchased.

THE WITNESS: Absolutely.

JUDGE CHAPPELL: All right.

THE WITNESS: And then Wall Street will be looking -- to just close out that point, Wall Street will be looking at the performance of that business, the performance of the life sciences business, because they're both sort of going to be judged differently, and so those P&Ls do matter in terms of as communicating to investors how the business is doing.

JUDGE CHAPPELL: Does Illumina have any other subsidiaries currently that operate like GRAIL is supposed to operate?

THE WITNESS: Not yet, but I suspect in the future we may.

JUDGE CHAPPELL: All right.

BY MS. MUSSER:

Q. And you spoke with the Court about the effect on the P&L and the effect on the GRAIL P&L of a purchase of a NovaSeq sequencer, correct?

A. That's right.

Q. And that will also appear on the Illumina P&L as well, correct?

A. Right. If they're buying it from Illumina, then Illumina will recognize it as a sale, and it will appear as a sale on our P&L.

Q. And when you combine the two sales together, that sale will net out to zero. Is that correct?

A. That sale will net out if you combine the two P&Ls together, but, again, Wall Street is going to focus on each of those two P&Ls more than they are going to focus purely on the net, because these are two different businesses that are going to be measured differently. So these P&Ls are very important from an investor perspective as separate P&Ls.

Q. And you spoke with Mr. Marriott about the effect of your behavior and Illumina's behavior in the oncology screening market on its customers in other markets. Do you recall that discussion?

A. The impact of what we do in one market rippling to the other markets, yes.

Q. And you sued -- Illumina sued customers in other markets. Is that correct?

A. We sue entities that, for example, infringe on our IP. Is that what you mean?

Q. So you've sued Ariosa, who is a customer of Illumina?

A. They infringed on our IP, yes.

Q. And you've sued Natera, who's a customer of Illumina?

A. We tried to settle for years, but ultimately, when we couldn't, we did sue them for infringing IP. We had to, because we are custodians of this IP patent

pool that has other owners, and we have an obligation to the other owners in the IP patent pool to assert, you know, if people are infringing. So it's not -- we don't get a choice on whether we sue people in that case, who infringe on that IP. We are obliged to, because of the other patentholders in the pool, to do that action.

Q. And are you aware that Illumina customers have described themselves as hostages of Illumina in this litigation?

A. I am not aware of that.

Q. And you spoke with Mr. Marriott and said that you wouldn't raise prices in the MCED market because you could lose sequencing customers. Is that correct?

A. That's correct.

Q. And that analysis depends on the assumption that these customers will have NGS alternatives. Is that correct?

A. That's right.

Q. And you spoke to Mr. Marriott yesterday about a company called Roche. Is that right?

A. That's correct.

Q. Roche currently does not sell an NGS platform, right?

A. It acquired a company that was developing an

NGS product, but hasn't launched it yet.

Q. And you spoke to Mr. Marriott about BGI. Is that right?

A. That is correct.

Q. And currently BGI is enjoined from selling its platform in the United States until at least 2023, correct?

A. It can sell services in the United States, so sequencing services. It has sequencing customers in the United States, but it cannot have a product in the United States until 2023.

Q. And you also spoke about a company called Ultima. Is that right?

A. Ultima?

Q. Ultima?

A. I am not familiar with Ultima.

Q. And did you speak about a company called Element?

A. I spoke about Element.

Q. And what you know about Element is, of course, based on publicly available information regarding its sequencing products, correct?

A. That is correct.

Q. Okay. Because you don't have access to their confidential, proprietary information. Is that right?

A. That's correct.

Q. And Illumina -- and Element does not currently have a commercial NGS platform on the market. Is that right?

A. That is correct.

Q. And you spoke about a company called Omniome. Is that correct?

A. That's correct.

Q. And, again, what you know about Omniome is based on publicly available information regarding its sequencing products?

A. That's correct.

Q. Because you don't have access to their confidential, proprietary information. Is that fair?

A. That's correct.

Q. And Omniome currently does not have a commercial NGS platform available on the market, correct?

A. They're being acquired by PacBio, which does have a commercially available sequencing platform on the market today. It has for several years. And Omniome has talked about launching its -- and they're saying it's a very high accuracy product -- they're saying in the beginning of 2023.

