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
August 24, 2021
10:17 a.m.
TRIAL VOLUME 1
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

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JUDGE CHAPPELL: Let me call to order Docket 9401 -- someone needs to turn their microphone off.

SCOTT: If I can reiterate, if you are not speaking, actively participating, please mute yourself.

JUDGE CHAPPELL: Let me call to order Docket 9401, Illumina/GRAIL, and that's "GRAIL" in all caps.

At this time we're going to start the trial, the evidentiary hearing in this matter, and we're going to hear opening statements today.

I'll start with the appearances of the parties, government first.

MS. MUSSER: Good morning, Your Honor.

Susan Musser for complaint counsel.

JUDGE CHAPPELL: And for respondents.

MR. MARRIOTT: Good morning, Your Honor.

David Marriott from Cravath, Swaine & Moore for Illumina.

MR. PFEIFFER: Good morning, Your Honor.

Al Pfeiffer on behalf of GRAIL.

JUDGE CHAPPELL: All right. Do we have any

matters to cover before we start the opening statements?

MS. MUSSER: Your Honor, complaint counsel just has two preliminary matters for Your Honor.

JUDGE CHAPPELL: Go ahead.

MS. MUSSER: The first is JX 2. We just sent an agreed-upon JX 2 per the rulings yesterday, and we now move that into evidence.

JUDGE CHAPPELL: Any objection?

MR. MARRIOTT: No objection, Your Honor.

MR. PFEIFFER: No objection, Your Honor.

JUDGE CHAPPELL: JX 2 is admitted.

(JX Number 2 was admitted into evidence.)

JUDGE CHAPPELL: Go ahead.

MS. MUSSER: And Your Honor, the second just housekeeping matter that I wanted to flag for this court was that respondents and complaint counsel had agreed to supplemental production. We might be adding a JX 3 based on that production. We have agreed to exchange any proposed additions by the end of the week and just wanted to give Your Honor notice that that might be coming down the pike.

JUDGE CHAPPELL: That is fine. There's no limit on joint exhibits. I encourage joint exhibits, stipulations, evidentiary agreements, et cetera.

Thank you.

MR. MARRIOTT: Your Honor, may I just make one clarification? I apologize.

JUDGE CHAPPELL: Go ahead.

MR. MARRIOTT: I have no objection to JX 2, with the understanding that it's subject to the objections we previously made as to which Your Honor already ruled. I didn't mean to waive those previously asserted but overruled objections in agreeing to the admission of JX 2, just for clarity of the record.

JUDGE CHAPPELL: All right. That's done.

Anything further?

MS. MUSSER: Nothing from complaint counsel, Your Honor.

JUDGE CHAPPELL: All right. Ms. -- is it "Musser" or "Musser"?

MS. MUSSER: "Musser," Your Honor.

JUDGE CHAPPELL: -- Musser, proceed when ready with the government's opening statement.

MS. MUSSER: Good morning, Your Honor.

May it please the court.

For years we have been battling a war on cancer, and now it looks like we are on the precipice of winning that war. We are winning that war through

competition among a dozen or so companies that are all developing tests to identify cancer in asymptomatic patients, so patients who don't show any signs of cancer. These tests are known as multicancer early detection tests and analyze DNA from a liquid biopsy.

Evidence will show that these tests have the promise to detect cancer years before a patient would exhibit any symptoms and this early detection will be nothing short of a miracle, because all cancer types can be treated better and with higher survival rates the sooner cancer is detected.

Now, the companies developing these multicancer early detection tests are dependent on one company for the sequencers and reagents they need to process their tests. Evidence will show that without access to Illumina's NGS or next-generation sequencers, MCEDs will be unable to develop and commercialize their tests.

Now, prior to this merger, Your Honor, Illumina focused on marketing the reagents and the instruments necessary for its MCED customers. Illumina, however, has recognized the profit potential for MCED tests is much higher than the profit it currently receives for selling its reagents and sequencers.

Evidence will show that seeking to tap into that profit, it purchased GRAIL. But as its purchase of GRAIL shifts it focus, so too does it shift its incentives. Before, Illumina had the interest in expanding and enabling all MCED testing. Now, its interests are aligned with GRAIL's success or failure in the MCED market.

JUDGE CHAPPELL: Just so the record is clear, let's make sure that it's understood -- and again, we don't have any evidence yet and nothing is proven or disproven, but based on what I read in the briefs, Illumina purchased the remainder of GRAIL. Is that not correct?

MS. MUSSER: Yes, Your Honor, that is correct.

JUDGE CHAPPELL: They own part of GRAIL already.

MS. MUSSER: So prior to the consummation of this merger, it owned approximately 12 percent in diluted shares, but now that that merger has been consummated, they own a hundred percent of GRAIL's assets.

JUDGE CHAPPELL: I had read 14.5 in the government's brief and 12 in respondents' brief, so is the 12 the accurate number?

MS. MUSSER: 12.5 is the diluted share number.

I think 14 percent is the undiluted share number, so it depends on how you look at it, Your Honor.

JUDGE CHAPPELL: But either way, whether it's 12 or 14, this is a purchase of the remainder of GRAIL by Illumina.

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right. Go ahead.

MS. MUSSER: And with that purchase of the remainder of GRAIL by Illumina, evidence will show that Illumina's incentives are now fully aligned with GRAIL's success or failure in the MCED market and that interest is in direct conflict with the interests of Illumina's other customers, GRAIL's competitors.

This shift in incentives will create serious problems for GRAIL's competitors and American patients. The evidence we have obtained through our discovery and investigation and that we will present to this court will show that Illumina now has the incentive and ability to disadvantage GRAIL's rivals to ensure that GRAIL success at the expense of Illumina's customers.

But, Your Honor, the injury to GRAIL's competitors will not be isolated, because by slowing down GRAIL's competitors' progress or ending it altogether, this acquisition ensures that American patients will not have the benefit of innovation by

companies all looking to develop better MCED tests and offer those tests to patients at a lower price.

In other words, Your Honor, evidence will show that the war on cancer, if it is to be won, will be won by competition, not by this acquisition.

With that backdrop, Your Honor, I would like to discuss our case.

And I want to start with where the parties appear to agree.

Here, we agree that the technology at issue here, MCED tests, will save lives.

We also agree that MCED tests need to be run on some sort of sequencer or platform in order to work.

We also agree that currently serious multicancer early detection test developers use NGS sequencers to run their tests.

Finally, we agree that MCED tests is a developing market, meaning, GRAIL is the only company that is offering MCED tests for sale in even a limited capacity.

But, Your Honor, here is the crux of the case and where we disagree.

Evidence will show that GRAIL is in a race and that GRAIL today is competing with other MCED developers in this innovation race to develop and

commercialize their tests.

Logos for some of GRAIL's competitors are listed on the left of this slide.

Prior to this transaction, Illumina benefited with every company who decided to enter the race to develop MCED tests. Now, Illumina's incentives have changed.

If this transaction is not unwound, evidence will show that Illumina will have the ability to decide the winner in this market by putting up obstacles for its competition, and they will have the financial incentive to anoint GRAIL the winner in this race to develop and commercialize multicancer early detection tests. Because, prior to this merger, Illumina won when its customers won, now Illumina wins when GRAIL wins.

And Your Honor, the stakes are high here. If this merger goes through and if respondents behave as their incentives predict they will, competition to develop and commercialize these tests will decline. And as a result, patients will face fewer MCED test options, potentially higher prices and lower quality for these limited options.

And Your Honor, to start with, I'd like to explain a little bit more about NGS tests and how they

work.

So NGS sequencers, which is shown on the left of this screen, are machines used for DNA sequencing. And DNA sequencing is a necessary step in the process of analyzing DNA to determine whether any abnormalities exist.

Now, NGS or next-generation sequencers were a revolutionary technology that supplanted the old method of sequencing. The result of NGS sequencers coming to the market was that you could sequence more, faster.

It's helpful to think of sequencers as a type of computer that can translate code embedded in DNA. And these sequencers are very technical and take years and years to develop. And there's two reasons for that, Your Honor.

The first, these aren't a widget. These are very technical, complicated machines just by their nature.

And the second reason is that these machines learn with every read or every run that it does, so every time it processes, you press "Start" on the machine, it gathers more data and learns more.

And Your Honor, I think I just got logged out of Zoom, so if you'll...

JUDGE CHAPPELL: I can see you. I think you're back.

We cannot hear you. You're muted.

SCOTT: I think she dropped, Your Honor, so hopefully she'll be back in a moment.

MS. MUSSER: Your Honor, can you hear me?

JUDGE CHAPPELL: Yes.

MS. MUSSER: All right.

So as I was mentioning, there's two reasons.

The first reason was just the general complication of the technology.

And the second reason that these machines are very technical is that they learn with every run that they do, so every time you press "Start," Your Honor, it learns more from that data that it developed.

Now, NGS sequencers are characterized by three main features.

The first is throughput, which is how much it can run -- read per run.

Your Honor, I'm sorry. I think I lost the feed again.

(Pause in the proceedings.)

All right.

SCOTT: You're back on, Susan.

MS. MUSSER: Thank you.

JUDGE CHAPPELL: Do you have a number of people on one line there so you can eliminate some people to improve your connection?

MS. MUSSER: Your Honor, let me see what we can do. I'm the only one on this computer, so I don't think that would impact it. But let's give it a go and see if we can -- I'm not sure what the technical issue is.

JUDGE CHAPPELL: All right. The last thing you mentioned was: "The first is throughput."

MS. MUSSER: Yes.

So the first is -- the first kind of key characteristic is throughput, which is how many runs -- reads -- how much can be read per run, the second is accuracy, the third is run time, and then the -- the first [sic] is price.

So when you take a step back, the key features are how much can it do at once, how accurate is it, how long does it take, and how much does it cost.

Now, different models of next-generation sequencers have varying degrees of throughput and accuracy and differing price points. And the level of throughput and accuracy, so the -- think of it as a computer -- the level of computing you need depends on what you're trying to do with it.

And MCED tests generally need a high level of throughput and a high level of accuracy given what they're trying to accomplish, which is the detection of cancer throughout a liquid biopsy test.

For MCEDs, that's the reason Illumina NGS sequencers are really the only option, because they provide that right level of accuracy and the right level of throughput, which is why most MCEDs use the NovaSeq NGS sequencer, which is shown on the left of this screen.

Evidence will show that there are currently no other comparable NGS sequencers that are viewed as an alternative by MCED test developers.

Now, MCED tests look for cancer in blood-based liquid biopsy tests, so, Your Honor, they look at a blood sample taken from a primary care physician or in your general checkup.

And what it's looking for in that blood sample is, when cells die, they break down, and components of those cells, including cell-free or what's called cfDNA, are released into the bloodstream.

Cancerous cells go through the same process and produce circulating tumor DNA when the tumor breaks down.

Now, MCEDs look for different biomarkers or

different characteristics in the blood to examine cfDNA to look for the presence of cancer in a blood sample.

And Your Honor, it's helpful to think of MCED tests and NGS as a lock and a key, with NGS systems being the lock and MCED tests being the key.

Evidence will show that when an MCED test is developed, it's developed with a particular sequencer in mind, so its underlying biology is keyed to the particular lock.

JUDGE CHAPPELL: That slide you showed earlier, the NovaSeq 6000?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: Is that considered short read or long read?

MS. MUSSER: That is a short-read platform.

So all of the --

JUDGE CHAPPELL: Do you want to explain to the people what that means?

MS. MUSSER: Of course, Your Honor.

So a short-read platform differs from a long-read platform in the length of DNA it's looking for, so a short-read platform looks for short segments of DNA to determine whether or not there's cancer in those short segments or any particular marker that it's

looking for.

What long-read platforms do is they look for -- look at a whole line of DNA to determine whether or not -- they analyze a longer strand.

So long-read sequencers are great for particular applications, so think of whole genome sequencing where you're looking for a lot of in-depth data across a long fragment, whereas short-read sequencers are good for looking at short fragments across many samples.

And the key difference between those two products is that short-read NGS sequencers have a higher throughput and generally a lower cost than long-read sequencers. Because the sequencing is looking for more in a smaller DNA fragment, it just takes longer and doesn't have the throughput that NGS sequencers -- that short-read NGS sequencers have, which is why you'll hear from MCED test developers that long-read sequencers simply aren't an option, because they can't -- it just costs too much money to do the same thing that a short-read sequencer can accomplish much more efficiently given its higher throughput level.

JUDGE CHAPPELL: Is it just money or is it money and time?

MS. MUSSER: It's money and time, Your Honor. It not only takes -- it costs more, but the reason it costs more is because you have to have more machines or smaller number of machines doing it for longer to accomplish the same goal.

JUDGE CHAPPELL: All right. And one thing for the parties in case I failed to mention it yesterday during my lengthy speaking time there, the parties are instructed not to use in camera information during opening statements. And if you had planned that, pull that from your presentation today.

Go ahead.

MS. MUSSER: Yes, Your Honor. And just for the record, all the information presented today is all public, so we've taken that into consideration, Your Honor.

JUDGE CHAPPELL: And along those lines, I'd like the parties to know, if I ask a question that would not be answered on the public record, let me know.

MS. MUSSER: Okay. I will.

And so, again, thinking about how the MCED tests interact with NGS, they're really fitted together in a pretty precise manner.

And the reason being is that -- and it's

helpful to think of MCED testing as a process, and that process is designed to work with a sequencer in mind. And this process is the methodology of determining what to look for in the blood, how to look for it in the blood, and how to prepare that test to be run on the NGS platform, and finally, how to analyze the results or the data analysis coming out of the sequencer.

So how NGS works is -- how MCEDs interact with NGS is first you have to prepare the blood sample in order to be run on the sequencer. And the way that you do that is by applying certain reagents or what's also called consumables on top of that sample. And that sample preps it to be run on the sequencer. But the process of -- the prep process and what reagents and consumables you are using depends on what machine you're going to be sequencing on step two.

Once you've prepared the blood sample to be processed, it then has to be sequenced.

And then finally, once that sequencing happens, a data analysis is -- can spit out of the machine, and the MCED test process then picks up that analysis, interprets the results, and provides the results to the patient.

Now, if that lock gets jammed, so, for example,

if an MCED test developer has technical issues, delays in supplies of reagents or consumables, delays in upgrades or limitations in technical upgrades, that key won't turn into the lock. And without the ability to have a functioning sequencing system, the doctor will not be able to unlock the door to access test results for its patient.

Now, other than Illumina, there are no viable short-read technologies on the market.

You will hear from a witness from Thermo Fisher and the evidence will show that Thermo Fisher, the other short-read technology, listed at the top left of your screen, Your Honor, doesn't have the data quality and doesn't have the right levels of accuracy that will make its sequencing platform work for an MCED test developer.

The second company that you will hear a lot about is a company called BGI. And this company is currently enjoined from selling in the United States. This company is enjoined right now through 2023, but there's litigation pending to extend that injunction through 2027 and beyond.

And as we just talked about, Your Honor, long-read technologies, such as PacBio and Oxford Nanopore, simply aren't good substitutes given

the cost and time and throughput that they need to run their machines.

And setting aside NGS technologies, other sequencing technologies and detection methods are also not substitutes and not alternatives for NGS -- or MCED sequencers.

So microarrays and PCR detection also will not work for MCED tests. Microarrays and PCR detection cannot detect the right number of biomarkers to provide the level of data and the accuracy that MCED tests need.

They also -- proteomics, or looking for protein levels in blood, also cannot provide sufficient information for MCEDs in order to make their MCED tests function properly.

So the evidence will show that Illumina is the only developer of these NGS platforms that MCED developers need in order to make their tests work, so Illumina functions as a gatekeeper between the MCED tests and the results for the patients. And that function, that ability to act as a gatekeeper or a lock on a door is what will give Illumina the incentive and the ability to foreclose GRAIL's rivals and is the heart of the anticompetitive nature of this transaction.

Your Honor, I want to briefly touch on the legal standard here.

So, as you have seen, Illumina is not a horizontal competitor of GRAIL; meaning, Illumina and GRAIL don't produce the same products. Rather, Illumina is a key supplier of an input and has a vertical relationship with GRAIL.

Nonetheless, courts have recognized for decades that vertical mergers can be harmful to competition, and bold enforcement agencies have robustly investigated and enforced anticompetitive vertical mergers.

Under section 7, all mergers, including vertical mergers, apply the same standards. And this is to assess whether the effect may be to substantially lessen competition or tend to create a monopoly.

The key difference is about -- is horizontal cases look at the extent of testing competition between merging products and the resulting elimination of that competition. Vertical cases are about the incentive and the ability to foreclose a competitor and whether that incentive or ability will result in a reduction or an elimination of competition.

But each case, vertical and horizontal, is concerned about the same thing, which is the effect of

competition at a horizontal level, so here, how a merger between Illumina and GRAIL will give Illumina the ability and the incentive to harm competition at the MCED level.

JUDGE CHAPPELL: What's the government's position on whether, being a vertical merger case, upstream market and downstream market are an issue here?

MS. MUSSER: So a relevant market -- the relevant market needs to be defined under both case law and the Vertical Merger Guidelines. As such, we have defined the relevant market as the market for MCED testing.

The government's position is that a -- the related product market does not need to be defined. Moreover, a related product just needs to be identified.

And the rationale behind that, Your Honor, is that if you look at the purpose of market definition, it's to assess where the harm to competition is going to occur, and here, the harm to competition is alleged to be at that horizontal level of -- or in the MCED test market. We're not alleging harm upstream in the NGS platform.

As such, per the Vertical Merger Guidelines and

per case law, the complaint counsel's position is that we need to do a market definition analysis for the relevant product market, MCEDs, but not for the related product. We simply need to identify it, which complaint counsel has done.

JUDGE CHAPPELL: Is that based on an assumption by the government that there are no competing NGS machines available, only by Illumina?

MS. MUSSER: So where -- how and whether or not NGS machines compete is relevant to the analysis is whether or not Illumina will have the ability to foreclose its -- GRAIL's downstream rivals, and so whether or not another alternative is in the market is the heart of whether or not Illumina will be able to harm GRAIL's downstream rivals, because if there were, the MCED test developer could quite simply shift.

However, evidence will show that there are currently no other options, nor will there be timely entry upstream such that it will offset that ability to foreclose and harm downstream competition.

JUDGE CHAPPELL: Okay.

MS. MUSSER: So once the government has met its prima facie case, the burden then shifts to the respondents to show that there are countervailing factors that outweigh the anticompetitive effects of

this merger. The stronger the prima facie case, the greater respondents' burden of production on rebuttal.

Here, complaint counsel will meet its burden by showing that post-transaction Illumina will have the incentive and ability to foreclose GRAIL's rivals in the market for the development and innovation of MCED tests, and that harm to innovation will outweigh any efficiencies or elimination of double marginalization or EDM.

First, Your Honor, I would like to introduce you to complaint counsel's witnesses.

Complaint counsel will present testimony from thirteen industry participants, six party witnesses, and three experts at this hearing.

On this slide are the twelve industry participants and two former employees that Your Honor will see. Let me introduce them to you.

You will hear from Dr. Bill Cance, who is on the top right. Dr. Bill Cance is from the American Cancer Association [sic], and he will explain the importance of innovation and why innovation for MCED tests matters.

You will also hear from nine witnesses from eight other MCED test developers. And while we cannot get into the specifics of their testimony due to the

in camera issues Your Honor mentioned, you will hear evidence that despite defendants offering its open offer or long-term supply agreement to our MCED customers and despite defendants' lobbying efforts, that each and every MCED witness will explain the following: that their company is currently developing MCED tests; that their company is competing with other MCEDs, including GRAIL; that their company is dependent on Illumina; and that Illumina has the ability and the incentive to foreclose their access to slow their development, their progress, their innovation.