Q. And PacBio does long-read sequencing. Is that

correct?

A. That is correct.

Q. And Omniome today doesn't have a commercially available NGS platform on the market, correct?

A. That's correct. They said their launch date is early 2023.

Q. And you also spoke with Mr. Marriott about a company called Singular. Is that right?

A. About Singular in the context of -- yes, I did. Yes.

Q. And what you know about Singular is also based on publicly available information regarding its sequencing products, correct?

A. That's correct.

Q. And you, again, don't have access to their confidential, proprietary information. Is that fair?

A. That's correct.

Q. And Singular's NGS sequencer is not commercially available, correct?

A. It's available in early access today, and what they have said publicly is they're launching later this year, so in the next couple of months. But they have today early access customers on their sequencing platform.

Q. And early access customers is different from a

commercially available platform, correct?

A. It's right near the end, right before they go commercial, that's right.

Q. You also spoke to Mr. Marriott regarding why Illumina decided to close its transaction with GRAIL. Do you remember that conversation?

A. I do.

Q. Is that a yes, sir?

A. I do.

Q. And you testified that you wanted to get a decision from the EC or European Court. Is that correct?

A. That's correct.

Are you hearing me? I said that's correct, right?

Q. I wasn't. I just wanted to make sure it was picked up on the realtime.

And you mentioned that there was a drop-dead date of December 20th, 2021. Is that right?

A. That's right.

Q. And that was when Illumina's merger agreement with GRAIL expired. Is that correct?

A. Yeah. That would be the extension we could get. It expires on September 20th, but we could have extended -- we could extend it to December 20th or

21st.

Q. And did you ask GRAIL to extend that deadline?

A. We evaluated that scenario, and here's what we ran into. If we got into March, the U.S. process would expire, and we'd have to refile for HSR and start the whole review with the FTC all over again, and it wasn't clear to us that we would get a decision, you know, by March from the European Commission.

And so we didn't feel that, you know, a couple-of-month extension was going to be enough, and it wasn't clear to us that GRAIL would do a couple-of-month extension given how long the process has been going on already.

And so given that we would only, at best, be able to do a couple of months before we had to restart the whole process, we didn't feel like that scenario, you know, gave us enough confidence that we would get to a decision in Europe by then.

Q. And so you didn't ask GRAIL to extend the deadline. Is that correct?

A. No.

Q. Okay. And you said you did not think that GRAIL would agree to an extension or you weren't sure. Is that correct?

A. I didn't know if they would.

Q. Why wouldn't GRAIL -- why didn't you -- why did you think that GRAIL wouldn't agree to an extension?

A. We just didn't know if they would.

Q. Once the deal expired, Illumina would have to pay a $300 million breakup fee to GRAIL. Is that right?

A. That's correct.

MS. MUSSER: I don't have any further questions at this time, Mr. deSouza.

JUDGE CHAPPELL: Were there -- I know you're not a lawyer, Mr. deSouza. Were there any exceptions to that breakup fee, any walk-away provisions?

THE WITNESS: No. We would be on the hook for the 300 million if the deal fell --

JUDGE CHAPPELL: Even if a government entity blocked the deal?

THE WITNESS: Even if a government entity blocked the deal.

JUDGE CHAPPELL: Okay.

Anything further, Mr. Marriott?

MR. MARRIOTT: Very briefly, Your Honor, if I may.

RECROSS EXAMINATION

BY MR. MARRIOTT:

Q. Mr. deSouza, you were asked about tailoring

certain of Illumina products to GRAIL's. Do you recall that series of questions?

A. I do.

Q. Does Illumina have any intention of tailoring its products to uniquely advantage GRAIL?

A. No.

Q. You were asked about a biannual audit in connection with the open offer. Do you recall that?

A. I do.

Q. Let's look, if we could, please, at RX 3935, and I want to point us, if I may, to Section 12(a), at the second bullet point there.