In addition to the MCED test developers, you will also hear from Andy Felton from Thermo Fisher, who will explain that even his company, an NGS provider, cannot meet the requirements for MCED tests.

You will here from two former Illumina executives, John Leite and Dave Daly. These executives will explain that when Illumina had incentives in the past, it disadvantaged its customers.

Now, defendants, on the other hand, will primarily present testimony of their employees in addition to seven hired experts. On defendants' side you will hear from only five third parties, one of which is an Illumina -- is an MCED developer, one of

which is a lobbyist with no plans to develop an MCED test, one of which is a banker, one of which is a company attempting to develop an NGS sequencer, and Dr. Cance.

JUDGE CHAPPELL: You said the respondents have seven hired experts. To be fair, the government has some hired experts as well; correct?

MS. MUSSER: Yes, Your Honor. We have three, two solely to rebut defendants' experts.

To understand Illumina's current incentives, it's helpful to understand Illumina's history with GRAIL.

Illumina founded GRAIL in 2015. A year later, Illumina spun GRAIL off as an independent company, eventually relinquishing its majority ownership in GRAIL in early 2017.

After spinning out GRAIL, Illumina owned approximately 12.5 percent of diluted shares or, as we've previously discussed, between 12 and 14 depending how you look at it.

Evidence will show that one reason Illumina spun out GRAIL was so that there would be as many shots on goal or opportunities as possible to encourage companies to develop and innovate in the MCED space. And Your Honor, that is exactly what happened.

Post spinoff, the market for MCED tests did indeed accelerate. As Francis deSouza, Illumina's CEO, explained, six months after its spinoff, that it wanted -- it did so to encourage development and that now there are 70-plus players in the liquid biopsy space. That spinoff incentivized and accelerated innovation into this key technology.

Evidence will also show that Illumina first began looking to acquire a company in an adjacent market in late 2019, and it quickly identified GRAIL as an ideal target.

GRAIL was identified as an attractive target for three reasons. The first was the potential total addressable market of MCED tests.

In GRAIL's IPO investment prospectus it noted that the potential market for overall early detection tests were 107 million individuals between the ages of 50 and 79 in the United States.

As this graph will show, that number of patients translates into a lot of potential money. Here, in an investor presentation, Illumina explained that the total market was over $75 billion for this technology by 2035. Of that $75 billion, the majority of it was cancer screening tests, the MCED tests that we're talking about here today.

Second, in addition to the amount of money, the large potential revenue that this up- -- this market could generate, the second reason Illumina was interested in GRAIL was due to the shift in margins that it was predicting as part of its supply chain.

Evidence will show that it is projecting that the margin in the supply chain will shift from NGS sequencers to MCED sequencers, so going forward, for each component of the supply chain, more money will be made per MCED sale on the downstream component than the upstream NGS component and the related consumables.

Recognizing the money to be made, Illumina recommended to its board of directors that they acquire GRAIL, and Illumina has in fact done so for $8 billion.

But, Your Honor, with big money comes big changes, in particular changes to Illumina's incentives regarding how it will treat its customers, GRAIL's competitors. Because it made sense for Illumina to spin off GRAIL because competition fostered MCED innovation, and that competition worked, but as the current MCED leader, Illumina will have every incentive to make sure that MCED innovation doesn't undermine their future MCED profits.

Prior to this merger, Illumina's incentive was to work with all of its customers, because its most profitable access to this huge market was by selling as many NGS sequencers and as many consumables to as many MCEDs to encourage all to innovate.

But postmerger, Illumina's incentives have now shifted. Now it stands to make more money for each sale of a GRAIL test than it makes for each sale of an NGS sequencer or consumable to GRAIL's competitors.

Put simply, prior to the merger, the more entry, the faster the MCED test developed and innovated as a whole, the better off Illumina was. Now, Illumina benefits more from GRAIL's success relative to its rivals, so the --

JUDGE CHAPPELL: To be accurate, there was an acquisition completed, but isn't there in fact a hold-separate agreement so that these companies are not one at this time?

MS. MUSSER: Yes, there is, Your Honor, there is a hold-separate.

So assuming this merger is allowed to be consummated, we expect those incentives to change.

And the reason that Illumina will be incentivized to expand its lead in this market is because GRAIL is Illumina's fastest and most profitable

mechanism to tap into this huge potential market.

And Your Honor, Illumina is a for-profit company. As such, it has a fiduciary duty to maximize profits for its shareholders, and the best way it can do that is to ensure GRAIL's success at the expense of Illumina's other customers.

Now, as Your Honor has already noted, the first step in assessing how this change in incentives will impact competition for innovation and development of MCED tests is to define a relevant market. Just as in horizontal cases, our analysis begins at the same place. And just as in horizontal cases, you use the same tools for that market definition.

First, as Your Honor is familiar, the Brown Shoe practical indicia will show that MCED tests are a relevant market here.

While I won't go through all of these tests, I'd like to highlight a few pieces of evidence that Your Honor will see.

First, you will see documents and you will hear from witnesses in this case, including respondents, who will show that MCEDs are currently competing against each other and identifying other MCED competitors as their competition.

Second, you will see that the public has

recognized MCED tests as a separate category.

For example, Congress recently introduced a bill to allow for Medicare coverage of multicancer early detection screening tests.

And MCED companies themselves have formed a consortium to chart a path forward in the use of new technologies to improve early cancer mult- -- early cancer detection.

Moreover, the evidence will show that a product's particular characteristics define its unique market from other liquid biopsy tests. Contrary to tests that are designed to detect multiple -- or single cancers or tests that are designed to assist in therapy selection or monitor treatment, here, all MCED tests want to do the same thing, to detect multiple types of cancer in asymptomatic patients.

To support the Brown Shoe practical indicia, complaint counsel will also present testimony from its expert, Dr. Fiona Scott Morton, who will explain how she has analyzed the market using the hypothetical monopolist test and found that the relevant market here is MCED tests.

In a vertical case, in addition to looking at the relevant market, as I mentioned previously, you also look at the related product to see whether

upstream control in that related product gives the merging parties the ability to foreclose or disadvantage the downstream component competitors. Here, that related product is Illumina's next-generation sequencers.

Evidence will show that Illumina's platforms are the only game in town for NGS sequencing and that Illumina will have the ability through that power to disadvantage GRAIL's rivals.

Evidence will tell you that NGS is the only sequencing option that provides the correct combination of accuracy, throughput and cost-effectiveness.

And these characteristics matter, Your Honor.

Accuracy matters. If a sequencing platform either provides false positives or false negatives, there are dire consequences. You are either telling people they have cancer when they don't, which is traumatic, or you are missing cancer, which obviously has its own consequences.

Throughput also matters. Throughput, at a high level, is how much can be sequenced at any one time in a given period. And because MCED tests are looking for biomarkers across a large number of individual pieces of DNA, MCED tests need a sequencer with high

throughput to run its tests effectively.

Our MCED witnesses will explain that they have no other options for NGS and that other technologies are not an option. PCR doesn't work. Microarrays don't work. Proteomics don't work. And long-read sequencers are not an option.

Evidence will show that Illumina is the only game in town.

And no one wants a single source of supply, Your Honor. Our MCED witnesses will explain that they don't want one either and that they have looked and there are simply no other options.

As such, each of our witnesses will explain that they have to use Illumina's NGS sequencing platform.

As Bill Getty from Guardant will explain, the result of this upstream power is that MCED test developers are a hostage to Illumina, that they don't have another supplier, because Illumina underpins their technology. This is what gives Illumina its power and this is what gives it its ability to foreclose its competitors down- -- GRAIL's competitors downstream.

JUDGE CHAPPELL: So if I'm understanding the government's presentation here, what's most important,

the key to the case, is not these blood tests but the next-generation DNA sequencing or NGS platform; is that correct?

MS. MUSSER: Respectfully, Your Honor, I think the harm that we're looking at is in MCED test development. And as I'm getting ready to explain, I think that the MCED -- where the MCED test developers are and how they're competing and innovating against each other is the heart of this case.

Illumina can simply affect the downstream competition through its NGS sequencers, but the fact that all of these MCED sequencers need that help, need access now, is also fundamentally important in this case.

JUDGE CHAPPELL: I'm just saying I think about 75 percent to 80 percent of what I've heard from you is about NGS platform.

MS. MUSSER: And Your Honor, I'm actually just ready to start discussing a little bit more about MCED test developers and what they're currently doing and how they're dependent on this upstream NGS sequencing platform.

JUDGE CHAPPELL: All right.

MS. MUSSER: Now, MCED test developers are in a race, and they're in a race to develop and

commercialize their MCED tests.

Right now, these -- respondents want to tell you that this race is speculative, that it hasn't started because MCED developers aren't selling a product.

So, Your Honor, the race doesn't start after commercialization. The beginning is innovation, and that gun has gone off, and the race has started.

You will hear -- you will hear and you will see evidence that MCED test developers are currently investing in R&D in order to develop an MCED test.

You will also see evidence that every MCED developer is working on a platform that is capable of delivering an MCED test.

You will hear evidence that these MCED test developers are currently either planning or have engaged in clinical studies or trials.

And this innovation and this competition is all designed to go to the same place, Your Honor, to develop an MCED test that will be commercialized and will compete with GRAIL.

Now, the evidence will show that the different MCED developers are trying to get to that goal different ways.

So, for example, you will hear evidence that

some of these MCED test developers are first planning to start with a single cancer, so detect one cancer, and then continually add from there. Other MCED tests are planning to go direct to market with a multicancer test.

Evidence will also show that these MCED companies are developing these tests in different manners, so they might be looking for different biomarkers.

But what the evidence will show is that every single one of these companies are developing, they're investing, and they're competing now, and that in that development, in that innovation, they are dependent on the Illumina NGS sequencer.

JUDGE CHAPPELL: And getting back to what I asked earlier, of course, the MCED market is the issue, but if I'm following your presentation, the key to every one of these developers is this NGS platform owned and sold by Illumina; correct?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right.

MS. MUSSER: And as you can see from this slide, this innovation is not speculative and this development is not speculative. Just looking at public sources, you can see that Guardant has engaged

in a pivotal study, that Thrive has joined the race for liquid biopsy tests, that Caris is presenting a study at an annual meeting, and that Singlera has unveiled detection of five common cancers, and Helio is recognized for its current innovation in this market.

You will also see that as part of its development, these companies are tracking the development and progress of its other competitors.

You will see information of companies looking and engaging in horizon scanning or looking for the competitive landscape to see what its other MCED rivals are doing, to see how they can improve, how they can run faster, how they can compete, how they can be better, and how they can commercialize sooner.

And GRAIL documents will show the same thing. You will see evidence that GRAIL tracks its competitors through a -- an CIA team and that it also hires third parties to assist with competitor tracking.

Evidence will show that GRAIL has identified as its key competitors the same companies that you have seen on your screen, Your Honor.

You will also see that in response to this competitive intelligence gathering that GRAIL has set up red teams to react and to respond to what it sees in

the market, in other words, Your Honor, to compete.

But if this merger is not unwound, evidence will show that Illumina will have the incentive and ability to hobble MCED developers in this race, because right now Illumina benefits every time a customer enters the race and as the race goes forward together faster.

But if this acquisition is not unwound, Illumina's incentives will change and it will succeed the faster lead GRAIL gets and the more market share it wins.

You will hear from Dr. Gary Gao from Singlera, and Dr. Gary Gao explains this best. He explains that if another company has an agenda which is different from yours, then they will try to be, you know, trying to give you a hard time, because there's no sincerity in their negotiation with you. They are just trying to slow you down until their own company develops a test.

That is the change in incentive, and that is what will result if this transaction is not unwound.

And Illumina is dependent on -- or MCED developers are dependent on Illumina in varying different ways. And different MCED developers will just testify that they're dependent on Illumina

differently, but what they all will explain is that they need Illumina's NGS sequencer.

And on your slide are just some examples of what you will hear and what you will see evidence of.

At a high level, MCEDs will explain that they're dependent on Illumina for service and support, because NGS machines are not washing machines. You don't hook them up to the wall and walk away.

MCED witnesses will explain how they rely on Illumina for service and support when a run goes wrong or something isn't calibrated correctly.

They also will explain how they design their MCED tests, their key, to work with a particular NGS test. Because of the interconnectiveness, the interdependence of this lock and key, MCED developers are particularly vulnerable to changes in technology, notice of those changes, and access to any performance enhancements or developments Illumina provides.

Finally, you will hear that for full commercialization, all MCED developers anticipate having to get FDA approval. And while the FDA approval process is uncertain, one thing is clear: FDA approval will require a lot of information and a lot of data, both on the MCED test itself as well as the NGS sequencer. As a result, some MCED witnesses will

explain that they anticipate having to rely on the collaboration or partnership with Illumina to get that done.

What's on your screen, Your Honor, are all levers that Illumina can pull to disadvantage MCED developers. As a result, tomorrow, MCED developers will be hobbled.

As Bill Getty of Guardant explained: One of the ways that Illumina could potentially do that is by, you know, throttling, if you will, our ability to operate our business. And so they are in a position where they can take a significant advantage by kneecapping our ability to run our lab, which of course would flow through to our inability to compete in this larger blood-based screening market, this cancer screening market.

Your Honor, it's not just speculation that Illumina will prejudice GRAIL's rivals. Here, the past is predictive of the future.

You will hear evidence of how in other scenarios, where Illumina had the incentive to disadvantage its customer to reap perceived benefits downstream, it did so.

You will hear evidence of how Illumina changes its behaviors to advantage its downstream components by

disadvantaging its rivals in both the NIPT or noninvasive prenatal testing space and therapy selection markets.

You will also hear evidence of how they pulled similar levels [sic] that we are talking about today to disadvantage or slow down its downstream rivals in those two markets.

Finally, you will hear evidence that in the past, when Illumina fully owned GRAIL, it advantaged GRAIL to the disadvantage of its rivals.

Your Honor, if MCEDs are forced to drop out of this race, to slow down or not to enter at all, it's not just these MCEDs that will suffer but also patients.

As Hans Bishop, GRAIL's CEO, explained: We could wake up tomorrow and read a publication about a new or existing technology that substantially outperforms the performance we have today. That is the essence of competition and the speed of scientific progress that we see across this field.

That is a differentiation, the innovation that will be affected if this merger is not unwound. And the people who will suffer for that are American patients.

Now, respondents will argue that there are

alternatives to NGS and that there will be entry that will negate the anticompetitive effects of this merger.

First, we do not believe a likely -- or entry will either be sufficient or likely.

First let's talk about "likely."

On the screen is a timeline when Dr. Willig in his deposition talked about some of the -- the timing that it would take for an NGS to enter this market.

Now, as a starting point, Dr. Willig and I agreed on two things. First, he could not identify any MCED test developer who was using a non-Illumina NGS, nor was he aware of any NGS test developer who was in a contract to have a non-Illumina NGS.

Now, he predicted that entry was possible as soon as one year.

Your Honor, we don't think the evidence will show that, but let's just take that as a hypothetical.

He then explained that after that one-year entry, the first step in NGS entry will be what's called early access stage.

Now, this early access stage is sitting an Illumina sequencer in the corner of your lab and occasionally running tests on it. And the purpose of this early access stage is to get that data that we

talked about that allows your machine to be calibrated, to learn and to benefit and to get better.

Once it has sufficient data, the next step will be to go to FDA approval. But Dr. Willig estimated that that early access stage could take between one to two years.

So, again, for the sake of this example, let's agree with those numbers.

The next step would be FDA approval. Now, that FDA approval could take another one to two years, according to Dr. Willig.

So best-case scenario, looking at Dr. Willig's math, we're looking at three to five years before there's a commercially viable NGS entry.

You will hear evidence from our MCED witnesses who will explain that switching, that changing that lock, will take years, because, Your Honor, it's not just going to Home Depot and making a new key or switching out the door, it's developing complicated technology and reprogramming that technology to work with the new sequencer.

So using Dr. Willig's timing, we're still looking at five to seven years, best-case scenario. But, Your Honor, innovation is happening today, and innovation will be affected and people will drop out of

the race if -- if entry waits five years. American patients cannot wait five years for MCED test developers to get another option.

Moreover, we don't think this timing is accurate. Roche, a very well-funded and very well-established company, has been trying for over a decade to make an NGS sequencer, but these machines are complicated, they take a lot of time to get right and a lot of time to recalibrate.

But under either scenario, entry will not be sufficient to offset the competitive harm that will happen as this innovation race is already midstream, it's already going, already developing, and MCED test developers do not have time to wait six years for another option.

Moreover, entry is speculative.

For example, one of the companies that you will hear a lot about is BGI. We've already talked about BGI's preliminary injunction. But they also have significant reputational barriers.

For example, the United States has declared -- or has said that BGI can -- is a national security threat.

You will also hear evidence that BGI takes the results from its NIPT tests, those noninvasive

prenatal tests, and provides them to the Chinese military.

You will hear from at least one MCED test developer that will explain there's no way he could convince his board to switch to BGI.

So even assuming that they weren't prevented from the law from selling in the United States and assuming that preliminary injunction isn't -- doesn't -- isn't extended, there are still significant barriers for adoption of BGI, one of the companies you will hear the most about.

Once complaint counsel has met its burden to show that Illumina has the incentive and the ability to foreclose GRAIL's downstream rivals, the burden shifts, and Illumina must show that elimination of double marginalization or efficiencies offset that harm.

For efficiencies, the same test that Your Honor is familiar with applies. Respondents must show that there are merger-specific efficiencies that have been verified. Similar to horizontal cases, efficiencies generated as part of the litigation process are viewed with skepticism.

Now, respondents have mentioned something called elimination of double marginalization.

Elimination of double marginalization means that theoretically, as a result of this merger, the combined firm of Illumina and GRAIL could save some money in their margins.

But complaint counsel focus on harm to innovation, Your Honor, this harm that it alleges will deprive patients of lifesaving screening tests. And respondents will be asking you to justify their merger because it can lower their costs by cents on the dollar. Even if showing that they can show this reduction in margins, which complaint counsel doesn't think they can do, the cents on the dollar cannot outweigh this merger's harm to innovation.

Illumina's efficiencies will similarly fail.

First, Illumina -- respondents will argue that this transaction will accelerate GRAIL's time to market. But they have failed in their burden to provide sufficient information to verify those claims and to substantiate when this will occur and how this will occur.

And second, when you pull the veil back on their argument, what you see is much of their supposed efficiencies really amount to more money for GRAIL, so that is merger-specific and that does not meet their burden.

And finally, their argument is inherent conflict with the terms of their open offer, and this open offer is a long-term supply agreement that they have offered their customers.

Respondents' alleged efficiencies inherently depend on collaboration between the two companies, while at the same time the open offer says that there will be a firewall between the two companies, and these two allegations are inherent conflict, Your Honor.

Respondents cannot meet their burden to show that this collaboration will occur to accelerate the market while at the same time keeping their promise that they will abide by the terms of the open offer. Those two -- those two claims are simply incompatible.

Respondents will not be able to meet their burden to show cognizable efficiencies or that any elimination of double marginalization will outweigh the substantial harm that can come -- complaint counsel will show.

Now, defendants have also proposed a remedy in this case, their open offer or long-term supply agreement.

Respondents bear the burden to show that their proposed remedy must replace the competitive intensity lost as a result of the merger.

Now, behavioral remedies, such as the long-term supply agreement, are viewed with inherent skepticism, because both research and experience have suggested that behavioral remedies pose significant administrability problems and have often failed to prevent the merged entity from engaging in anticompetitive tactics enabled by the transaction.