If there is a finding of noncompliance before the next audit is completed, is Illumina required to notify the customer?

A. Yes, we are.

Q. And within what time frame from the finding of noncompliance must the customer be notified?

A. Within ten days.

MR. MARRIOTT: Your Honor, I have nothing further -- oh, actually, I take that back. I apologize. I do have one further thing.

BY MR. MARRIOTT:

Q. You were asked a series of questions about prior deposition and IH testimony concerning

efficiencies. Do you recall that?

A. I do.

Q. And do you recall testifying at great length at both your IH and at your deposition about the efficiencies that you believe will result from this transaction?

A. I do. We spent a lot of time talking about the efficiencies, both in the IH and then again at the deposition.

Q. Okay.

I will spare us all going through that. Thank you very much.

Your Honor, I have no further questions at this time.

JUDGE CHAPPELL: Any further questions of this witness?

MS. MUSSER: No, Your Honor. Thank you.

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

THE WITNESS: Thank you.

JUDGE CHAPPELL: Call your next witness.

MS. MUSSER: Your Honor, Sarah Wohl will be calling the next witness on behalf of Complaint Counsel.

JUDGE CHAPPELL: Okay.

MS. WOHL: Good afternoon, Your Honor. Complaint Counsel calls William Getty from Guardant. He may be in -- they were in the waiting room, so let me just check.

All right, they appear to be here.

JUDGE CHAPPELL: All witnesses and all witness attorneys are present now?

JADA: Everyone is in. You're good to proceed, Your Honor.

Whereupon--

WILLIAM JOHN TOLAN GETTY, III

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

JUDGE CHAPPELL: All right, go ahead.

MS. WOHL: And, Your Honor, I would like to introduce Steve Holley from Sullivan & Cromwell who will be representing Mr. Getty and Guardant Health.

JUDGE CHAPPELL: All right.

MR. HOLLEY: Good afternoon, Your Honor.

JUDGE CHAPPELL: Good afternoon.

DIRECT EXAMINATION

BY MS. WOHL:

Q. Mr. Getty, can you please state and spell your name for the record?

A. Sure. My full name is William John Tolan

Getty, III. I will spell from William to Getty. W-I-L-L-I-A-M, John, J-O-H-N, Tolan, T-O-L-A-N, Getty, G-E-T-T-Y, and the III, I-I-I.

Q. Thank you, Mr. Getty.

And who is your current employer?

A. Guardant Health.

Q. If I refer to Guardant Health as just Guardant, will you know what I mean?

A. Yes, I will.

Q. When did you first join Guardant?

A. I joined in 2017.

Q. Can you briefly describe your work background prior to joining Guardant?

A. Certainly. I've worked in life sciences for many years, and prior to Guardant, I worked at Pfizer as well as an organization called Medivation, who was ultimately purchased by Pfizer, and then a company called Exelixis, and then eventually I moved on to Guardant. Prior to Pfizer, I had a handful of years post-college in different companies.

Q. And what was your position when you first joined Guardant?

A. Sure. So when I joined Guardant, I was the vice president of marketing for the portfolio that existed at this -- at that time, which now is referred

to as our Oncology Division.

Q. And what is your current position with Guardant?

A. Sure. I am the senior vice president of commercial for the Screening Division.

Q. When you say "Screening Division," what does that mean?

A. Sure. So Guardant Health is a precision oncology company, and our initial products are focused on patients with cancer or living with cancer, if you will, and we have now, or I should say, we are getting ready to commercialize in a space which is screening for cancer, and that's a different population, a different set of products, and different customer types.

So the organization has most recently been split into two parts, one that is focused on oncology -- and the easiest way to think about that is those are individuals -- that division is focused on oncologists as customers, and then a screening division which is focused on cancer screening, and that is for -- you know, and the primary customer there is a primary care physician or an internal medicine physician.

Q. And when did you become senior vice president

of commercial for the Screening Division?