Quite simply, a bad contract can't fix bad incentives.

As Dr. Willig himself explained, if the incentives aren't right, then the contract is not going to be successful in terms of promoting business effectively for both parties. And sure, the parties try to build in the protections they think they can get into the contract, but the real details of the business, of how the business is going to work, evolve from appropriate business incentives shared between the parties.

And as complaint counsel has just explained, if this transaction is allowed to go through, Illumina and its customers will no longer share the same incentives, and a bad contract can't fix bad incentives.

Your Honor, this merger matters.

As Dr. Cance will explain, having multiple approaches to compare against each other can

ultimately lead to better clinical outcomes for patients and more cost-effective approaches to cancer detection for the benefit of those patients.

A good example of the importance of multiple approaches to innovation is the development and efficacy of COVID vaccines from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, Novavax, and others.

At this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variations, RNA variations, protein markers or some other method for detecting cancer in blood will prove the most effective, but that innovation and that competition for everyone to try to do the best they can is important.

We have all grappled with the effects of COVID over the last year. We have seen the importance of innovation firsthand as people have raced to get vaccines. More innovation and more development meant more shots on goal.

And Illumina partnered with those vaccine companies to help spur this innovation because, like all of us, Illumina did not have a dog in this race, did not have stake in these pharmaceutical companies, and we all wanted as many winners to win -- as many companies to win as possible.

Now, some of those vaccines worked out, some didn't, but the innovation resulted in more choice for patients, with vaccines varying in doses required, ease of administration and handling, and efficacy against different variations.

Your Honor, it would have been crazy to put all of our eggs in one basket in 2020, and it would be crazy to put all of our eggs in one basket here, which is exactly what Illumina is asking you to do for cancer testing.

But here, Illumina -- evidence will show that Illumina's incentives are different. Here, they will make more money for every test that GRAIL sells than it could make selling to its competitors.

Your Honor, Illumina has picked their winner.

But despite its clear incentives, what Illumina is asking you to do is to trust them, to trust them that they will act against their economic incentives when it has not done so in the past.

But to put it simply, Your Honor, the stakes here are too high just to trust Illumina, just to trust any one company. Cancer is a disease that impacts us all, and giving cancer patients the most shots on goal to detect cancer earlier and treat cancer sooner is too important.

Instead, complaint counsel will present evidence that will show innovation is happening and competition, not Illumina, should decide the winners in this market, which is why at the close of this case complaint counsel will be asking you to unwind this transaction.

Your Honor, thank you for your time today.

JUDGE CHAPPELL: Let's talk about the actual market.

How many of these MCED developers that you told us about have an actual multicancer detection test that a patient can then take today?

MS. MUSSER: So only one test is even on the market in a limited capacity, which is GRAIL, but all of these companies are trying to develop a test.

JUDGE CHAPPELL: All right. Thank you.

Respondent, go ahead.

MR. MARRIOTT: Thank you, Your Honor.

I wonder whether it would be convenient now to take our morning break given that you have a long slog in front of you for the next little bit but obviously will defer to whatever approach Your Honor wishes to take.

JUDGE CHAPPELL: I was just pondering that. And we've been going a little over an hour. Why don't

you go ahead and around noon let me know when it's a good time to break in the middle of your presentation and we'll take a short break, but not now, just, you know, go ahead and start.

MR. MARRIOTT: Okay. Fair enough, Your Honor.

JUDGE CHAPPELL: I'm trying to space out -- we have a very long day today till about 7:00 p.m., so go ahead and, you know, when it gets to be around noon, let me know if it's a good breaking point.

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

So good morning, Your Honor.

David Marriott from Cravath, Swaine & Moore for Illumina. We appreciate the opportunity to be heard here this morning.

Complaint counsel, Your Honor, would have you believe that the reunion of Illumina and GRAIL will not produce any benefits just hard. And that, that, Your Honor, is wrong, with all due respect to the FTC, and with your permission, what we'd like to now do in our opening statement is preview for you why we say that, what we believe the evidence will actually show, and why it is we think the reunion of Illumina and GRAIL is good for competition, good for consumers and, Your Honor, we think great for patients.

So before we dive too much into the detail here, I should I think make one thing clear from the outset, Your Honor, and that's that this transaction is I think no ordinary deal. Many M&A transactions are mostly about money. This transaction, Your Honor, and this case are I think about much more.

And we intend to show Your Honor that the reunion of Illumina and GRAIL will speed the development and the adoption of a lifesaving test.

Illumina founded GRAIL about five years ago, Your Honor, and it has always owned part of it.

GRAIL has developed a test. That test is called Galleri. And that test has the potential to revolutionize the fight against cancer, but it needs help, Your Honor, to do that. And the reunion of Illumina and GRAIL will we think provide that help. It will accelerate the adoption of GRAIL's Galleri test, and in doing so it will save we believe thousands of lives.

JUDGE CHAPPELL: Let me ask you about that test. You said it's called Galleri?

MR. MARRIOTT: I did, Your Honor, and it is.

JUDGE CHAPPELL: And that's something that is available today. A patient can take that test.

MR. MARRIOTT: It is available today,

Your Honor, albeit on a somewhat limited basis, but yes, it is available today.

JUDGE CHAPPELL: Is it considered final? In other words, if someone gets the test today, is it going to be a result that's reliable, or is GRAIL still working on the test? Is it considered developmental at this point?

MR. MARRIOTT: Well, great questions, Your Honor.

I believe the test is reliable, and I think at the same time the test -- one is always trying to refine and develop and improve these tests, so I'm confident that the test will continue to be improved, but it is also I believe today reliable, Your Honor. One can always make a test more reliable.

JUDGE CHAPPELL: Okay. Just so we're clear, we've heard about other MCED developers, but your client -- well, Mr. Pfeiffer's client, GRAIL, they have a test called Galleri that a person can go pay for, and I guess it's not covered by insurance, but someone could go get the test today.

MR. MARRIOTT: That is correct.

JUDGE CHAPPELL: And anyone else, any competitor offering anything like that, as of today?

MR. MARRIOTT: No, sir.

JUDGE CHAPPELL: All right. Go ahead.

MR. MARRIOTT: Thank you, Your Honor.

So, look, accelerating the adoption of this Galleri test by one year is projected to avert between 18,000 and 25,000 deaths worldwide by 2030. And those, Your Honor, are I think just staggering numbers.

And of course, they're not just numbers. Behind each one of those is a person, and behind each person are children and parents and siblings and friends. And we think, with all respect, that the FTC's challenge here threatens not only to derail the widespread adoption of Galleri but also to imperil future cancer patients everywhere.

So this case presents I think a choice and a choice, Your Honor, between the near-certain benefits the transaction will bring to consumers and to cancer patients and to people everywhere and the alleged harm that the FTC speculates it may cause down the road.

On the one hand, Your Honor, the evidence will show we believe that cancer screening saves lives, that the Galleri test will save lives, that the accelerated adoption of Galleri will save still more lives, and that the merging of Illumina and GRAIL will provide the needed acceleration.

The FTC's theory asks the court to forgo the

lifesaving benefits of this transaction that are we think highly likely to avoid, Your Honor, the potential harm that could not possibly occur for years, that could only occur we submit if other tests are actually in fact ultimately developed and only if they turn out to be substitutes for the Galleri test and only if, contrary to what we think the facts will show, there are no alternatives to Illumina's NGS. And even then, Your Honor, foreclosure is we think unlikely given the open offer and the reputational harms that any foreclosure would cause here to Illumina.

So the FTC's theory is we think at the end of the day a theory that needlessly gambles with human life.

JUDGE CHAPPELL: What about their point, the government's point, that this NGS platform controlled by your client Illumina is the key to these other developers in the race?

MR. MARRIOTT: There's no question, Your Honor, that NGS is an important platform for the development of multicancer early detection tests, but it is not the only option and Illumina is not the only provider of NGS sequencing technology. There is a -- there is currently competition in that regard and there is expected competition that we think provides

near-term, reasonable alternatives for developers of MCED tests. Nor, as I'll come to in a moment, Your Honor, do the incentives line up in quite the way the FTC suggests.

JUDGE CHAPPELL: But your position is that an MCED developer can purchase an NGS platform equivalent to your NovaSeq 6000?

MR. MARRIOTT: Well, there are other platforms -- "equivalent," Your Honor, is a tough term, so I think there are alternatives out there within the marketplace. I don't know that any one machine is equivalent to the other, but there are alternatives out there that allow MCED developers to do the kind of thing here that we think can be done on an NGS sequencing platform, and we think there are other alternatives coming.

JUDGE CHAPPELL: From what I'm hearing, it sounds like the NGS system, platform, whatever -- is that the major part of Illumina's business? Is it a hundred percent of Illumina's business? Is it, you know -- and we're in public session, but is that the major product that your client provides?

MR. MARRIOTT: Our major product, Your Honor, is in fact sequencing equipment, instruments and consumables. The principal part of the business is not

clinical, which is what we're focused on here, but instead research and development, but yes, Your Honor, sequencing instruments and consumables are a very important part of the business.

JUDGE CHAPPELL: And let's say I'm an MCED developer, and I want to purchase your sequencer. Is that something that you actually put it on a truck, ship it, and it's mine, or do I lease it and you have a contract where you fix it if something goes wrong, you monitor it? What's a typical contract or business relationship there with that MCED developer, if you can tell me that?

MR. MARRIOTT: What I can tell you, Your Honor, and our witnesses will be able to tell you much more, but what I can tell you, Your Honor --

JUDGE CHAPPELL: I understand. This is not evidence, but this is opening statement, and there are a lot of people attending here, especially by phone, that would like to have a base knowledge level here.

MR. MARRIOTT: Yeah. Fair enough. And I'm happy to answer the question.

Typically the machines are purchased, Your Honor. There's no need to lease the machines. There are service contracts with all sorts of bells and whistles that can be associated with them, different

grades of service that can be purchased and that are available. But typically the machines are purchased, Your Honor, and I believe they are typically shipped on trucks.

JUDGE CHAPPELL: And if I said, "I've got a lab here. I'm developing an MCED. What's your best product?" is that this NovaSeq 6000 that we saw earlier?

MR. MARRIOTT: Well, I think "best" is a function and part of what you're trying to do, Your Honor, but the NovaSeq is a great product and I think for the kind of thing we're talking about here I think for many people the best choice.

JUDGE CHAPPELL: And again, it's short read.

MR. MARRIOTT: That is correct.

JUDGE CHAPPELL: And short read being faster, cheaper and more accurate; correct?

MR. MARRIOTT: Well, I think it --

JUDGE CHAPPELL: For these tests.

MR. MARRIOTT: I think it depends on exactly what you're trying to do, Your Honor, but for many it can be faster, cheaper and accurate, correct.

JUDGE CHAPPELL: All right. Go ahead.

MR. MARRIOTT: Sure.

So, Your Honor, the FTC is not here entitled

of course to any presumption of anticompetitive effect.

There's no dispute that the reunion of Illumina and GRAIL is a vertical transaction. Illumina doesn't have a downstream cancer screening test, and GRAIL is not in the market -- or in the business of marketing and selling sequencing instruments.

As the court in the AT&T case said, there is recognition among academics and courts and antitrust enforcement authorities alike that vertical mergers create -- can create vertical integration efficiencies between purchasers and sellers, and so it is here, Your Honor, in this case. The FTC has got to show to make out its case actual evidence of anticompetitive effect.

As I said, Your Honor, the evidence will show here we believe that the FTC's case is built on speculation.

And just to give Your Honor some examples, the FTC assumes, for example, that there will be rival cancer screening tests on the market. There are in fact, Your Honor, none today.

The FTC assumes that those cancer screening tests will be close substitutes to the GRAIL test,

Galleri. GRAIL is in fact you will hear very different from known tests in development.

The FTC assumes that Illumina will raise prices. In fact, we're going to show you, Your Honor, Illumina will raise prices -- will lower prices, rather, as a result of this transaction.

The FTC assumes that Illumina will disfavor GRAIL's potential rivals. In fact, Your Honor, we intend to show that it has no incentive to do that.

The FTC assumes there are no efficiencies that would offset the alleged anticompetitive harm here, and we intend to show Your Honor that there are numerous efficiencies.

And by way of final example, they assume at the FTC that Illumina will face no upstream NGS competition even in the near future. And in fact, Your Honor, Illumina faces competition now we will show, and that competition is expected to increase.

So we aim, with your permission, Your Honor, through the course of trial to walk you through each of the layers of we think impermissible speculation that underpin the FTC's case.

For now, right, let me just say this, Your Honor. No case, in our view, has ever done what the FTC asks this court here to do, which is to enjoin

a vertical transaction on the ground that it would have an anticompetitive effect in a market that does not really even exist.

So the FTC's case, Your Honor, depends on the proposition that the transaction here will harm competition in the so-called market for early cancer detection or MCED. And we'll use that term for simplicity, Your Honor, but to be clear, in our view, the FTC's proposed market definition is fundamentally flawed, and we think that those flaws undermine the entirety of its case.

But even if, Your Honor, even if the market were as the FTC imagined, the reunion of Illumina and GRAIL would not cause Illumina to disadvantage other MCED test developers, as is alleged.

This transaction guarantees that prices will drop and that customers will have more access, not less access, to Illumina products. This transaction --

JUDGE CHAPPELL: I'm assuming you're going to get to what those flaws are that you addressed some moments ago?

MR. MARRIOTT: I am coming right to them, Your Honor.

JUDGE CHAPPELL: All right.

MR. MARRIOTT: This transaction, Your Honor, means in effect that there will be more tests sooner than there otherwise would be.

So to make out their case, the FTC has to show at least two things, in our judgment. They have to show, one, that Illumina would have an incentive to raise costs to GRAIL's rivals, because doing that would divert more MCED tests to GRAIL than Illumina would lose in NGS sales. And they have to show that GRAIL's rivals couldn't avoid the increased costs by switching to platforms other than Illumina's. And we think here, Your Honor, that they'll be able to show neither.

Raising costs to GRAIL's rivals wouldn't divert sales to GRAIL because GRAIL has no substitutes, Your Honor, at present.

Moreover, there are alternatives, as I've said and as we've discussed, to Illumina's platform now, and other NGS competitors have firm commercial plans and near-term projected launch dates.

So Illumina has we think, Your Honor, no intention of foreclosing GRAIL's rivals, so Illumina has basically, you know, in our view, put its money where its mouth is. It has made a binding offer that eliminates we think any realistic possibility of harm

to competition.

And among other things, Your Honor, that open offer makes a twelve-year commitment. It guarantees no price increases. In fact, what you'll hear, Your Honor, is it actually guarantees price decreases. It ensures full cooperation with GRAIL's rivals. And it provides for binding arbitration to resolve certain disputes.

Despite that offer, there have been complaints about the deal, Your Honor. We acknowledge that. You're going to hear from some witnesses about that. But we intend to show, Your Honor, that those complaints should have no antitrust merit. They are not based, in our judgment, on cognizable antitrust concerns. They are based we intend to show, Your Honor, primarily on complaints about avoiding competition with a more competitive GRAIL, about maintaining existing contractual advantage over other customers or about getting better deals in negotiations.

JUDGE CHAPPELL: This open offer we've heard now from you and previously from the government, is that an offer Illumina is making to its customers of NGS systems?

MR. MARRIOTT: It is an open offer made to

oncology customers, Your Honor, so -- so test developers, for example.

And you'll hear all about that in its -- all its splendor, Your Honor. It is a lengthy and an involved series of documents making real concrete commitments about what the company will do if allowed to proceed with this transaction.

Even if -- and I'm going -- I'm almost going to finish here, Your Honor, kind of an introduction and then I'm going to comment in some detail for the market questions Your Honor asked about. But just by way of further introduction, even if the transaction here, Your Honor, had an anticompetitive effect in what we think is effectively a nonexistent market and even if this open offer we've talked about didn't resolve any potential concerns, the benefits we intend to show far outweigh the speculative effects that are imagined here by the FTC. There are a number of efficiencies associated with the transaction.

As I said at the outset, Your Honor, it will save lives. I think that's quite easily the most important benefit. Indeed, we think it's going to save many thousands of lives. But there are other benefits, and it's not just about EDM, as was suggested by complaint counsel.

This transaction we think will have the procompetitive advantage of accelerating FDA, Medicare, and payer approvals, of generating R&D efficiencies, of reducing royalty burden, and of creating supply chain and other operational efficiencies, Your Honor. And you're going to hear about those from our witnesses.

And importantly, right, all of this is going to result in real cost savings to consumers and to patients. Indeed, we estimate these efficiencies to be in the tens of billions of dollars, Your Honor.

In short, right, the benefits of this transaction we intend to show are going to far outweigh any anticompetitive effect here alleged by the FTC.

Now, contrary to the suggestion of the government, we think the government actually bears a pretty heavy burden here, to justify enjoining a vertical merger. And I'll say more about that here in due course.

So far as we've been able to determine, Your Honor, the FTC has not successfully litigated a vertical merger to decision in decades. And the reason I think for that is simple. It is simply rare that potential anticompetitive harm from a vertical transaction outweighs the benefits. And here, we think

the benefits of this deal far outweigh the speculative benefits imagined by the FTC.

So with that introduction, Your Honor, what I would propose is the following.

I'd like to give you a little bit of a roadmap of what we contemplate doing during the balance of our opening remarks, and I want to begin, with your permission, highlighting certain background facts, including that the FTC's case depends upon this market as I've described it.

And then we'd like to do three things. We'd like to walk Your Honor through why it is we think the reunion of Illumina and GRAIL will not have any meaningful anticompetitive effect. We want to outline for Your Honor the efficiencies of the transaction as we see them and then describe for you why we think blocking this transaction will harm patients and consumers and the public health.

So with that, Your Honor, a little bit of background.

So Illumina was founded in 1998 in San Diego. And the company's mission is to improve human health by unlocking the power of the genome.

Illumina is a developer and a provider of sequencing solutions for genetic and for genomic

analysis.

And as you probably know, Your Honor, genetic analysis is the study of a sample of DNA to look at differences. A genomic analysis is the identification, the measurement, the comparison of genomic features, such as DNA sequence and structural variation, gene expression, and so on.

Illumina's contributions to the science of genomic sequencing have been well-recognized, and you'll hear about those here in the trial. I'm going to say a little bit more about sequencing here in a few minutes.

As part of its sequencing business, Illumina sells instruments and it sells consumables.

A consumable for purposes of this case at least, Your Honor, is a product that is consumed during sequencing, like a flow cell, which is a channel that can absorb the DNA fragments to be analyzed.

And Illumina sells these products to customers in a number of different segments. Those segments include clinics and research labs and hospitals. They include healthcare systems and government agencies, academic institutions and pharmaceutical companies.

And I think importantly here, these segments

encompass many hundreds of different applications and use cases, not just the use case we're talking about here with respect to MCED tests.

So one of our big focuses here in this case, Your Honor, our primary points of interest is sequencing, so a little bit about that.

By "sequencing" what we mean is the process of determining the order of the nucleotides in a given DNA fragment.

And Illumina sequencing enables a variety of applications that allow researchers to ask and hopefully people to get answers to virtually any question that somebody would want to ask about the genome. And early cancer detection is one of many, many applications and use cases that are enabled by and supported by the same Illumina instrument and the same Illumina consumables.

So without getting, Your Honor, too much into the weeds here -- and let me say just a little bit about the sequencing workflow, and Ms. Musser alluded to this in her opening remarks as well. I think some background here may be of some help to the court as you process the evidence that you're going to receive.