A. I believe it was in the -- right before the change of the year. I think -- I officially joined the Screening Division in January of '21, but if I recall correctly, my transition and appointment to the -- or promotion to the role happened a few months prior to that time.

Q. And what were your responsibilities immediately prior -- or what was your position immediately prior to being senior remember vice president of commercial for screening?

A. I was still a vice president of marketing for the Oncology Division.

Q. And what are your current responsibilities in your current role?

A. Sure. My responsibilities are to lead the commercialization of our screening product in development, which we refer to internally as LUNAR-2, and that encompasses sales, marketing, medical affairs, commercial development, all manners of activities that will support the commercialization of the product, and so I am responsible for the development of that team, all of those different functions, and, you know, product development and the like.

Q. What, if any, responsibilities do you have

relating to the development of Guardant's cancer screening tests?

A. Sure. So as the commercial leader, I certainly interact with the broader organization on a strategic basis, and so, you know, I have a lot of input into what does the product look like in the long run and in the short run.

What I mean by that is, you know, what's going to have the largest impact? What's going to potentially have the largest adoption in the marketplace? So I am constantly talking about product design and features and relating that to the marketplace we exist in.

Q. What responsibilities do you have relating to Guardant's strategic plans for its cancer screening tests?

A. Sure. So I'm a -- as a -- as the commercial leader, I report in to the co-CEO of our organization, AmirAli Talasaz, so he and I spend a lot of time talking about strategic planning. I've led the strategic planning process prior to this role for three years for the organization, as well as this year I am leading the strategic planning process for the Screening Division. I'm also a member of the executive management team where, you know, those discussions are

happening across the broader portfolio.

Q. What responsibilities, if any, do you have relating to Guardant's long-range planning?

A. I would say those are kind of one and the same, if you will. The -- you know, there's different, let's call it, time frames that we leverage to talk about the broader long-range/strategic plan. So, you know, when I refer to strategic planning, I'm really talking about, you know, next year through the next ten years. And my interaction is the same in both those instances.

Q. Why does Guardant engage in long-range planning?

A. Sure. Certainly it's a fast-moving marketplace, and the timelines for development and then regulatory approvals and adoption cycles are extremely long in our business, and it's a fast-moving marketplace and sort of juxtaposed to those long timelines. So we need to be thinking about the future of healthcare and where it's going in order to make sure that our products are competitive and that we fit into that, you know, future state.

Q. In your role at Guardant, do you have any responsibilities relating to Guardant's competitive assessments?

A. I do. Certainly as part of, you know, pretty

much everyday commercialization discussions, we are thinking about what our competition is doing, and going back to my previous answer, as I think about, you know, when I referred to the marketplace changing rapidly, the marketplace changing rapidly is really due to the competitive environment and what's going on. And so, you know, we're constantly staying abreast of what we can in terms of the competitive environment, how they are moving, and what that means for us as an organization, either to compete, or what it frankly means about the market longer term.

Q. And do you know what responsibilities you will have after Guardant commercializes its cancer screening test?

A. Yes. I will be responsible for overseeing the execution and our performance relative to the uptake of the test and the -- and obviously then the responsibilities around revenue generation and making sure that we are moving forward.

Q. And when you -- you said "uptake" of the test, what does that mean?

A. I mean adoption of the test. So as the commercial leader, I will be responsible for ensuring that, you know, physicians are adopting the test, we are meeting the forecasts internally that we've set,

and making sure that we have a profitable business as we move forward.

Q. You mentioned you were part of the executive management team at Guardant. Can you explain a little more about what the role of the executive management team is?

A. Sure. So the executive management team, just for context, is made up of senior leaders within the organization, like myself, as well as our co-CEOs. There -- I think there are ten of us, if I recall correctly the exact number. And we have the responsibility of guiding the organization on a strategic basis.

So, you know, decisions, for instance, about mergers and acquisition are something we would be talking about on a regular basis, or talking about competitive threats and/or things that are affecting our -- our -- the broader organization. In the current context, we spend a lot of time talking about COVID.