But what -- next-generation sequencing workflow contains three basic steps: library preparation,

sequencing, and data analysis.

So step one is the library prep. And this step prepares the DNA or the RNA samples to be compatible with the sequencer. And sequencing libraries are typically created by fragmenting DNA and then adding specialized adapters to both ends. And then so to save resources, multiple libraries can be pooled together and they can be sequenced in the same run.

So step two, Your Honor, is the actual sequencing. And during this step, the fragments are amplified in a process that's called cluster generation, and that results in millions of copies of single-stranded DNA. On most of the Illumina instruments, clustering occurs automatically.

And then following that, in a process -- there's a process that's called sequencing by synthesis which takes place, and that chemically modifies the nucleotides to bind to the DNA template strand.

And each of these nucleotides, interestingly I think, contains a fluorescent tag and a reversible terminator that blocks the incorporation of the next base. And this fluorescent signal indicates which nucleotide has been added, and then the terminator is

cleaved so that the next one can bind. And then after reading the forward DNA strand, the reads are then washed away and the process repeats itself.

So that's step two, Your Honor.

And then step three is the data analysis. And in this step, the instrument software identifies nucleotides in a process called base calling and then the predicted accuracy of those base calls.

And during DNA analysis you can import your sequencing data into a standard analysis tool or you can set up, you know, your own sort of pipeline. Today, Your Honor, you can use intuitive data analysis apps to analyze NGS data, and those tools would provide -- so these tools, they provide sequencing alignment, variant calling, data visualization and interpretation. And you'll hear more about those concepts, Your Honor, during the course of trial.

JUDGE CHAPPELL: In which of these three steps is the reagent applied?

MR. MARRIOTT: Reagent is applied, Your Honor, in -- excuse me. I'm having a little difficulty -- the reagent is applied in the flow cell, Your Honor, which is during the sequencing step.

JUDGE CHAPPELL: All right.

MR. MARRIOTT: Okay.

So Illumina has played we intend to show -- and I don't think, frankly, there's much dispute about this -- a key role in driving down the costs of sequencing.

It cost approximately $3 billion to sequence the first human genome. And when Illumina first launched a sequencer in 2009, Your Honor, it cost $64,000 to sequence a genome. By 2017, a genome could be sequenced using Illumina's NovaSeq 6000 for approximately 600 bucks.

Virtually all of the per-genome cost reductions between 2009 and now have I think the evidence will show been driven by Illumina.

So why bring down the costs in this way, Your Honor, because doing that increases the market size, which benefits Illumina and we think benefits everybody else, and so for that reason Illumina has no incentive we intend to show to stop bringing down prices.

On the contrary, it has every incentive to bring down prices because that is what drives the business. Driving down costs expands the potential uses for sequencing in healthcare, and it expands the demand for Illumina technology.

JUDGE CHAPPELL: So what you might lose in per

unit you gain in volume.

MR. MARRIOTT: That is correct.

Illumina's open offer here, Your Honor, is going to bring these prices down even further.

The company is committed to and plans to reduce the cost of sequencing a genome to approximately $100, which I think is a staggering fact.

Okay. So Illumina, Your Honor, has in fact done historically very little vertical integration. But in 2013 Illumina vertically integrated by acquiring a company called Verinata Health, a developer of prenatal fetal health products.

At that time, Your Honor, over a hundred thousand expectant mothers had taken Verinata's noninvasive prenatal test, which is referred to as NIPT. After the acquisition, in a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic or an abnormality in the fetus.

But Illumina's scientists went to work. They gained access to and they analyzed the data. And they discovered, Your Honor, that the NIPT tests had detected circulating tumor DNA fragments present in the mother's bloodstream.

And it is that discovery which led Illumina to

pursue one of the most critical goals of cancer care, and that is detecting cancer at its earliest stages and doing so in the blood.

So it was based on that breakthrough, Your Honor, with Verinata --

JUDGE CHAPPELL: Let's back up there a second.

MR. MARRIOTT: Sure.

JUDGE CHAPPELL: The previous slide.

So with the NIPT test, Illumina is actually in the market, you're actually doing the testing as well as sequencing; is that -- you're doing the whole test; is that correct?

MR. MARRIOTT: That is correct, Your Honor.

JUDGE CHAPPELL: And do you have competitors in that market?

MR. MARRIOTT: Yes, sir, we do.

JUDGE CHAPPELL: Is the NGS required for the NIPT?

MR. MARRIOTT: I don't know -- and I might quibble with the word "required." It is used, Your Honor. It is an important part of the process. Could someone do testing with another platform? I think they probably could. But NGS is the platform of choice for this purpose, to my knowledge.

JUDGE CHAPPELL: Are there other testing

markets where your client is in the market from bottom to top, in other words, you're -- just like the NIPT?

MR. MARRIOTT: Your Honor, therapy selection is another marketplace in which we are vertically integrated.

JUDGE CHAPPELL: Explain that.

MR. MARRIOTT: Therapy selection is when you -- a patient has been determined to have cancer and what one is trying to figure out is what is the best therapy to be used to treat that patient, and so that -- some of that work can be done using NGS sequencing equipment, and there are downstream products that are -- that are tests that help figure out what that is, so we are vertically integrated there, Your Honor, in therapy selection, and we are vertically integrated in NIPT.

JUDGE CHAPPELL: But as we discussed earlier, the major part of Illumina's business is providing these NGS platforms.

MR. MARRIOTT: You are correct.

JUDGE CHAPPELL: All right.

MR. MARRIOTT: So in 2013, Your Honor, as I said, we vertically integrated. We acquired Verinata here. And I think you're going to hear about that experience and there's going to be differences of

opinion between the FTC and respondents as to the effects of that vertical integration on competition, and I'll preview that for you here again momentarily.

So it was based, Your Honor, on its breakthrough with Verinata that Illumina actually founded GRAIL in 2016. And the objective here was to develop and to deploy a universal screening test that was capable of detecting cancer in its earliest stages. It was a -- the so-called moonshot mission, Your Honor, that was aimed at bending the curve of cancer mortality.

And I call it I guess the moonshot mission because very costly studies were needed to determine whether this theory, which was then unproven at the time, would actually work and because it was -- it was frankly highly speculative at the time whether there could be true clinical utility here.

So after some time, right, Illumina -- after the formation of GRAIL, Illumina concluded that the best way to get GRAIL off the ground was to partially spin it out of Illumina. And the idea was that spinning out GRAIL would bring focus. It would create new opportunities. It would diversify risks with new investors.

And so, look, at the initial stage of

development, the best way they concluded for GRAIL to succeed was to adopt a structure that encouraged the focused attention of scientists in a small organization.

And vertical separation in the early stages of development the evidence is going to show can be a very effective way of motivating people. It can -- for example, it can assure -- ensure that entrepreneurs are given and able to kind of capture value of their investments if they succeed and are later acquired by or partnered with a firm that has complementary assets.

So since it was partially spun off from Illumina, Your Honor, GRAIL conducted -- has conducted four clinical trials. They have involved many thousands of participants and have shown that GRAIL's test has enormous potential. These trials are I understand, Your Honor, among the largest of clinical studies ever done.

GRAIL's most promising product, as you've heard, is called Galleri. Galleri screens for 50-plus cancers. It identifies early-stage cancers. It identifies cancer location. It reduces diagnostic costs of overall diagnostic workup. And it aims to improve health outcomes for people.

GRAIL projects, Your Honor, that if it can get

the help that it needs, the help that we believe this transaction provides, that this test can save many thousands of lives annually. And again, the acceleration by one year is expected to avert between 18,000 and 25,000 deaths worldwide.

JUDGE CHAPPELL: This test not only detects, it can inform as to the location of a cancer.

MR. MARRIOTT: That is correct, Your Honor, which is we think a very important factor and a significant differentiating factor between this test and tests in development.

However, Your Honor, however -- and I think this is important -- GRAIL faces significant hurdles to gaining widespread adoption of the Galleri test. The widespread adoption of this test is going to require the approval of the FDA and the Centers for Medicaid and Medicare Services or CMS.

And it's also going to require that payers, like the MetLifes, the UnitedHealthcares, the Blue Cross Blue Shields of the world, that they agree to reimburse for the test. Payer approval is we think critical to the widespread adoption of any cancer identification test.

And GRAIL, Your Honor, has frankly little experience and some -- and limited capabilities in

getting FDA, CMS and payer approval. And by contrast, what you're going to hear is that Illumina brings significant expertise and significant expert to all of these areas.

And so, Your Honor, in September of 2020, Illumina and GRAIL agreed to fully reunite and Illumina agreed to -- Illumina already owned -- and Your Honor alluded to this during Ms. Musser's opening -- Illumina already owned 12 percent of GRAIL on a fully diluted basis, but the companies agreed that Illumina would reacquire the remaining approximately 88 percent of GRAIL's shares.

The plan is for GRAIL to operate as a division within Illumina. What I'll call core Illumina, Your Honor, will continue to focus on NGS innovations, to reduce sequencing costs, to increase the penetration of NGS into new applications, and then the fully reunited companies are going to collaborate in driving down prices, broadening access to GRAIL's tests, and facilitating further innovations.

When the FTC expressed opposition to the transaction, Illumina made what is a binding commitment to ensure against the harms that the FTC expressed concern about, Your Honor. But making this offer was not a hard decision for Illumina, and it

wasn't a hard decision because Illumina has no intention of doing and we think no incentive to do, when its business is properly understood, the things that the FTC says that it worries about.

So what was this offer?

So as I said earlier, Your Honor, it was and it is very detailed. Your Honor will have occasion to review it as much as you wish in detail. You're going to hear some witness testimony about it.

But at a very high level, Illumina offered customers a binding twelve-year supply contract. And the offer guarantees, among other things, no price increases for sequencing products -- and I'll reiterate that, no price increases for sequencing products -- a 43 percent decrease or greater for Illumina's highest-throughput sequencing products by 2025, access to Illumina's latest sequencing products at the same time as GRAIL has access, continuity of supply for all sequencing products, binding arbitration, a firewall, audit rights, you know, and so on, Your Honor, a full set of rights that you're going to hear testimony about that ought to be we think more than sufficient to address any concerns of competitive harm.

JUDGE CHAPPELL: Are you saying this is going to be offered or it's currently offered and available

to customers?

MR. MARRIOTT: The latter. It has been offered and it is available. It is contingent upon this transaction happening, Your Honor, but it is available to people. And in fact, some customers have signed the open offer. You'll hear some evidence about that.

JUDGE CHAPPELL: You mean this transaction not being unwound.

MR. MARRIOTT: Yes, sir.

Effectively ignoring Illumina's open offer, Your Honor, the FTC filed suit. And the FTC contends, as you've heard, that this transaction will raise costs to GRAIL's rivals and it will discourage innovation. And according to the FTC, that will happen in this MCED test market.

What we intend to show, Your Honor, is -- is this.

As you know, to show a violation of the Clayton Act, the FTC has to make out a prima facie case that the merger is likely to substantially lessen competition. In the case of a vertical merger, that requires a fact-specific showing.

We expect to show, Your Honor, that the FTC can't meet its burden to show anticompetitive harm. In fact, what we will show Your Honor is that the

speculative harms that are imagined here are far outweighed by the procompetitive benefits of the transaction. And as a result and in a nutshell, Your Honor, we'll ask the court to reject the FTC's challenge to the transaction because it hasn't met its burden and because we believe, respectfully, that the decision here, a decision to block the transaction, would harm consumers and would harm patients.

Your Honor, the -- I have reached the hour you asked me to flag for you, which is approaching noon, and I am about to begin a new segment. Would you like now for me to -- to take a break or would you like me to persist?

JUDGE CHAPPELL: Right. Let's go ahead and take a short morning break.

We will reconvene at 12:10.

We're in recess.

(Recess)

JUDGE CHAPPELL: Proceed, Counselor.

MR. MARRIOTT: Thank you, Your Honor.

Just before the break, I had spoken about the open offer. I wanted to just clarify something I said, Your Honor, and then I want to talk about anticompetitive effect.

To be clear, the open offer is currently in

effect because the transaction has closed, so people are getting -- those who have signed it are getting the benefits of the open offer. I want to make sure there's not any uncertainty about that.

Were the transaction to be unwound in some sense, there might be certain provisions that would no longer apply, but the transaction is in effect, Your Honor, and people are getting -- or the open offer is in effect and people are getting the benefit of that.

JUDGE CHAPPELL: So it sounds like that if someone accepts that deal, whether the acquisition is unwound or not, your client is committed to that; right?

MR. MARRIOTT: That's correct.

JUDGE CHAPPELL: All right. Go ahead.

MR. MARRIOTT: So, Your Honor, the next thing I'd like to do, with your permission, is to talk a little bit more about the FTC's specific allegations and what we believe the evidence is going to show with respect to those allegations.

So we aim to show, Your Honor, that the FTC will be unable to meet its burden here really for three reasons.

First, the theories of harm on which its case

depends depend upon an imagined market. I'm going to come right to that, as Your Honor asked that I do earlier.

We're going to then show you that the transaction here the evidence will show will not harm competition but instead promote it.

And finally, we'll say a little bit more along the way about the open offer.

So let me turn if I may to each of these propositions in turn.

So, to begin, the FTC's market allegations we think fail, and they fail we believe because of really two reasons. We think they misdefined the relevant downstream market, which they call the MCED test marketplace. And we think also that they mischaracterize and really fail to demonstrate the related product market.

And of course, the related product for this purpose, Your Honor, is simply a product that's supplied by the merged firm, so here Illumina, and is positioned vertically to the products in the relevant market, so here the Galleri test.

So -- so what is the problem with the FTC's alleged relevant market?

The FTC includes in its market a handful of

potential tests, Your Honor, that have not yet been developed and let alone launched. And as we've discussed earlier, Your Honor, no company, no company is doing now what GRAIL is doing. No other test is like the Galleri test.

And just by way of example, right, the Galleri test can identify more than fifty cancers. No other test developer, to your knowledge, has identified more than ten.

Galleri can detect the location of cancer, the so-called tissue of origin. And here again, so far as we know, Your Honor, no other test developer has identified tissue of origin for multiple cancers.

Galleri uses a technique called methylation, which you'll hear about during the course of trial. Other developers, as I think complaint counsel acknowledged, are experimenting with other techniques.

JUDGE CHAPPELL: Why don't you explain that, methylation, for the people that are listening on the phone.

MR. MARRIOTT: You know, I was afraid, Your Honor, you might ask me a tough science question like that.

So methylation is, as my nonscientist mind understands it, a way of turning on and off a gene

without changing the DNA sequence. It's a type of epigenetic modification.

And I think beyond that, Your Honor, our experts are going to have to tell you, but that's my understanding of methylation.

JUDGE CHAPPELL: Let's go back one slide, please.

MR. MARRIOTT: Sure.

JUDGE CHAPPELL: About misdefining the market.

It appears to me from listening to the government and now to you that there's a disagreement, which is not surprising in a merger case, of how to define the relevant market, but this one appears to go further in that you're saying the government must identify two relevant markets, upstream and downstream. Am I correct?

MR. MARRIOTT: Effectively you're correct, Your Honor, yes.

JUDGE CHAPPELL: And if I understood their approach or their opening statement, they don't have to define two relevant markets.

MR. MARRIOTT: I believe that --

JUDGE CHAPPELL: I know you can't speak for them, but that's what I heard.

MR. MARRIOTT: I believe that's their position,

Your Honor.

JUDGE CHAPPELL: All right. Go ahead.

MR. MARRIOTT: So, so -- so why does -- why do we care, Your Honor, if the -- if the market they have defined is overbroad. We care because the purpose of market definition, in our view, in a vertical case is to identify the boundaries where competition is impacted. And if you misdefine the market, as we believe, respectfully, the FTC has done, then you can overstate the amount of competition that GRAIL will likely -- that Galleri will likely face, you can overstate the amount of diversion that a foreclosure scheme could cause, and I think you can mischaracterize and we think here they do mischaracterize Illumina's incentives.

So there is, Your Honor, we believe no substitute for Galleri. There is -- and thus no test in this market as -- besides Galleri as the FTC has defined it.

You're going to hear during the course of trial from two M.D.s, Dr. Richard Abrams and Dr. Richard Cote.

And Dr. Abrams will tell you I believe that Galleri is fundamentally different from MCED tests in development and that a primary care physician would be

very unlikely to treat a test for up to ten cancers as a substitute for the Galleri test.

And Dr. Cote, Your Honor, will tell you that the purported MCED market defined by the FTC just doesn't exist today and that an MCED test that screens for two or three types of cancer is unlikely to compete with a test that screens for fifty.

So you'll hear testimony, Your Honor, from a company that's developing an MCED test.

Now, this screen is quite deliberately blank, Your Honor. It's redacted pursuant to your general guidance which even without your repeating it today we understood there would be no third-party confidential information disclosed, so we'll give Your Honor, you know, off-line the version of this that's not redacted, and I will speak around any third-party confidential information.

But you're going to hear testimony during the course of trial from at least one developer that is developing an MCED test. And a former executive of that company, Your Honor, I believe has testified -- and you'll have this evidence -- that its test is likely he believes to be a complement to Galleri and that a patient, at least if he is a patient, would take both tests.

You're going to hear evidence to that effect, Your Honor, and we present in fact -- we intend in fact to present considerable evidence that the tests in development in this space are going to be complements for one another. They're not going to be alternatives to one another. They're not going to be substitutes. They are going to be complements for each other.

The FTC's market, Your Honor, as they define it, which I think again underpins the entirety of their case because its informs their analysis of supposedly anticompetitive conduct, is we think impermissibly speculative.

The Galleri test is the only one on the market.

Other developers are at very early stages. It's not clear whether they will succeed. It's not clear when they will succeed. It's not clear, if they succeed, what features and functions their tests will have. And the evidence is going to show in any event, given what is being developed, given the nature of this marketplace, other tests are likely to be complements for one another, not substitutes.

So as for the related product market, Your Honor, the FTC from our perspective really just

simply says Illumina is a monopolist. That's effectively the effort I think to define the so-called related product. They don't really define it, in our view.

It is true, Your Honor, that Illumina has been successful in NGS sequencing and that NGS sales account for a significant portion of Illumina's U.S. sales. But very importantly, Illumina is not the only provider of NGS sequencing.

There are alternative platforms that can be used by MCED test developers today, and there are alternative NGS products expected to launch in the near term. In fact, forthcoming NGS products are we think, Judge, far less speculative in the MCED tests that the FTC claims could be foreclosed if they ever come into existence.

JUDGE CHAPPELL: Is it fair to include BGI on that exhibit, because we heard that BGI is prohibited from doing business in this country?

MR. MARRIOTT: Yeah, it's a great question, Your Honor.

I think it absolutely is fair. I think it's fair because, as you're going to hear, BGI is expected to enter the U.S. marketplace in 2023 and because, frankly, contrary to what we heard from

complaint counsel, what you're also going to hear is that there are companies currently working with BGI, albeit out of the United States, in the development of MCED tests.

And so with them expected to enter the U.S. marketplace in 2023 and given the development pipelines and of those working to bring MCED tests, Your Honor, I think it's absolutely fair and appropriate for them to be viewed as an alternative in this space.

So the FTC's claim that Illumina will face no NGS competition is we think belied by the market realities.

And you're going to hear from Dr. Willig on this, on this issue, Your Honor. He'll tell you that the FTC's theory in his judgment is not only speculative but is belied by both investments made by MCED developers and by Illumina's projections and by its willingness to pay $8 billion for GRAIL.

Complaint counsel, Your Honor, made a point of emphasizing the degree of investment by MCED test developers. What they have not so far acknowledged is the investment pouring in to NGS platforms relevant to cancer early detection.

But as you can see from this table -- and again

it's partly redacted, Your Honor, and I'll speak around the third-party information -- significant entry is expected in the near term, and that entry is backed by major investment events.

So these NGS entrants, Your Honor, are viewed as competing for cancer screening applications.

BGI, as I said, expected to enter the U.S. market in 2023, already working with one test developer, publicly disclosed that Natera is working with them.

Element, Omniome, Roche, Singular Genomics, and another entity whose identity I can't reveal here, Your Honor, for confidentiality purposes are entering into this space and are targeting cancer screening.

So test developers' conduct also, Your Honor, we submit will belie the FTC's claim that Illumina faces no NGS competition. If -- you're going to hear this from one of our experts. If the FTC were correct that Illumina will face no NGS competition, then post R&D, commercialized NGS-based tests would be vulnerable to profit extraction by Illumina regardless of this merger. And it would the economists will tell you make no sense for them to commit investments into developing tests that would be vulnerable to Illumina.

And in fact, what you're going to see,

Your Honor, is that substantial investments to develop many NGS-based cancer screening tests have been raised before and after the merger announcement. And these investments we believe reject the FTC theory of vulnerability to Illumina, and instead we think they're market evidence that NGS competition is expected in time for commercialization.

What's more, Your Honor, Illumina's projections and its willingness to pay $8 billion for GRAIL demonstrate that Illumina expects NGS competition to constrain its future pricing.

As the FTC readily acknowledges, Illumina projects that absent a merger, it would earn a much smaller share of the profits than GRAIL on each Galleri test. And that would make no economic sense, Your Honor, if Illumina were going to be the sole NGS supplier going forward. If Illumina were going to be the sole NGS supplier, it could command a much greater share of profits on each Galleri test.

So, in sum, Your Honor, we think the evidence here is going to show that the FTC's relevant market and their related product market allegations suffer from serious flaws.

Even if --

JUDGE CHAPPELL: Can you go back to that

screen?

MR. MARRIOTT: I can.

JUDGE CHAPPELL: This chart here, this graph, that's assuming consummation of the deal or not?

MR. MARRIOTT: It is.

JUDGE CHAPPELL: Okay.

But isn't the government correct that your company stands to earn more money by owning GRAIL and making money on the test as well as the NGS rather than just selling the NGS machines?

MR. MARRIOTT: Yes, Your Honor. We certainly expect that the company will make money on the sales of MCED tests by GRAIL.

JUDGE CHAPPELL: I mean, you are a for-profit business and there --

MR. MARRIOTT: Absolutely.

JUDGE CHAPPELL: -- must be a reason why you wanted to complete this acquisition.

MR. MARRIOTT: No question about that.

JUDGE CHAPPELL: All right.

MR. MARRIOTT: That's absolutely true. We don't think it changes the incentives, as we'll explain, but that's absolutely true, Your Honor.

Okay. So even if, Your Honor, we expect the FTC's market -- even if they weren't flawed as we

believe they are, the evidence here, Your Honor, will not support, we submit, the government's claim that the reunion of Illumina and GRAIL would permit Illumina to foreclose competition by raising rivals' costs.

So the FTC theory basically, Your Honor, is that if Illumina reunites with GRAIL, then Illumina will raise prices to GRAIL's rivals at the risk of forgoing sales to some of its top customers in order to divert sales from GRAIL's rivals to GRAIL in the hope that doing so would be more profitable to Illumina. And the evidence we submit, Your Honor, will just not support that theory which again we believe layers one level of speculation upon another.

Raising costs, raising rivals' costs, would reduce Illumina's sequencing sales.

As we've discussed, Illumina's primary business, Your Honor, is developing sequencing techniques and selling sequencing inputs and platforms. The company sells sequencing products for many applications outside of the MCED test, applications like single-cancer screening and minimal residual disease and diagnostic aid to cancer, cancer therapy selection and NIPT, which we've mentioned.

Raising costs, Your Honor, would deter those NGS sales and sales to MCED test developers. Illumina

would lose sales to existing and emerging rivals, and it would discourage development on Illumina's platform by innovators who would otherwise expand the NGS market.

And in that scenario, downstream developers would be far less likely to invest in Illumina if they thought that Illumina was going to be behave opportunistically.

What's more, raising cost would be damaging to Illumina's reputation as it would break from the company's longstanding, demonstrable practice of driving down the cost of sequencing and expanding the demand for its products by encouraging new uses of those products.

JUDGE CHAPPELL: We talked about your -- the clients for Illumina's NGS platform would be the MCED developers.

What about current customers, say, national lab companies, say, like LabCorp or Quest Diagnostics? Are they current customers of Illumina?

MR. MARRIOTT: I believe they are, Your Honor, yes.

JUDGE CHAPPELL: And would they for their testing that they do when, you know, people go to a lab and they do the analyzing and the testing -- do you

know if they're using the NGS-type platform for those tests?

MR. MARRIOTT: I believe they are, Your Honor, yes.

JUDGE CHAPPELL: Okay.

I guess what I'm getting at is, if the deal is consummated, you would still have an incentive I suppose to sell your NGS platform to these labs that are doing the tests; is that correct?

MR. MARRIOTT: Absolutely. Absolutely.

JUDGE CHAPPELL: Go ahead.

MR. MARRIOTT: Thank you, Your Honor.

Let's see.

Okay. So -- so even if, Your Honor, even if, Illumina wanted to risk its sequencing profits to raise prices to GRAIL's rivals in order to divert sales to them, that strategy just wouldn't work, right. Sequencing costs are projected to be a small share of downstream revenue.

In fact, Your Honor, GRAIL's sequencing costs are projected to be less than 4 percent of GRAIL's revenue by 2025, so an increase in sequencing costs is unlikely to significantly influence downstream pricing.

A rival could be -- could completely absorb an

increase of even, say, 50 percent, Your Honor, without significantly impacting margins. And of course, any large increase would accelerate switching to rival platforms, resulting in significant losses of profitable upstream sales.

And as we'll talk about, Your Honor, as we've already talked about, Illumina's open offer guarantees not only no price increases but a 43 percent reduction in sequencing costs by 2025.

And I should just say, look, parenthetically, Your Honor, there's only one logical inference I submit to draw from the fact that Illumina's prices are projected to drop. And that is that Illumina fully anticipates an influx of upstream competition in the near future, which the evidence is going to show is coming and it's coming fast.

Moreover, Your Honor --

JUDGE CHAPPELL: Let me ask another question related to what I was getting at earlier.

How does it work -- and this is just baseline information for these markets. You told us that GRAIL actually has this test available today.

MR. MARRIOTT: Yes.

JUDGE CHAPPELL: Now, are they actually doing the blood analysis or does that go to someone like

LabCorp or Quest?

MR. MARRIOTT: Yes, they are doing the analysis, Your Honor.

JUDGE CHAPPELL: And is that their plan in the future, they're going to continue to do that?

MR. MARRIOTT: They operate a centralized lab, and they will continue to operate in that way in the future, to my understanding, Your Honor.

JUDGE CHAPPELL: All right. Thank you.

MR. MARRIOTT: You're welcome.

Moreover, Your Honor, on this point of supposedly raising rivals' costs and I think critically here, a rising rate -- a raising rivals' costs -- it's a mouthful -- a raising rivals' costs strategy, Your Honor, would not work because the GRAIL test is simply very different from the other tests in development.

A supplier can only divert sales by raising rivals' costs where the products involved are substitutable or relatively undifferentiated. If the products are not substitutes, then an increase in price of the one is not going to result in diversion to or from the other.

And here, as we intend to show, none of the downstream cancer screening tests mentioned by the FTC

is a substitute for Galleri. The tests in development again are far more likely to be used as complements than they are as substitutes.

JUDGE CHAPPELL: You said that earlier. Can you give us some more info on that? When you say "a complement" -- I think you told us GRAIL's Galleri tests for 50 cancers. By "complement" do you mean like another of these companies would test for something in addition to those 50?

MR. MARRIOTT: Yeah. What I mean, Your Honor, is simply that a person would want the benefit of both. The person would want the benefit of the test that screens for 50 cancers, that tells you tissue of origin, and lets you then take that information and do further things with it.

That's not going to foreclose that there may not be some advantage to a test that screens for, say, five cancers but has different specificity and different sensitivity and tells the physician, tells the patient something other than you can learn from doing the 50-cancer screening test.

So what I'm suggesting and what one of the MCED test developers' former executive said at his deposition -- and I can't reveal him because we're on the public record -- is that he would expect a patient

to want to use both of those things, that they're not competing for the same exact sale, they are -- complement each other. They build upon one another.

And that's what I think you'll hear, Your Honor, from the real experts who will talk about that, Dr. Cote and Dr. Abrams.

JUDGE CHAPPELL: All right.

MR. MARRIOTT: Okay. So, again, the tests are -- because the tests are complement, they're just not going to be used in a way that would permit the diversion strategy that the FTC is concerned about.

Moreover, Your Honor, Illumina will have we think no incentive to raise rivals' costs for additional reasons. Doing so wouldn't divert sales to GRAIL. All it would do is discourage sales of Illumina instruments and consumables.

What the evidence here is going to show is that substantial differentiation among these tests -- and this is along the point I was just making -- because of the substantial differentiation, the clinical value is going to be different for different patients. It's going to depend on age and personal and family and other characteristics.

More commercial entry by differentiated NGS-based tests will lead to more utilization of NGS.

The foreclosure of a differentiated MCED test wouldn't significantly divert sales to GRAIL because the products would have different clinical strengths, and so for that reason, the FTC's theory that foreclosure would be profitable for Illumina after integrating with GRAIL is we think undermined by both the fact that it would repress NGS sales and the fact that it would likely result in little to no diversion to GRAIL.

And in any case, Your Honor, Illumina's binding offer here removes any realistic prospect that the transaction will allow Illumina to raise costs to GRAIL's rivals. We've committed not to raise prices. We've committed to drop them. Customers are given the same pricing as GRAIL, and they're subject to all sorts of protections that certainly would not have existed in the premerger world.

So the FTC also says, Your Honor, that the transaction will delay or deny GRAIL rivals access to information and to cooperation and new technology. And that, too, we think respectfully is incorrect.

To begin with, the customer here doesn't really need the MCED test, so it doesn't really need extensive support from Illumina to develop an NGS-based test. They're doing that on their own.

Moreover, Illumina's service contracts guarantee technical support for Illumina's sequencing instruments. And of course, the long-term commitment otherwise provides guarantees that protect against the kind of things the FTC is concerned about.

So the cooperation theory of the FTC, Your Honor, is really focused on Illumina's clinical business, and as I've said, that is not the largest part of the company's business.

Illumina's clinical customers, they sell clinical products on two models that are relevant to this case, one a single-site model, which is an -- either an LDT, which is a laboratory-developed test, or a single-site premarket approval test, or it's a distributable kit, a distributable IVD, in vitro diagnostic test.

And the cancer screening field, Your Honor, is expected to run first on an LDT model -- that's what the Galleri test is -- and then, Your Honor, and only if and when FDA approvals are received, to run on a single-site premarket approval model.

Clinical customers operating under an LDT or a single-site premarket approval model, they can commercialize a test without any agreement with Illumina. And in fact, the vast majority of

Illumina's U.S. customers who market oncology tests do so very successfully, Your Honor, under a single-site model.

To the extent that customers want to distribute a test using an IVD model in the future, and that is not expected for years, Your Honor, but to the extent somebody in the future wants to do that, they would need to enter into an agreement with Illumina for limited additional support. But Illumina has entered into agreements with test developers in the past even where the contemplated product would compete with an Illumina product. And in any case, and in any case, it is worth noting here that the open offer provides people the right and opportunity to have these kinds of IVD agreements. That offer has been made.

So I won't dwell further on this at the moment, Your Honor, except to say on this question of support cooperation, there are specific provisions of the open offer that give assurances that people will get the same service received by GRAIL, that they will have access to the same sequencing instruments and consumables, that the company will enter into development agreements to optimize sequencing products.

And if somebody wants an IVD agreement, which again not -- not -- some years off, the company has agreed to a six-year open offer to enter into an IVD agreement for commercial IVD tests on standard terms.

You're going to hear from at least one witness who's an expert on this issue, Your Honor, Margaret Guerin-Calvert, one of respondents' experts. She'll tell you about the open offer. Specifically she'll explain that, in her view, it effectively addresses the concerns raised, that it provides clinical oncology customers with comprehensive, long-term protections against alleged -- the alleged foreclosure, and that it represents in fact a significant improvement over the status quo for customers.

So that brings us sort of finally here, Your Honor, among their theories to the idea that the transaction will harm innovation, and we think --

JUDGE CHAPPELL: Before you do that, getting back to some of my earlier questions -- and again, I haven't heard any evidence and I'm coming at this with an open mind, but I expect to hear evidence or have it in the record in this case, so we can do a thorough analysis of these markets, of completely -- everything about how this business model works, for example, with GRAIL, from the time blood is taken, what happens

during the next few steps, until there's actually a printout or a result of that test, because we're going to have to really drill down into this market and these business models.

MR. MARRIOTT: I totally agree, Your Honor, and I'm confident you're going to hear that evidence.

All right. So as I was saying, Your Honor, the suggestion here is that somehow this transaction will hamper or harm innovation. And respectfully, we think that's wrong. We think it's just the opposite. We think this transaction will help innovation. Far from discouraging it, we think it's going to increase interest in the field.

So since the reunion of Illumina and GRAIL was announced there has been significant interest in diagnostics, as evidenced by the number of transactions that have just been announced, Your Honor.

This chart lists selected M&A transactions announced since the announcement of the Illumina-GRAIL deal, and more than $11 billion in diagnostic transactions have been announced.

Now, some test makers the FTC says will suggest they're worried about the transaction. But we submit, Your Honor, that the actual investments when people are

speaking with their wallets and with their actions, they suggest instead great optimism arising out of this transaction and the markets it brings, not the pessimism suggested by the FTC.

The market capitalization, Your Honor, of the diagnostic companies identified by the FTC increased, interestingly, during the six-month period following the announcement of the transaction.

And just so, for example, Natera's market cap increased by 113 percent, and Exact's market cap increased by 68 percent during the six-month period after the announcement of the deal. And similarly -- and you'll see this on the right side of the table, Your Honor -- these same companies raised more cash in the six months after the announcement of the transaction than they did in the six months before. And that comparison I think as I said appears on the right side.

Not listed here but still worthy of mention, Your Honor, Singlera obtained $150 million in financing in December of 2020, primarily for early cancer screening product research and development, and Caris raised $830 million in May of 2021 to help launch an MCED test among other applications.

That investment has poured into the field,

Your Honor, is also evident from a review of the market and industry press. The FTC's suggestion that the transaction has scared away investors of a vertically integrated Illumina is I think not going to be supported by market evidence.

As I mentioned to Your Honor, the very formation of GRAIL is itself an example of the kind of innovation that can result from Illumina vertically integrating into a downstream marketplace.

You will recall that it was Illumina's acquisition of Verinata that led scientists at Illumina to discover that cancer could be detected from circulating tumor DNA fragments. The Verinata deal demonstrated the potential for that investment.

GRAIL was spun off to motivate the entrepreneurial spirit that created the product, and now that there is a product available, there are huge benefits to a merger that will allow the world to benefit from that product.

So in sum, Your Honor, we don't think the FTC is going to be able to show this transaction will harm innovation. In fact, Your Honor, the evidence will show that Illumina has made vertical investments before -- this is the reference to the NIPT Verinata -- and that the results, Your Honor, were what. They were

more competition. They were lower input costs. And they were a growing, thriving, new marketplace.

The FTC pointed to Verinata and NIPT in both in their papers and I believe this morning in their opening statement as evidence of Illumina having done bad stuff in the past and being some indication that Illumina is going to do bad stuff in the future.

What I think Your Honor is going to actually find is that the facts concerning the Verinata acquisition don't support the FTC's theory. They undermine it.

Since Illumina acquired Verinata, Verinata's share of downstream sales has generally declined. The prices that Illumina charges its NIPT customers have declined. Output of NIPT offerings has exploded, and there has been substantial new entry.

So the NIPT market, Your Honor, is I submit a thriving marketplace.

So we acknowledge, Judge, and I said this before, that there are some companies who have expressed opposition. You're going to hear from them. We think, however, that the evidence will show that those companies largely have an incentive to avoid competition with a strong GRAIL, not to promote it.

And as the Supreme Court has made clear,

antitrust law of course protects competition, not competitors. And neither those who prescribe or will prescribe nor those who use the Galleri test, Your Honor, are the complainers here. They know we think that this deal will save lives.

And I would submit that if physicians thought this deal would cost lives or raise prices or limit choice to patients that the FTC would have a different witness list than the witness list it has.

Moreover, Your Honor, a number of customers have in fact expressed support for this transaction, and I anticipate that you'll hear the views of some of those customers.

You will also hear, Your Honor, from two economists on behalf of respondents, both -- both are former chief economists of the Department of Justice. Both will speak in favor of the transaction.

One is Dennis Carlton. Dr. Carlton will tell you that vertical mergers generate efficiencies and are unlikely to cause significant anticompetitive harm except in narrow circumstances not present in this case. He'll tell you that Illumina's vertical acquisition of GRAIL is unlikely to result in a raising of rivals' costs and he'll tell you that it is unlikely to result in Illumina withholding key information or

expertise to foreclose or disadvantage GRAIL's rivals. And I think really importantly he'll tell you that the transaction will likely lead to significant efficiencies that will benefit GRAIL, GRAIL's customers, and patients.

Dr. Willig will tell you that the FTC has failed to reliably define the relevant product market, and he'll explore how the FTC's theories of anticompetitive effects are belied by the actions of market participants.

That, Your Honor, brings me to the efficiencies, which is the last piece that I hope to preview for the court.

So for the transaction to be illegal, Your Honor, as you know, any anticompetitive effects here have to outweigh the efficiencies. And if the efficiencies outweigh the anticompetitive effects, then the FTC's challenge fails.

There are we submit a number of procompetitive benefits to this transaction. I previewed them before. Let me briefly describe what the evidence is going to show as to these now.

To begin, Your Honor, the transaction will accelerate the adoption of GRAIL's test. And that's going to save lives.

As I mentioned at the outset, while Galleri is now available, it faces significant challenges, and I think you'll hear more about that from counsel for GRAIL.

The widespread adoption of the test, Your Honor, will require approvals from FDA, from CMS and from private payers. And GRAIL is going to face challenges in obtaining Medicare coverage for Galleri, and that's in part, Judge, because there are, as you probably know, statutory limitations that prevent Medicare from covering most preventative services, leaving only limited pathways that GRAIL can pursue.

And GRAIL will face challenges in obtaining private payer coverage for Galleri as well. The payers are likely to require very robust evidence of affordability and clinical utility for a novel MCED test.

And here, Your Honor, Illumina can make a unique contribution, a unique contribution in obtaining those approvals, which GRAIL we believe on its own will not be able to achieve in a timely enough way. Illumina has, in short, Your Honor, what GRAIL does not.

Among other things, Illumina has significant resources and experience in obtaining regulatory

approval. It has experience obtaining reimbursement for NGS-based products and partnerships with insurers. And it has the ability to run large-scale clinical trials and generate the clinical evidence that payers will require in order to cover the Galleri test.

We expect, Your Honor, to show that Illumina can accelerate the widespread adoption of this test, as I said, by at least a year, and it is that acceleration that will save thousands of lives.