Q. Is Darya Chudova part of the executive management team?

A. She is.

Q. Do you interact with Ms. Chudova as part of your responsibilities?

A. I do.

Q. How so?

A. Darya and I spend quite a bit of time together. She's our chief technology officer or senior VP of technology, I should say, and she and I spend a lot of time talking about technical development, clinical development, and really just, you know, more broadly about the program overall.

As senior leaders within the organization and individuals like Darya who have a vast amount of experience in life sciences, you know, we counsel and educate and question one another quite often.

Q. I want to talk a bit more about Guardant and its business, but please keep in mind we are in public session. So if any of my questions you feel you require to provide competitively sensitive information, just let me know, and I can ask it again when we're in camera.

A. Sure.

Q. Do you understand?

What is Guardant's mission?

A. To conquer cancer with data.

Q. From your perspective, what does that mean?

A. Sure. So cancer is a disease largely born of the errors in our genome, and so one of the challenges of understanding and actually getting ahead of cancer

is the fact that you are -- you really don't have a lot of information about what the tumor is doing, and the reason is is because for years, in order to get information about a tumor, you were dependent on tissue samples of that tumor such that you could sequence it and then determine what was wrong in that particular individual's genome.

And so with liquid biopsy -- and liquid biopsy broadly being referred to in this context as, you know, taking a blood sample, interrogating that blood sample, and finding DNA from the tumor floating around in that blood sample -- you have a more ubiquitous source of that data about different tumor types.

So what essentially has happened, you know, over the last ten years is through the technology that Guardant has pioneered, we have been able to amass a lot of information about the genomic defects of an individual who develops cancer, and that information is extremely valuable as you think about, you know, attacking the problem of cancer.

And so conquering cancer with data is really just an -- you know, sort of calling out the fact that one of the challenges with conquering cancer is we have been data-starved with this technology. We open up a whole another world where we can amass the amount of

information hopefully necessary to develop new therapeutics or, you know, diagnostics to help tackle the problem.

Q. What products does Guardant currently offer today?

A. Sure. So in the context of our clinical setting -- so I'll just make the distinction of research use only, which we do have some of those products -- in the clinical setting, meaning a physician can order it and use it with a patient.

There is the Guardant360 CDx product, there is Guardant360 LDT, which stands for laboratory-developed test. We also have Guardant Reveal. We have a Guardant Next, which is a tissue offering. And we also have something referred to internally as Guardant Response, which is a molecular response product, which is essentially just a secondary offering of the Guardant360 CDx product.

We also have a product we refer to as Omni, and that's offered in a research-use-only format for our biopharmaceutical customers primarily.

Q. Do any of Guardant's current tests have FDA approval today?

A. They do. The Guardant360 CDx product that I mentioned at the outset has FDA approval.

Q. What type of test is Guardant360 CDx?

A. It is referred to as a therapy selection test, and what that means is it's intended for patients who have advanced cancer or also referred to as Stage 4 disease, so malignant tumors, it's spread somewhere else in the body. And those individuals are typically undergoing some sort of systemic treatment, immunotherapy or perhaps chemotherapy most commonly.

And when those patients are then put on treatments, there is an opportunity to sometimes exploit some of the genomic errors in terms of what is fueling their cancer, and there are drugs that have been matched to those errors, and the way that you match the right drug to the error, if it exists, is by interrogating that tumor type, or that tumor, and that tumor, in the case of Guarant360 CDx, you're able to see those different errors and then tell the patient, you know, hey, here's the error, and a physician could ostensibly match the treatment with that particular patient's error in order to more effectively exploit the error in that cancer.

Q. And for clarity, is the Guarant360 CDx test an early cancer detection test?

A. It is not.

Q. You mentioned liquid biopsy tests before. Is

Guardant360 CDx a liquid biopsy test?

A. It is. All of our tests, excluding the tissue test, are based on liquid biopsy, broadly speaking, as a term to describe the technology.