Now, as I said, Your Honor, GRAIL was born of an R&D effort. You know, it arose out of Illumina's acquisition of Verinata. And we expect the same kind of efficiencies here from reuniting Illumina and GRAIL.

Reuniting Illumina's expertise in NGS with GRAIL's tests and machine learning is certain to lead to improved analysis and new insights. Whether it be -- whether it be Alzheimer's or any number of other possibilities, Your Honor, we expect great efficiencies to come from this transaction. Those efficiencies, you know, will come not only from working together but from internalizing the full benefits of investments by upstream and downstream entities.

As the court in the Deutsche Telekom case said, efficiency claims that are substantiated by

analogous past experience are those that are most likely to be credited. And that, Your Honor, is exactly what we believe we have here.

The transaction will also eliminate double marginalization or EDM, though I think that this is far from the great benefit of this transaction.

EDM, Your Honor, is an automatic benefit where an input product has a positive margin. It's a standard benefit associated with vertical mergers. It arises, Your Honor, because, premerger, vertically related firms each apply their own markups reflecting their own margins in pricing their products, and then both margins are incorporated into the final price that consumers pay for the product. By vertically integrating two such firms into one, the merged company is able to shrink that total margin, leading to lower prices for consumers.

And here, postmerger, Illumina will not treat the margin that it earns now on GRAIL purchases as a cost, and it will have an incentive to lower the price for GRAIL's tests. Illumina will have strong incentives we think to lower prices because those lower prices will increase the number of tests GRAIL sells, which will -- and Your Honor alluded to this before -- increase Illumina's overall profits.

We estimate these savings, Your Honor, in the hundreds of millions of dollars, and we think the FTC's claim that there will be no EDM here will be shown to be at odds with longstanding economic thinking.

In addition, Your Honor, to eliminating double marginalization, the transaction will eliminate the royalty that GRAIL owes to Illumina. Absent the deal, GRAIL would not owe Illumina -- would owe Illumina a roughly 7 percent royalty on all of its oncology tests.

Now, part of that 7 percent royalty, Your Honor, will be replaced by a contingent value right, a CVR. The CVR was a percentage of the net sales and was paid to shareholders as partial merger compensation or at least to some shareholders.

But the royalty eliminated from the supply relationship with Illumina is larger than the CVR percentage, so the net effect, Your Honor, is not a full elimination of the royalty but still a significant one.

And we estimate savings here of more than a hundred million dollars, and we estimate that those savings will be passed through to consumers and that consumers will be the beneficiary of those savings.

JUDGE CHAPPELL: Regarding the savings, I saw in the respondents' brief that the 12 percent interest, ownership interest, Illumina retained, you participated in profits of GRAIL; correct?

MR. MARRIOTT: That's correct, Your Honor.

JUDGE CHAPPELL: Were you also on the hook for losses?

MR. MARRIOTT: You know, that's a great question.

I don't think so, Your Honor. I think it was simply a -- I mean, we were in the sense that it was an ownership interest, so if the company performed poorly, then the value of the 12 percent interest would decline. Beyond that sort of sense of being on the hook, I don't think so, Your Honor, but I can confirm that for the court.

JUDGE CHAPPELL: Probably there will be some witness at this trial who could tell us that.

MR. MARRIOTT: I expect so, Your Honor.

JUDGE CHAPPELL: All right. Thank you.

MR. MARRIOTT: So we also think here that there will be supply chain efficiencies.

Illumina and GRAIL share a number of common suppliers. Combining the parties' spend under one supply agreement will reduce risk. It will reduce

supply costs. It will reduce lead times. And we think that Illumina can reduce GRAIL's spend on common suppliers by at least 5 to 10 percent, contributing cost savings of another 80 to 150 million dollars, and those savings too we think will be passed on to consumers and to customers and that they will be the beneficiaries.

Now, Illumina has you probably won't be surprised to hear, Your Honor, a very significant experience in running high-throughput, high-complexity laboratory services operations. It's been running -- it's been doing that since 2002. It has three clinical testing laboratories, two in California and one in the U.K.

And Illumina will share those competencies with GRAIL in order to optimize GRAIL's laboratory workflow, in order to reduce the time and cost entailed in hiring new skilled laboratory staff, and in order to reduce its laboratory costs, and we estimate that savings in excess of $50 million.

Finally, Your Honor, the combination here of these companies will accelerate the international expansion of GRAIL's test.

Why do I say that?

GRAIL has virtually no international presence

and no international expansion plans. By contrast, Illumina has boots on the ground across the globe. Illumina has platforms and tests registered in over 45 countries globally, and Illumina has substantial experience commercializing clinical tests internationally.

Illumina's global footprint, Your Honor, will significantly accelerate the availability of GRAIL's products outside the U.S., and we think it will do that by years.

And international acceleration here, Your Honor, will benefit not only patients in those foreign jurisdictions but also U.S. patients and also the U.S. healthcare system. And that's because the diverse datasets that are generated from testing patients in different regions of the globe can be used as evidence of additional clinical validation as part of GRAIL's FDA submission here and to demonstrate the economic benefits of Galleri to U.S. consumers.

Contrary to the FTC's contention, Your Honor, respectfully, we believe these efficiencies could not be achieved absent the merger. They are merger-specific. They will be the direct result of it.

Nor do we think they could be achieved by

contract. Illumina has never contracted to offer the benefits that it would provide here to GRAIL. Neither party in the past has or could be reasonably expected in the future to provide access to its most sensitive and important technology by way of contract.

If Illumina and GRAIL, Your Honor, could have already achieved these benefits by contract, then I submit to you that they would have done so. And tellingly, they have not.

In summary, Your Honor, the transaction here will result in substantial procompetitive efficiencies. These efficiencies will save lives by ensuring that Galleri is available sooner and at lower costs than would be the case without the merger. And the widespread adoption of Galleri as a result of the merger will catalyze we think the acceptance and access of other cancer screening tests, saving even more lives.

The FTC's case we think, respectfully, ignores the very substantial upside of reunifying Illumina and GRAIL.

Bottom line, Your Honor, this transaction will save lives, blocking it will harm consumers and patients, and we urge Your Honor when all is said and done, when all the evidence is in, to reject the FTC's

challenges.

Thank you very much, Your Honor, for your time and attention.

JUDGE CHAPPELL: All right. Counsel for GRAIL.

MR. MARRIOTT: Your Honor, we're going to just -- Mr. -- Mr. Pfeiffer is here, so we're just going to switch seats if that is okay.

JUDGE CHAPPELL: Okay.

(Pause in the proceedings.)

Scott, are you there?

SCOTT: I am here.

JUDGE CHAPPELL: I suppose I can wait for the respondent's attorney since this will be on the record.

Okay.

Are you with us, Mr. Pfeiffer?

MR. PFEIFFER: I am here, Your Honor, for -- my apologies. We're just taking one more moment or two to load my presentation.

JUDGE CHAPPELL: All right. You can hear me; correct?

MR. PFEIFFER: I can.

JUDGE CHAPPELL: Great.

Scott?

SCOTT: Yes, sir.

JUDGE CHAPPELL: There seems to be a problem with the AT&T line.

SCOTT: Okay. Let me --

JUDGE CHAPPELL: Someone somehow got through to my office and left a message that it dropped, the call dropped during opening statements, and I would like for you to have someone look into this, see -- and someone needs to be monitoring it, and if it drops, you need to let us know and we will pause.

SCOTT: Okay. Will do. I will reach out to them and find out what happened and -- yeah, in the past they'd already reached out to me if there was a problem, so I will reach out to them.

JUDGE CHAPPELL: I expect someone to be monitoring and I thought there was an AT&T representative --

SCOTT: They have a moderator -- yeah. I'm sorry to interrupt, but they have a moderator, so they should be paying attention.

JUDGE CHAPPELL: All right. You'll take care of it?

SCOTT: I will take care of it.

JUDGE CHAPPELL: Thank you.

Go ahead, Mr. Pfeiffer, when you're ready.

MR. PFEIFFER: Thank you, Your Honor.
Good afternoon.
May it please the court.
I am Al Pfeiffer of Latham & Watkins, and I wanted to deliver a limited opening statement on behalf of GRAIL. As we discussed before, I'm hopeful this will take only about a half an hour.
JUDGE CHAPPELL: And for planning purposes, those on the call and those on the Zoom platform, our plan is we'll take our lunch break when Mr. Pfeiffer completes because we need to transition to the first witness and that will be a good time for a lunch break.
Go ahead.
SCOTT: Your Honor, if I may interrupt -- this is Scott -- the public line is not in, so --
JUDGE CHAPPELL: Are you saying it's not working?
SCOTT: No. It's not in. It dropped, so let me --
JUDGE CHAPPELL: Which means it's not working.
SCOTT: Right. Exactly.
So I'm going to have to call out to them and find out what's going on, so if you need to take a, you know -- hold off for a few minutes, I can call them

right now.

JUDGE CHAPPELL: I would like to know how long it's been dropped --

SCOTT: Yeah, I will find out.

JUDGE CHAPPELL: -- and that it's not going to happen again and that someone who is supposed to be monitoring is monitoring it.

SCOTT: I will do all of those things.

JUDGE CHAPPELL: All right. Here's what we're going to do.

We've lost the public feed. We're going to take a break. And Scott, let me or my office know when this is fixed, and until then, I don't know if it will be a minute or longer, how long it will be, but we'll just take a brief recess.

SCOTT: Okay. Yeah. It probably will be I'm guessing about five minutes. Let me find out.

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

Off the record.

(Recess)

JUDGE CHAPPELL: Mr. Pfeiffer, proceed.

MR. PFEIFFER: Thank you, Your Honor.

I really hope everyone grabbed some lunch during that break; otherwise, they're really going to be eager for me to finish and shut up, but I will

still try to keep things to a half an hour, Your Honor.

I'm here to talk about this case from GRAIL's perspective. There's two fundamental questions that I really want to focus on from GRAIL's perspective.

First, why did GRAIL want to merge with Illumina? Why do we think that this merger is a good thing?

Second, who is it that's been opposing this merger and why are they really complaining about it?

And I want to start with the first question: Why did GRAIL merge with Illumina?

It's a logical question to ask from a certain perspective. GRAIL was an R&D start-up company, had a lot of buzz around them, a breakthrough product that's going to save lives. Why would GRAIL want to become part of Illumina, which is so much bigger and not just focused on R&D and not just focused on their product?

And the answer is pretty straightforward: Because GRAIL wants Galleri to succeed and to start being used and to start saving lives as quickly as possible. That is the GRAIL mission, Your Honor.

And the reason we're here today in this trial is because we have determined at GRAIL that combining with Illumina is the best and the fastest and the

surest path to get Galleri from where it is today, which is a great idea that works, but has no market presence, to one that is widely commercially accepted, to where Galleri is a test that doctors and Medicare and insurers know and trust and prescribe.

The beauty of this merger from GRAIL's perspective is acceleration, acceleration of that widespread commercial acceptance of Galleri.

Now, you're going to hear in this case about what it is that GRAIL does. You'll also hear testimony during the case, Your Honor, about what we don't do and what we need help doing.

Now, let's start with what we do.

GRAIL set out to develop and did develop a unique type of cancer tool.

And I want to emphasize a few things about Galleri, what it does, in these next couple of slides.

Galleri is a -- is designed to be and is a prophylactic blood test, so it's for people who don't know they have cancer, who don't have any symptoms yet. It's a way that you can bring a cancer screening benefit to populations that are at elevated risk for cancer in general, meaning, for example, people like me who are over 60. We're an elevated risk category. We can then with Galleri get tested as just part of an

annual physical.

By reaching people at a broad base at risk in that asymptomatic stage, Galleri will allow doctors to detect cancers earlier, and earlier detection just means more people live longer. That, I think everyone agrees about in this case.

The other real emphasis point about Galleri is that that's a remarkably noninvasive way to screen for cancer. It's just a simple blood draw. People already get blood drawn as part of every annual physical. It's just a normal thing.

There's no particular special preparation needed for Galleri. You don't have to fast or anything like that. There's none of the stress or the risk of a full-body PET scan or anything like that.

This is a great idea, a great product, but it was totally uncharted territory when GRAIL started out. No one was doing this.

Let's talk a little bit about Galleri's particulars because, as I said, it is an incredible breakthrough. It really is unlike anything else the oncology world had ever seen before.

Galleri very accurately screens for 50 or more cancers, identifies those cancers at an early stage, identifies the cancer location, which helps doctors

then inform their next steps in terms of treatment, and reduces the overall diagnostic workup costs by over 65 percent.

This is not pie-in-the-sky, aspirational stuff, Your Honor. This is not what GRAIL hopes to achieve with Galleri. You will hear in the evidence this already works today.

And doctors can -- in answer to a question you had asked earlier, Your Honor, doctors can prescribe it today in the real world. Nobody else can say that. No one else has any kind of multicancer screening test actually available for patients to use in the real world.

A key virtue of the Galleri test is not just that it screens for 50 or more cancers. It also tells where that cancer is located. And you'll see documents and hear testimony in the case referring to that variously as cancer signal of origin or sometimes tissue of origin.

A potential competitor who is going to testify in this case -- I won't identify them because we're on the public record -- they commissioned a survey that shows that doctors think that the signal of origin is going to be an important attribute when choosing a multicancer screening test, assuming someday more of

them are available. And that's just basic logic that that would be true because it informs how you treat the patient without requiring stressful follow-up conditions, stressful follow-up treatments like a full-body PET scan, for example, which at least some potential competitors will require.

How did we get to the point where we have Galleri?

You heard earlier today that the original discovery that led to the launch of Galleri and to the launch of GRAIL for that matter was unanticipated. It was a side benefit of work that Illumina and Verinata were doing in another testing field.

But GRAIL developing Galleri was no accident. That was not unanticipated. It was our mission. It took years of tremendous hard work to get there to the point where Galleri actually works.

Now, in addition to some really remarkably talented and dedicated people, that took a lot of money. GRAIL has been to the capital markets a number of different times already, as this slide depicts. And as we'll get to, that's not an easy process and it's not a bottomless well. You see the numbers there. You can add them up. When investors have put in well over a billion dollars into a company, they expect to

see commercial results to know when that's going to happen.

Now, you're also going to hear during the course of the trial about where that money has gone. And the answer basically is R&D, and much of that is related to the clinical trials that you heard Mr. Marriott refer to earlier that GRAIL has conducted over time.

Clinical trials are the backbone, the essential backbone, of developing a cancer screening test. You need to run clinical trials under carefully controlled conditions on large populations to make sure that the test actually works, to make sure that it is, in Your Honor's words, reliable.

GRAIL succeeded in putting together its first trial just a year after it was founded by Illumina, the CCGA study. It's done multiple studies since and the -- the encouraging results have been consistent throughout that testing process, so much so that now GRAIL has a version, version 2, of Galleri that is available to the public. And again, it's the only multicancer early detection test that a patient can actually get.

JUDGE CHAPPELL: What's the FDA approval status of that?

MR. PFEIFFER: Still very much in the works, Your Honor. I don't want to get into confidential details, but we have -- we have a ways to go. And you'll hear during the trial specifics about where we stand and feedback we've gotten from the FDA, but I don't want to disclose the details of that in this public setting.

JUDGE CHAPPELL: But yet a doctor can still prescribe or order the test if you request it?

MR. PFEIFFER: Yes, Your Honor. Yes.

They're -- and the specific type of FDA approval that we're talking about is what's called premarket approval. That's what we want to get for Galleri. That will allow for it to be marketed and -- and I guess most importantly, frankly, paid for by the payers in the healthcare system.

Without FDA approval of a PMA, we're not going to get to that kind of authorization, so that even though you could buy the test, it costs too much money for the vast majority of people to get because there's no reimbursement for it.

JUDGE CHAPPELL: Okay.

MR. PFEIFFER: So, Your Honor, one more point on this slide. While this slide cuts off in 2021, the required clinical testing does not. GRAIL still has a

lot more testing to do, and that is particularly true with the version 3 or V3 you may hear it referred to of Galleri. That's the version we're going to seek the FDA premarket approval on.

And this, this issue, getting FDA approval and getting it as soon as possible, is exactly the kind of area where Illumina's specialized expertise and their specialized infrastructure will accelerate us.

JUDGE CHAPPELL: Do I understand you to say this version 3 will be a new test, a different test?

MR. PFEIFFER: So not a different test, Your Honor. What we're doing with version 3 in the main, again without getting into proprietary details, is really two things.

One, we are trying to create more efficiencies in how we use some of the inputs, including the reagents, in order to drive the price down. And we're also trying to automate the process of its development much more, again to drive its price down.

In terms of the basic chemistry of the test, if that's the right bucket to put it into, it will be the same test.

JUDGE CHAPPELL: And I know we're in public, but I think I heard or perhaps the government said FDA approval was necessary for not only the test but for

the NGS as well that's involved in the test? Is that correct?

MR. PFEIFFER: No. Actually, that's not. You're -- there are certain circumstances where FDA approval of the NGS equipment would also be required, not for the way we plan to deploy our testing.

That would be much more in a situation what's called distributed testing, and that's -- we don't think that's even a feasible model in this, in this industry, and it's not the model we intend to undertake, so we will not be seeking distributed test approval.

JUDGE CHAPPELL: All right. So there is a type of approval, though, that would require approval of the test as well as the NGS platform?

MR. PFEIFFER: Yes. Although I think the evidence will show not one that applies to the multicancer early detection segment of the market.

JUDGE CHAPPELL: All right.

MR. PFEIFFER: Your Honor, I just want to talk briefly about what -- again, our focus in the case, much of it is going to be on acceleration, that merging with Illumina gives GRAIL the tools and the resources to get Galleri to the general public the fastest way possible. That's what we mean by

"acceleration."

Now, it is true, as I've mentioned and I know the government and Mr. Marriott have mentioned as well, GRAIL is definitely much further along than anybody else who's trying to develop this test. But -- but being ahead is not enough to get to where we need to get. Having a breakthrough product is not enough to get to where we need to get. Having a test that works today is not enough.

We need resources that we do not have. And GRAIL has determined that there's no better, surer, faster, more practical way to get those resources than this merger with Illumina.

I want to look at what some of the specific ways are in which Illumina will accelerate GRAIL's -- Galleri's availability compared to how quickly GRAIL could get there on its own.

We talked a little bit already about FDA approval. I don't want to belabor the point, but we will require FDA PMA approval in order to get to where we need to get. And that's an extremely complicated process, Your Honor, complicated in the best of circumstances, more so here because this is truly a first-of-its-kind product.

The FDA has never considered, much less

approved a 50-cancer screening test before. In fact, the FDA has never approved any kind of MCED test before, so GRAIL is heading into uncharted waters when it's dealing with the FDA on this. We don't know how complicated it's going to be. We just know it's going to be complicated.

And before the merger with Illumina, we were heading into these uncharted waters without really any meaningful experience dealing with the FDA.

That's not a hypothetical problem for us. You will hear in this trial in evidence that I will not get into the details of now but feedback that we've gotten from the FDA that indicates a lot more needs to be done.

Now, Illumina gives us the expertise, the actual experienced in the trenches employees, the internal FDA approval infrastructure that we lack, so that we can navigate that process faster.

And it's also important to note, Your Honor, that Illumina's FDA expertise and infrastructure, they come in the unique context of NGS-based testing, so it's exactly the kind of expertise we want. It's not just, sure, we know the FDA. They know the FDA in the context of this kind of testing. That's critically valuable to us.

Now, there's more standing in the way of us getting to commercialization of Galleri than just FDA approval.

And I know you saw a similar slide during Illumina's opening, so I won't belabor this.

But we also really depend on getting payer authorization. The insurers have to agree to reimburse patients for the cost of the test or it will have no impact on people's lives.

We know that with scale the cost is going to come down over time. But it's still going to be an expensive test, still probably going to be in the hundreds of dollars per test for the near-term future, so as a practical matter, most patients are going to need insurance coverage to get access.

This is another area, payer approval, where we don't have experience. We've not -- we're an R&D company. We've not dealt with this.

And as with the FDA, Illumina has real-world experience dealing with payers and the internal systems and the software and the templates that are set up to deal with them that GRAIL simply did not have. This merger will give us the benefit of that and will get us to authorization faster.

Now, you'll hear during the trial that

Illumina brings tremendous strengths in precisely the areas where GRAIL needs help.

It starts again with that experienced team of employees who know the tricky issues. They know the mistakes to avoid. They have relationships already with payers. But it is more than just people. And I know I alluded to this earlier, but I want to mention, there is an entire Illumina approval infrastructure that includes specialized software, specialized form templates, quality management systems that payers insist on and, as was mentioned earlier today, existing clinical sites across the country.

I'm going to avoid going into details now because we're public, but at trial we'll lay out specifics about how the lack of these kinds of advantages has affected us, including in our interactions with the FDA.

And the evidence is going to show that having Illumina's expertise and tools and infrastructure will accelerate Galleri.

Scale is another factor that's really a positive from this merger, Your Honor. Any company trying to commercialize a true multicancer screening test needs to find ways to drive down the cost of that test, because, again, the idea is for doctors to

prescribe it as part of annual physicals, not just after they're already symptomatic.

So it has to be priced at a level that it will make sense for insurers to say, yeah, make that part of a preventative checkup.

Again, prices are expected to drop. We're doing things in the development of the three of Galleri to get price down, but that's a real challenge for a small company. And you'll hear evidence about particular ways in which Illumina's scale and its deep financial backing will help GRAIL and accelerate Galleri.

There is more than just money that comes from what Illumina can give us. As we get into large-scale production, we need large-scale production efficiencies. That requires expertise in things like automated operations.

Many, many aspects of product delivery require automation or at least become much more efficient and therefore less expensive, driving down prices, if you've got automation. Manufacturing, packaging, testing, billing, all of these things can and should be automated.

We don't again have expertise at GRAIL with that. We're an R&D company. We're not a scale

company. We'll show evidence again when we're not on the public record that gives some of the details about how that affects us, some of the particulars, and how Illumina can accelerate us.

But the bottom line is, Illumina brings tremendous existing expertise in these areas that we don't have. This is not just a matter of money.

Now -- and I don't need to spend too much time on this because it's been talked about already, but another obvious benefit to GRAIL and Galleri that relates to acceleration of widespread acceptance of Galleri is eliminating the royalty that GRAIL used to have to pay to Illumina before this merger.

It amounts, as you saw earlier, to enough money to matter. And it's money that absent this merger GRAIL would have had to figure into the pricing of Galleri, which, all else being equal, would slow its uptake, would make it a less attractive product. Now we don't have to factor those savings into the price. We can pass them on to customers and have a lower-priced Galleri.

And again, all of the ways that the merger saves GRAIL money lead to acceleration of Galleri because the lower the price point of Galleri, the better and the sooner we can gain widespread

acceptance. The uptake is higher with lower prices. That's our incentive, is to get to scale.

And we project that by getting to scale sooner and therefore having greater availability of and use of the test sooner, we will save thousands more lives.

You will see in the course of the evidence that acceleration by just one year will save more than 10,000 lives over a ten-year period just here in the United States. And as you saw from the slide used in the Illumina opening, when you count the whole world in that, it's many thousands more.

That is again a nonmonetary benefit that is a tremendous benefit of acceleration.

This slide, Your Honor, really just sums up the things that I've been saying.

Illumina provides what we need in so many different areas: FDA and payer authorization expertise, the ability to scale, automation expertise, the international reach that we lack, the financial depth that we lack, and the supply chain savings. All of that gets us to the finish line faster and reduces prices, which builds on itself and also gets us to the finish line faster, and that saves lives, period.

Now, complaint counsel are going to argue in this case that the efficiencies that we've been

talking about, those benefits, shouldn't count here because they're not merger-specific they say, which means, in their view, that we at GRAIL could have achieved these benefits without the combination with Illumina.

And Your Honor, respectfully, that's just wrong. The acceleration of Galleri and the resulting saving of thousands of lives that we've been talking about is absolutely merger-specific.

The evidence will show you that no other practical alternatives exist that are going to accelerate Galleri's approval and commercial acceptance like this merger is going to do. That's the key point of this merger from GRAIL's perspective. No practical, real-world alternatives give us this acceleration.

And I emphasize the word "practical," Your Honor, for a reason. It's not enough for complaint counsel or their witnesses to come in here and hypothesize about other possible alternatives that might provide some benefits.

The agency's own Merger Guidelines make that clear. Speculation about hypothetical alternatives aren't enough. Alternatives must be practical to count. And to be practical, they have to actually

produce the benefits that we're talking about. And the main benefit here again is acceleration.

I want to look at some of the things that have been discussed in the course of the discovery in this case as potential alternatives and how the evidence is going to show none of them is a practical alternative.

And let me be clear with this first slide, Your Honor, dealing with IPOs. Of course, an IPO is possible. We're not suggesting that we can't do an IPO. We've looked into IPOs before, but we didn't do them. And it's because, as a practical matter, an IPO is not going to provide the acceleration benefits that this merger will do.

All an IPO is going to do is provide an initial infusion of cash, but it's not going to provide any expertise, any scale benefits, any infrastructure, any efficiencies. A one-time infusion of cash you're going to hear from the witnesses, Your Honor, is not the answer.

An IPO, even if it went well, wouldn't provide remotely enough money to get GRAIL to FDA approval, much less to commercialization, so in a best-case IPO scenario, we'd have to go back to other capital or debt markets to raise hundreds of millions more dollars to get where we need to go.

Even a successful IPO would also not give us the other benefits that this merger with Illumina provides. It's not going to eliminate double marginalization. It's not going to eliminate the substantial royalty you hear about. It won't give GRAIL the benefit of any of Illumina's in-house regulatory expertise or infrastructure or tools, won't provide the supply chain or automation cost savings.

An IPO is not a practical alternative to produce the benefits of this merger, even though of course an IPO can happen.

The same issues -- I'm not going to belabor this slide in the interest of time, Your Honor, but other capital market options are really the same story, only probably worse.

We've already been through four rounds of private investments. We've raised a lot of money. That's not a well you can go back to forever. But again, even if we had gone down that path successfully, it wouldn't have produced the benefits of this merger, no EDM, no elimination of the royalty, no supply chain efficiencies, and none of the efficient expertise, infrastructure, automation benefits that Illumina provides, so it's not a practical alternative to this merger.

There's also been at least some suggestion about whether GRAIL could have or should have simply merged with someone else.

As a starting point, Your Honor, I'm not even sure how to categorize the level of speculation that that entails since there's no evidence that any other potential buyer is out there that can offer the benefits that Illumina does. But even if one had existed, they still wouldn't have eliminated double marginalization. They wouldn't -- not only wouldn't have eliminated the royalty, but the royalty would presumably have affected the price that they'd be willing to pay for GRAIL, and they'd need to recover that cost in the pricing of Galleri.

And of course, no one has been suggested who would have Illumina's NGS-based testing expertise in the FDA and payer authorization sectors, and so all of those shortcomings mean this is not a practical alternative either.

There's been a suggestion, particularly from complaint counsel's experts, that Illumina and GRAIL do not have any merger-specific benefits because they simply could have entered into a different kind of contract instead of a merger to achieve these benefits. And this one, Your Honor, I think may be the

least practical of them all.

There's no real-world example of the kind of contract that they are imagining here and for good reason. Take it from GRAIL's perspective. To achieve real acceleration, GRAIL would need to disclose to Illumina the absolutely most sensitive confidential details about Galleri, including its proprietary artificial intelligence and its clinical test results. Companies in the real world just don't share that kind of sensitive information with their suppliers, especially when it's dealing with patient medical information.

From Illumina's perspective, there are different dilemmas that this imagined contract would present.

Illumina obviously couldn't offer this kind of contract to every customer. That's not its business model. It would have to become a totally different kind of business than it is.

But if it tried to offer this to just GRAIL, you'd be hearing others, other potential MCED makers who are Illumina customers, making exactly the same kind of complaints that they're making here, that it's wrong for Illumina to be favoring GRAIL, so this is -- this is not just a no-win situation. It's a null set.

There is no contract that would actually work as a practical alternative and give us at GRAIL the benefits that we get from this merger.

This one again I think is a related point. There's been a suggestion that the efficiencies are not merger-specific because GRAIL could just go out and hire consultants.

Again, it's certainly possible. I'm not suggesting that it is not a possibility to hire consultants, but it's not a practical alternative here because you can't hire consultants who have -- can bring to us the kinds of benefits that Illumina brings.

This is not a situation where Illumina is just providing us some outside advisors or just consulting on high-level strategy. That's the kind of stuff that consultants are good at.

Illumina is again providing us an entire team and infrastructure that is highly specialized to this industry, to NGS-based testing. Consultants -- you will not hear evidence of anybody identifying consultants who could match the offering that Illumina is providing to us and accelerate us the way this merger will.

Now, I've been talking about some of the

emphasis that complaint counsel has put on what I would call impractical alternatives to the merger, but I want to turn to the second question I asked before, Your Honor, and talk about who is it that the FDA was going to -- sorry -- the FTC is going to be putting forward as those who are objecting to this merger.

During the course of this trial, it will be clear who those companies are. It will be clear why they're complaining. And the bottom line is, what they want to do is slow GRAIL down because GRAIL is a better product, much closer to commercialization than anything they can hope to produce anytime soon.

But that's not a reason to slow GRAIL down. Slowing Galleri down will cost lives.

I want to talk a little bit about who you are going to hear from, but I want to point out who you're not going to hear from in opposition to this merger.

Complaint counsel argued earlier today that this merger was problematic in that it would reduce innovation in cancer screening and cost lives.

If that were so, you'd hear the actual constituents in the cancer community saying so, because they all want cancer screening and multicancer early detection screening to become a reality as quickly as possible.

But during this trial, you're not going to hear those constituents come in and say that the Illumina-GRAIL merger is bad for oncology patients or bad for the cancer screening industry. You're not going to hear that from the patients. You're not going to hear it from the doctors. There's someone going to be testifying from the American Cancer Society, and he's not going to say that.

NGS investors you've already heard about don't think that. They're investing in this sector.

Cancer screening investors don't think that. They're investing in this sector.

And payers aren't going to be coming in here and saying that either.

So there is no support for this notion that this merger will reduce innovation and slow people's access to treatment.

The parties who are objecting are not neutral parties. These are companies who hope someday to compete with Galleri. They are the definition of interested witnesses.

And I say that they hope to compete, Your Honor, for a reason, because there are no real competitors to GRAIL today, no real competitors to Galleri today, and it's at best unclear when there will

be.

Your Honor, I'm avoiding at this point trying to get into some of the details about what other putative competitors' capabilities are. We'll get into more of that when we're in sessions I imagine in camera. For today I'll keep it at a high level, but I'll do this by contrast.

Where we stand today is that Galleri is the only multicancer test that identifies anywhere near 50 different types of cancers and does so while identifying the cancer signal of origin, has been through validated testing, and is available for purchase today.

And you will hear from the various people who hope to be producing competing products confirmation of that. They will not be able to contest any of those things.

Now, you'll also hear from some witnesses at least during the course of this trial confirmation about the benefits of this merger that we have talked about.

This one is a public press release, so I think we can rely on it.

When Exact and Thrive merged, they talked about the benefits of their merger. And that merger,

by the way, took place after Illumina and GRAIL had announced this merger, and Exact still thought it made sense to pay a lot of money and buy Thrive. And when it did, they talked about acceleration synergies as exactly what they expected to see even in a horizontal context, so much the more so here in this vertical context where Illumina has such specialized NGS testing expertise.

These parties who are objecting, Your Honor, are not objecting because they're legitimately afraid of Illumina slowing them down. They are trying to slow Galleri down.

Slowing Galleri down to help Galleri's potential rivals is not the proper role of antitrust. Slowing Galleri down only costs lives. That's why, Your Honor, at the end of this case we will ask you to reject complaint counsel's claims and find they have not met their burden.

Thank you.

JUDGE CHAPPELL: Thank you.

Okay. We're going to take our lunch break that we were delayed by the technical problems earlier, so when we return, the government, I want you to be prepared to call your first witness.

We will take a break until 3:25.

We're in recess.

(Whereupon, at 2:18 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(3:29 p.m.)

JUDGE CHAPPELL: Okay, let's go back on the record.

Call your first witness.

MR. MOHR: Good afternoon, Your Honor. Steven Mohr on behalf of Complaint Counsel. Complaint Counsel calls as its first witness Dr. Christoph Lengauer, a partner at Third Rock Ventures and consultant to Thrive, a subsidiary of Exact Sciences.

JUDGE CHAPPELL: I don't see the witness.

MR. MOHR: My understanding is the witness was in the waiting room pending admission to the --

SCOTT: No. There is no one in the waiting room.

JUDGE CHAPPELL: I see two witness counsel. Is that correct, we need two?

MR. KELLEY: Your Honor, this is Derek Kelley representing Exact Sciences. Dr. Lengauer has an employment relationship with Exact Sciences but also Third Rock Ventures, so he's represented by two counsel, one in the Third Rock capacity, another on the Exact Sciences side, just to protect the confidentiality of the materials that belong to Exact Sciences.

JUDGE CHAPPELL: Okay. Can we have your names for the record?

MR. KELLEY: So this is Derek Kelly, D-E-R-E-K, K-E-L-L-E-Y. I'm with the law firm of K&L Gates, and I represent Exact Sciences, to which Dr. Lengauer is acting as a consultant.

JUDGE CHAPPELL: All right.

SCOTT: Your Honor, there is no one in the waiting room.

JUDGE CHAPPELL: Wait a minute.

Go ahead, Ms. Drake.

MS. DRAKE: My name is Ashley Drake from Goodwin Proctor, and I represent Third Rock.

JUDGE CHAPPELL: Okay. We have two counsel for the witness. Can one of you figure out where the witness is?

MS. DRAKE: Yes. I will do that now.

JUDGE CHAPPELL: Thank you.

(Pause in the proceedings.)

MS. DRAKE: I see him on the screen now.

JUDGE CHAPPELL: Let's do a sound check. Tell us your name, sir.

THE WITNESS: Christoph Lengauer.

JUDGE CHAPPELL: Susanne, please swear the witness.

Whereupon--

CHRISTOPH LENGAUER

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

JUDGE CHAPPELL: Go ahead.

MR. MOHR: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. MOHR:

Q. Good afternoon, Dr. Lengauer. Can you please spell your first and last name for the court reporter?

A. C-H-R-I-S-T-O-P-H, and my last name is L-E-N-G-A-U-E-R.

Q. Before we proceed, is there any reason you are unable to provide truthful and complete testimony today?

A. No, no.

Q. Dr. Langauer, who is your current employer?

A. Third Rock Ventures.

Q. What is Third Rock Ventures?

A. Third Rock Ventures is a venture fund that invests mainly in companies that we ideate and launch and build ourselves.

Q. What is your current position at Third Rock Ventures?

A. I'm a partner at Third Rock.

Q. How long have you been a partner at Third Rock?
A. Hmm, two or three years. Prior to that, I have been venture partner at Third Rock.
Q. What relationship, if any, does Third Rock have to Thrive, a subsidiary of Exact Sciences?
A. Thrive was ideated in the context of Third Rock, and then Third Rock invested in the Series A of Thrive, and several of the Third Rock individuals went into the company, including myself, in management leadership roles.
Q. And what is Thrive?
A. Thrive is -- was an early detection company that has been developing a test for multicancer, early cancer detection. Now it is as part of Exact Sciences.
Q. Approximately when was Thrive founded by Third Rock Ventures?
A. A little bit over two years ago.
Q. Do you currently perform any work for Thrive?
A. Yes. I'm a consultant to Exact Sciences, and in that role I oversee strategy at Thrive.
Q. And can you please describe your current responsibilities as a consultant and overseeing strategy at Thrive?
A. I'm part of the management leadership team of Thrive, and I'm involved in the progression of the

CancerSEEK test. That's our liquid biopsy test in product development.

Q. How many days per work do you perform work for Thrive?

A. It's approximately 20 to 25 hours a week.

Q. As a partner at Third Rock, were you personally involved in the founding of Thrive?

A. Yes. I'm a cofounder of Thrive.

Q. Did you hold any position at Thrive after it was founded?

A. Yes. I believe the title was chief innovation officer for most of the time.

Q. Can you describe what work you performed at Thrive when you served as chief innovation officer?

A. I was part of the management leadership team there as well. I oversaw the development of our liquid biopsy test. I was also involved in decision-making and strategy development of regulatory strategy.

Q. How long did you hold the position of chief innovation officer at Thrive?

A. From the beginning of the company throughout its acquisition by Exact Sciences.

Q. And approximately when was Thrive acquired by Exact Sciences?

A. Approximately 18 months or so after it being

launched.

Q. Before asking more questions about Thrive generally, I just want to ask a few final questions regarding your professional experience and education.

Can you briefly describe where you worked prior to joining Third Rock Ventures?

A. Yeah. I was chief scientific officer at Blueprint Medicines, a biotech company in the area of oncology drug discovery; and prior to that, I was global head of oncology research for Sanofi.

Q. Do you currently hold any teaching positions as a professor anywhere?

A. I have an adjunct associate professor position at Johns Hopkins.

Q. And can you please describe any graduate-level educational degrees you have earned?

A. Yeah, I have a Ph.D. in biology, which I got from the University of Heidelberg in Germany, and I hold an MBA degree that I got from Johns Hopkins.

Q. I would like to spend a few minutes just asking you some questions about Thrive generally. Is Thrive currently developing any type of cancer screening test?

A. Yeah. We are developing a test that we currently call CancerSEEK. It's a multicancer blood test for the detection of -- for the early detection of

cancer.

Q. Are you a member of any teams currently at Thrive related to the research and development of CancerSEEK?

A. Yes, we've got several teams. Of course, we call them the CancerSEEK leadership team, the CancerSEEK FDA team. Those are different board teams. There's the CancerSEEK LTD strategy team. I'm also a member of the strategy team of Thrive, which is called North Star, and several smaller, maybe less relevant teams as well in the development of the assay.

Q. Without going into any proprietary or confidentially sensitive details during this public session, can you please describe at a high level what Thrive's CancerSEEK test is?

A. Yeah, it's a -- first, it's a blood test, which means we look for certain biomarkers in blood that indicates the existence of cancer somewhere in the body.

Secondly, it's a multi-biomarker test, which means we are not looking at only one type of marker but several different biomarkers that are defined biologically or genetically.

And then thirdly, it's a test for the detection of most cancers, and that's why we call it a

multicancer test. That's in stark contrast to single organs test that only look for one particular organ. This is a test that is intended to detect all types of cancers.

Q. And without going into any confidential details right now, can you describe what types of organs CancerSEEK concurrently tests for?

A. In principle it can detect or test for all type of organs. We have shown there is -- for most of them, but in principle, it's made for the detection of basically all organs.

Q. In describing the test, you used the term "biomarker." What do you mean by the term "biomarker"?

A. A biomarker is some form of signature or fingerprint that one can deduct out of blood that indicates the existence of cancer. There can be changes in the DNA that is derived from cancer cells. It can be certain proteins levels. It could be other changes on the genetic information that indicates the existence of cancer.