Q. Does Guardant360 CDx use next-generation sequencing technology?

A. It does. All of our tests rely on next-generation sequencing, including the tissue test.

Q. And when Guardant360 CDx was granted FDA approval, do you know if any other NGS-based liquid biopsy tests have received FDA approval?

A. As the horse race goes, we were first, but there were quickly follow-ons that had FDA approval. One is -- the other one is FoundationOne Liquid, which is made by a company called Foundation Medicine that was bought by Roche a few years back.

Q. Going back to Guardant's cancer screening business --

A. Sure.

Q. -- you mentioned -- you referred to it as the LUNAR-2 program. Is that right?

A. That's correct, yes.

Q. Can you describe Guardant's LUNAR-2 program?

A. Sure. So when the company was started in 2012, there was a program launched at that time referred to

broadly as the LUNAR program, and the LUNAR program was intended to really be focused on two areas, the first being early cancer detection, and then second, detection of minimal or residual disease.

What that essentially means collectively is that you're looking for very small signals in the blood that either say this patient has an early-stage disease or this patient, who perhaps had a surgery to remove cancer, the cancer is still there.

So the LUNAR technology is really the underpinning of the -- of both pursuits, and the LUNAR technology then eventually migrated into two different products. One was referred to as LUNAR-1, which eventually became Guardant Reveal, and I mentioned that earlier; and then LUNAR-2 is still in development for early-stage detection -- excuse me, early cancer detection.

Q. Without delving into any competitively sensitive information, what is the current status of LUNAR-2?

A. Sure. So LUNAR-2 is still in its development phase, and on a public basis we have shared data from the assay using case controls, so individuals who have cancer and interrogating that cancer to demonstrate our ability to find early-stage disease.

Q. Under the LUNAR-2 program, does Guardant have plans to develop a multicancer screening test?

A. So the LUNAR program, just to go back to the genesis of it, was intended to find small signals in the blood that indicate that a patient has cancer or that cancer has returned subsequent to some sort of intervention. Again, the example there on the second point is somebody who has surgery and you're looking to see if the cancer is still there.

So the underlying technology has always been intended to be something that could be used to interrogate for all different manners of cancer, and so as it pertains to LUNAR-2 specifically, we still very much intend to pursue a broader multicancer platform. We have focused our strategy in a way that will establish the technology, but the LUNAR-2 platform is agnostic of tumor types.

It is focused on early detection of cancer in a broad sense, and then we'll, you know, continue to develop clinical data in order to support our business strategy to implement the test.

Q. Why does Guardant intend to pursue a broader multicancer test?

A. Sure. So the technology intended here -- you know, again, just to go back a bit, the intention here

to look for early cancer signals is a really important factor in the notion of conquering cancer with data, and what I mean by that is that cancer typically is much more treatable in the early stages. So regardless of the tumor type, if you can find it early and then you can intervene early, the likelihood is that you'll be able to actually cure that cancer, versus if you catch it later when it has metastasized, unfortunately, it's just sort of a losing proposition.

So the reason that we are pursuing a LUNAR-2 platform in order to enable early cancer detection is simply that, you know, this is the most attractive way, most likely, or the most effective way, I should say, to actually get ahead of cancer.

And certainly cancer comes in all, you know, shapes and forms, if you will, and so our goal would be to have the maximum patient impact. And so having the maximum patient impact means you're interrogating an individual for all manners of cancers, not just one, two, or three different cancers.

Q. In pursuit of Guardant's multicancer early detection test, are you beginning with any particular type of cancer?

A. Yeah. I alluded to this a bit earlier, and I'll expand. Our business strategy for pursuit of

early cancer detection in a broad sense, a cancer, you know, across multiple tumors, is focused on creating a test which will be rapidly adopted initially in order to then move us into the next phase of adoption, which will be in a more multicancer fashion.

And so we have focused in initially of embedding this technology in the healthcare system, if you will, through colorectal cancer. So we have a clinical development program, a clinical trial referred to as ECLIPSE. That is running currently. That will ostensibly read out sometime next year, and hopefully, you know, fingers crossed, it is positive.

Once we have that clinical data, what we will be able to do then is move forward to hopefully FDA approval, and, again, assuming positive outcomes on that front, we will then move to, you know, really drive adoption within the primary care physician's office.

By driving the adoption of this test, you now have established a beachhead, an operating system, if you will, that will allow us to then pursue additional tumor types, and we think that the fastest path to adoption of a multicancer test is actually through a business strategy which is focused on colorectal cancer in the short term.

Q. And I've mentioned Guardant's multicancer early detection test. If I refer to that as an MCED test or M-C-E-D test, will you know what I'm talking about?

A. I will.

Q. After Guardant completes validation for its colorectal cancer screening test, does Guardant need to restart development efforts in order to pursue an MCED test?

A. It does not, and we are -- we are actively pursuing multicancer development activities internally, and we've also indicated publicly that we will -- we plan to initiate trials in a multicancer context in the near future.

Q. And why do you not have to restart development efforts for your MCED test?

A. Sure. So the underlying technology that I referred to earlier of finding cancer early in the blood is generally a pursuit that is -- can be applied to all different tumor types. So the technology platform really underlying the LUNAR-2 test is applicable to all manners of cancers, and that was the intention when the test was developed.

It wasn't developed in a way that said, you know, we're only looking for colorectal cancer. Again, that's really more a business strategy than it is a

technology decision. And so the development activities that need to go on subsequent to the development of a CRC assay are such that you're leveraging the same technology, and you certainly need to think about optimizing that technology for different tumor types -- I'm not suggesting there's, you know, just a drop and replace -- but ultimately the underlaying technology that took years and years to develop is actually the more challenging development exercise, in and of itself, to pursue.

Q. You mentioned that Guardant publicly announced some of the details about its MCED test. Has Guardant published all of the details of its development plans for its MCED test?

A. It has not.

Q. Why not?

A. Certainly, you know, that is something that is inherent to our business strategy, and, you know, we would be -- you know, I think we would give our competitors a very easy advantage to follow our lead if we published all of our development activities in a public fashion.

Q. Has Guardant published the details of its commercialization plans for its MCED test?

A. No. Again, there I think that would be sort of

shooting ourselves in the foot, allowing our competition to follow our lead.

Q. You mentioned -- you talked about this a bit when we talked about Guardant's business, but under Guardant's current plans, what patients do you plan to target for Guardant's MCED test?

A. There is going to be a focus on cancers that are screened for most -- most often in the primary care setting initially, and then as the data continues to develop, we will, you know, move beyond that.

So in terms of the initial focus, those cancers are often lung, breast, colorectal cancer is another example, and then you start to move beyond that, and that's really dependent on how the data develops both internally and externally, and by externally, I mean data that suggests it's a good idea to screen for additional cancers.

Q. Particularly, who would be the patients who would be receiving the MCED test?

A. Sure. So our intention is to develop data in a way that supports average-risk screening essentially across the board, and so our goal would be to make this available to, you know, patients who are of average risk of cancer, but also as well patients who may be of higher risk due to things like smoking and lifestyle

choices.

Q. When you say "average risk," what is an average risk patient?

A. Sure. So an average risk patient is a patient who doesn't have any specific disposition towards cancer. So, for lack of a better example, I would be defined as average risk, as a 43-year-old male, no history of cancer in my family, and never smoked or not obese. You know, there are certainly certain elements that make myself average risk, but, you know, that's a pretty broad definition.

So, you know, I'm sure I'm forgetting one or two different factors that could make you more high risk, but oftentimes it's genomically derived as well. You could be high risk if you're a smoker, you could be high risk if you have a BRCA mutation, you could be high risk if you're of a certain population, any number of factors. But generally speaking, people are of average risk.

Q. Is there a certain age population that Guardant plans to target its test towards?

A. So the increase in age is actually a risk factor associated with cancer development. If you look at the guidelines for screening average risk patients, in general -- and in general meaning it spans a couple