Q. Dr. Langauer, are you familiar with the term "next-generation sequencing" or NGS?

A. Yes.

Q. What is next-generation sequencing?

A. It's a -- it's a term that we loosely use for

many types of sequencing efforts that either comprise bigger parts of the genome or some form of more massive sequencing in contrast to maybe just the detection of a small stretch -- one small stretch of DNA.

Q. Before you worked at Thrive, did you have any personal experience using next-generation sequencing technology?

A. Yeah. I had experience when we were developing cancer drugs at Blueprint, Sanofi, or Novartis, but I had significant hands-on experience when I was working at Johns Hopkins, where I spent about 12 years in a faculty role.

Q. And, again, without going into any competitively sensitive information during this public portion of the exam, can you explain whether the current version of CancerSEEK uses next-generation sequencing as part of its test?

A. Yep. It's using next-generation sequencing, um-hum.

Q. Can you describe at a high level how Thrive's CancerSEEK test uses next-generation sequencing to try to detect cancer?

A. Yeah. The detection of several biomarkers requires next-generation sequencing, and that might sound kind of optimistic. What that means is those

changes in the DNA are rare, because most of the DNA in blood is derived from normal cells. Therefore, there's just a very small amount of cancer cell and very small or very rare changes that we need to identify.

And one uses technologies that allow you to amplify those rare events, and in order to then make those visible, we need to apply next-generation sequencing in order to read out whether that DNA stretch is normal or it carries any changes that are coming from cancer.

JUDGE CHAPPELL: I have a question. If this is available now, currently, why is it called "next-generation sequencing"?

THE WITNESS: Hmm, that's a good question. I think the term came from a time where we aspired to develop new sequencing technologies, and we just thought or we as a community thought we will call that aspirationally the next generation of sequencing compared to what used to be the standard of sequencing. That name -- once this became reality, the name stuck, and now it's called next-generation sequencing.

JUDGE CHAPPELL: So if someone invents another generation, a better name has to be created, I suppose.

THE WITNESS: Yep. I guess that's sort of like one of those -- we do those things in science. We give

them funny names like, you know, playing with words and -- yes, that will be the problem of that next discoverer, um-hum.

JUDGE CHAPPELL: Thank you.

BY MR. MOHR:

Q. And, Dr. Langauer, in explaining the CancerSEEK test, you mentioned that there may just be a small amount of cancer -- cancer cell DNA in a blood sample. Can you describe how much or how little the amount of cancerous DNA that you are looking for in that blood sample when running the test?

A. Yeah. Techniques are so sensitive that we are limited by sort of -- by biology. What does it mean? We can detect one molecule of DNA in ten milliliter of blood. Of course, you know, that becomes stochastic, because the ten next milliliters might not contain any cancer molecules.

Therefore, biology becomes limiting. The technology is now so good that we can find that proverbial needle in the haystack because of the technologies that we just spoke about.

Q. I will ask you some more detailed questions regarding the specifics of the CancerSEEK test that involve material that's been designated in camera during the nonpublic portion of this, but I'd like to

move on.

When you were the chief innovation officer for Thrive, did you have any responsibilities related to the clinical and regulatory strategy for CancerSEEK?

A. Yeah, yes.

Q. And in your current role as a consultant to Thrive, do you have any responsibilities related to the clinical and regulatory strategy?

A. Yes.

Q. Has Thrive's CancerSEEK test been tested in any clinical studies to date?

A. Yes. We are in actually a very big, the biggest, the largest interventional, thus far only interventional study in the screening setting of a multicancer test, where we tested 10 -- approximately 10,000 women.

Q. And you used the term "interventional study." What do you mean by "interventional study"?

A. Interventional means that you actually get -- that you get the test, that you get the result, and then give those results back to the physician and the patient.

Q. And is this -- does this study that you're referring to, does it have a name that's been publicly disclosed?

A. Yeah. We called it DETECT-A.
Q. And what was the purpose of the DETECT-A study?
A. If you develop a multicancer test that didn't exist before, you have to sort of very careful -- progress very carefully. You like to understand its performance, which means its sensitivity and specificity, but also, most importantly, you need to get a good -- you need to get a good understanding about the safety of such a test because it didn't exist before.

And then, lastly, you need to understand how it -- how such a test integrates in the workflow of primary care physicians and how patients respond to that. Those are the three primary goals that we pursued in this DETECT-A study.
Q. Were the results of the DETECT-A study published in any peer-reviewed scientific journals?
A. Yes. We published the results of the DETECT-A study in one of the most prominent journals in life sciences called Science.
Q. Approximately when were the results of the DETECT-A study published?
A. Early summer last year.
Q. You described the goals of the DETECT-A study. What were the results of the DETECT-A study?

A. We got a good understanding about the performance of the test. It can be summarized by saying that we could -- this test now could double -- more than double the cancers detected by the test compared to the classical standard of screening methods.

We also could show that the test is very safe, the way we sort of integrated it in clinical care, but it had no impact on compliance to standard of care, which is very important from a safety perspective, and that it integrates well into the work flow of physicians.

Q. And in explaining the goals of the DETECT-A study, you mentioned the term "specificity." What did you mean by the term "specificity"?

A. Specificity is a measure that relates to how frequently one generates false-positives, or in other words, a false alarm; for example, if you were to say you have cancer, but it ends up being that there is no cancer.

Q. And was the specificity of CancerSEEK measured in the DETECT-A study?

A. It was approximately -- actually, a little bit over 99 percent, which is an important requirement for a screening test of asymptomatic individuals, which

means individuals that have no knowledge or prior knowledge of cancer.

Q. Why do you say that is an important requirement?

A. Yeah, the test is designed for individuals that are asymptomatic, which means individuals that would go to their annual exam, not that they have cancer by any means, and in that context get this test. In such a group it is very, very important that we are not causing false alarms because there are consequences.

If you were to have a positive test, then there is a followup, because you need to find those cancers. That might include interventional methods, like biopsies or other form of surgeries, all of which have some level or risk -- some level of harm or risk associated with them.

In an asymptomatic -- or maybe we call it in lay terms healthy population -- when you apply a test, it's extremely important that the false-positives that such a test cause are very, very rare.

Q. When explaining the goals of the DETECT-A study, you also used the term "sensitivity." What did you mean by the term "sensitivity"?

A. Sensitivity relates to how -- what -- what's the fraction of cancers that one can identify from all

the cancers that are out there in principle.

Q. Was the sensitivity of CancerSEEK analyzed in the DETECT-A study?

A. Yes, and it was measured in several ways, because you can do it as a -- you can make a measurement across all cancer types. You can make a measurement across -- like where you determine sensitivity for an interventional cancer type that relates to a certain organ, like breast or colon. You can measure sensitivity for those cancer types for which no standard of care screening methods exist, but you can -- the different flavors of that, we measure all of those sensitivities.

Q. And at a high level, how did this -- how did CancerSEEK perform in the DETECT-A study in terms of sensitivity?

A. CancerSEEK as a test is meant to be in addition to standard of care. That's very important. We want an individual to continue to comply with standard of care, like mammography or colonoscopy, and these tests should augment, which is an additional standard of care to detect cancer.

Today, only 25 percent of cancers can be detected by screening methods. 75 percent of cancers are detected by symptoms, signs and symptoms, which

means cancers are usually detected late. The outcome of our study showed that now 52 percent, which means -- of cancers can be detected by screening first, which means we can now double the numbers -- the number of cancers first detected by screening, which means cancer in most individuals can be detected now earlier.

Q. And you've referred to the term "standard of care screening methods." When you use that term, what are you referring to?

A. Standard of care screening means like screening methods that are approved and accepted in the medical field, and as it relates to screening for cancer, that's really 2 1/2 such tests. One is mammography, the second one is screening for colon cancer; and the third one is chromatography measures that are done for individuals who are heavy smokers -- that's why I referred to it as half -- heavy smokers in the context of the detection of lung cancer. All other organs -- cancers from the other organs have no standard of care screening methods.

Q. Subsequent to completing the DETECT-A study, has Thrive continued to work to develop CancerSEEK?

A. Yes. As with all the tests, even if the performance is outstanding, we were very, very happy with what we could show because it's unique, because

nobody has done this. It's, again, today the sole interventional study ever performed on earth.

Nevertheless, we want to always improve our test, and with that spirit in mind, we engaged in further improvements of the test while we are preparing towards a registrational trial. That's planned to come up soon.

Q. You mentioned a registrational trial. What do you mean by "registrational trial"?

A. Devices, tests, and so on seek usually or companies usually seek approval by the agency, in this case the FDA, that evaluates the benefit/risk ratio and with that sort of can give the approval stamp to a test. That's very, very important for acceptance of tests in the community.

It also is very often a requirement for potential reimbursement of the test, and for that you need to engage in what we call a registrational study, which is -- which the FDA agreed upon execution of a study, very much like the way we just talked about in the context of DETECT-A, but maybe a defined -- maybe it's a different patient population number that allows you to read out on those important endpoints like sensitivity or specificity.

Q. I'll ask some more questions related to the

registrational study during the in camera session to the extent it relates to competitively sensitive details.

You mentioned the FDA. Have you personally participated in meetings with the FDA regarding CancerSEEK?

A. Yes.

Q. Do you know if Thrive's CancerSEEK test has received breakthrough device designation from the FDA?

A. Yes, we have received that.

Q. What is a breakthrough device designation?

A. It's a designation that the agency can give if there is very strong medical need and where it would be beneficial to actually accelerate the potential approval of such a test for the benefit of patients.

Q. Approximately when did CancerSEEK receive breakthrough device designation?

A. I think the first breakthrough designation was received more than two years ago, and it was confirmed then in some other definition in a more broader way, so to speak. Maybe a year and a half or something like that ago.

MR. MOHR: Your Honor, the remainder of my direct examination covers subject matter that Thrive and Third Rock have identified as being proprietary and

competitively sensitive, including subject matter discussed in documents and transcripts that have been granted in camera status pursuant to this Court's order on August 19th. Therefore, I would request to move in camera at this time to complete the remainder of my direct examination.

JUDGE CHAPPELL: All right. At this time, we are going to go into an in camera session. Before we do so, 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'll need the lead or questioning counsel for each party to view the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there. If there is anyone who is not authorized to be in an in camera session, you are to instruct that person to use the raise hand function on the Zoom screen. Open Exchange will then move that person into a waiting room.

Go ahead.

SCOTT: Just to confirm, Roland and Steve, you will have to be moved over. Is that correct?

MS. GOSWAMI: Yes, that's right.

SCOTT: One second. This can take a moment.

Sorry, just give me a moment. Okay, Steve,

moving you over now. And, Roland, I'm moving you over now.

Is there anyone else?

MS. GOSWAMI: I'm just taking a look. I don't think that I see anyone else.

SCOTT: Your Honor, the only name I didn't recognize was a Mike Lyon from Illumina.

MS. GOSWAMI: Mike Lyon is our, you know, hot seat operator, so he's appropriate under the protective order.

JUDGE CHAPPELL: I believe he's approved.

SCOTT: Okay, thank you. I don't see anyone else, Your Honor.

JUDGE CHAPPELL: Scott, this is the first time we have done this in this trial. I see 53 participants. That doesn't indicate they are now in this room, does it?

SCOTT: There are -- the public -- minus the public line and the two people I just moved over, that would put us at 50. Yes, there's 50 people in here.

JUDGE CHAPPELL: And all of those people are supposed to be able to view the in camera session? I saw one just drop.

SCOTT: If anyone else knows that they're not supposed to be in camera, you can raise your hand.

There's a little icon at the bottom that says "raise hand," and I will move you, but I believe, Your Honor, that it's incumbent upon the lead counselors to identify, correct?

JUDGE CHAPPELL: Yes, and if that's been done, we'll now go into in camera session and proceed with questioning.

(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: At this time we will take a short break. We will reconvene at 6:00 p.m. We're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: All right. Is the public back online?

SCOTT: Nope, but I will -- they are now. One second, let me confirm that. Yep, okay. Let me bring those other two people back, too.

JUDGE CHAPPELL: All right.

SCOTT: One second, Your Honor.

Okay. Let me confirm everybody's on.

Okay, Your Honor. You are good to proceed.

JUDGE CHAPPELL: Okay. We are back on the record. We are back in public session. The in camera portion of the witness examination has now finished, at least at this point, and the public is back online.

Proceed with your cross exam, please.

MS. GOSWAMI: Okay, thank you.

BY MS. GOSWAMI:

Q. So, Dr. Langauer, I believe you testified earlier about the version of the CancerSEEK test that

was used in the DETECT-A trial. Do you recall that?

A. Yes.

Q. And the results of that trial, those were published in the Lennon paper from 2020. Is that right?

A. That is correct.

Q. Mr. Lengauer, Thrive has historically categorized the types of cancer by the primary cancer organ. Is that right?

A. Yes, it is.

Q. And in the DETECT-A trial, CancerSEEK showed the ability to detect cancer in ten unique primary cancer organs. Is that right?

A. Yes.

Q. And I believe you testified earlier that DETECT-A was a prospective interventional study. Is that right?

A. No. Of course, pros -- did you say prospective?

Q. Prospective. I probably mumbled. Prospective interventional study.

A. Yes. We are very proud of that, prospective interventional.

Q. And that means that it reported results to the participants in the trial, right?

A. Yes.

Q. And the participants in the trial, those were the 10,000 women that you referred to earlier.

A. Yes.

Q. And the verdict of CancerSEEK that was reported to those women was cancer or not. Is that right?

A. Yes.

Q. And I believe you testified earlier that for a multicancer screening test, a high specificity is extremely important. Is that right?

A. Yes.

Q. And the goal would be that the specificity of a multicancer screening test would be in the ballpark of 99 percent or more. Is that fair?

A. Yep.

Q. And the related metric to specificity is positive predictive value. Is that right?

A. Yes.

Q. And positive predictive value is the number that tells you that when -- in a population, when you say that you have cancer -- sorry, strike that.

So positive predictive value is when you get a positive result from a test, how many times those positive results actually have cancer, right?

A. Yes.

Q. And that's also an important parameter, right?
A. Yeah.
Q. And I think you talked a little bit about sensitivity earlier. Do you recall that?
A. Yes.
Q. And I think the examples that you have given before is if you have ten individuals with cancer and your test identifies three of those individuals as having cancer, the sensitivity of that test would be 30 percent. Is that right?
A. Yes.
Q. So those seven individuals, those would be, you know, false-negatives, at least according to that hypothetical test. Is that right?
A. Yes.
Q. So I spent a lot of time with your Lennon paper where I think you're an author. Is that right?
A. I don't know if you spent time on it.
Q. Sorry. I meant you're an author of the Lennon paper. Is that right?
A. Yes.
Q. And I prepared some demonstratives that take portions of the Lennon paper that I am going to go through with you. So if we could put up RDX 3-1, we can look at these demonstratives.

So this shows just the first page of the Lennon paper and then a flow chart that appears in the Lennon paper. Do you see that?

A. Yes.

Q. And don't worry, I am going to zoom in a little bit more so you won't have to read it quite so -- quite so small.

So the first step of the DETECT-A protocol was a baseline blood test. Is that right?

A. Yes.

Q. And the baseline blood test in the DETECT-A protocol was the CancerSEEK Alpha test. Is that right?

A. No.

Q. What was the baseline blood test in the -- in the DETECT-A trial?

A. The baseline blood test was part of the work flow that's shown here, the whole work flow together, that is CancerSEEK Alpha.

Q. So if we take a look -- actually, let's switch from the slides for a moment. If we look at RX 3419, which is Lennon 2020, we can look at the testing process, which I understand to be the work flow, and go to page 3 of that. So that's RX 3419-3.

So if you could zoom in on that Figure 1, so what you're saying is that CancerSEEK Alpha is the

entire work flow on the left. Is that right?

A. Yes.

Q. So there was a baseline blood test, and that was the first step. Is that right?

A. Correct.

Q. And then for individuals who had a positive baseline blood test, they then had a confirmation blood test. Is that right?

A. Yes.

Q. And in that confirmation blood test, such -- take a step back.

So the baseline blood test, that looks at those biomarkers that we talked about earlier, the sure variant biomarkers and the protein biomarkers. Is that right?

A. Yes.

Q. And in the confirmation test, there was another version of the biomarker test that was done, and then there was also what's called a CHIP test. Is that right?

A. Yes.

Q. And CHIP is a blood mutation that might cause, you know, false-positives in those biomarkers, right?

A. Yes.

Q. And so the CHIP test was done so that you could

rule out that some people were having an abnormal biomarker reading because they had CHIP, right?

A. Yes.

Q. And so if both the baseline and the confirmatory blood tests were positive, then the overall blood test was considered positive. Is that right?

A. Yes.

Q. And the participants with two positive blood tests were then reviewed by a multidisciplinary review committee as part of the trial. Is that right?

A. Yes.

Q. And at that point the multidisciplinary review committee recommended whether a full body PET-CT scan would be performed, right?

A. Yes.

Q. And that diagnostic full-body PET-CT scan was used to confirm the results of the blood testing and also to localize the potential cancer. Is that right?

A. Yes.

Q. And that's because with the blood tests, you don't know the location of the cancer, so you need to do the scan. Is that fair?

A. Yes.

Q. And so at least if you're doing a PET-CT scan,

the physician would then need to refer the patient to a radiologist to locate the cancer, right?

A. Say this again.

Q. I'm sorry. It was probably a very basic question.

So because you need to do a PET-CT scan, the physician would need to refer the patient to a radiologist --

A. Yes.

Q. -- to locate the origin of the cancer.

A. Yes.

Q. And in the DETECT-A study, the investigators recognized that a source of potential harm from this protocol was the radiation exposure from that PET-CT scan. Is that right?

A. No. I mean, we could determine that prior, right? You can calculate what that -- the dose of radiation is, and when we conceptualized the protocol, it was considered, and the institution approved that this was a safe way of going about it.

Q. I understand.

If we could just look at, in this document, page 9, which is RX 3419-9, and if you could just zoom in on the language that appears in the paper.

And so at least in the Science publication that

was done by the investigators, they recognized that another source of potential harm associated with the DETECT-A protocol was the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer. Is that right?

A. That is correct.

Q. And a diagnostic full-body PET -- you can take that down.

A diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT, right?

A. It depends on the machines, but roughly, yes, lightly.

Q. And in the Lennon article, the investigators recognized the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings. Is that right?

A. That is correct. That's why PET-CT is not approved as a diagnostic test, yeah, screening test.

Q. And even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. Is that right?

A. Which is normal, yes, um-hum.

Q. All right. So then turning back to the flow

chart in DETECT-A, if we could pull up RDX 3-2.

So if you look at the very top left corner, that's where it talks about how there were 10,000 participants in the DETECT-A trial. Do you recall that?

A. Yes.

Q. And just so -- at least I can't see very well -- I've prepared some slides that go through this flow chart, just zoomed in. So if we could turn to the next slide, which zooms into part of the flow chart, and do you recall that some participants were excluded from the trial for various reasons, so about 9,900 participants actually were tested with the baseline blood test?

A. Yes.

Q. And of those 9,900 participants, 9,421 had a negative baseline test, right?

A. Yes.

Q. And 4 --

JUDGE CHAPPELL: You are going to have to speak up louder when you answer. We can see you're saying yes on realtime, but people on the phone line cannot hear you.

BY MS. GOSWAMI:

Q. And 490 participants had a positive baseline

test. Is that right?
A. Yes.
Q. And so just roughly speaking, about 5 percent of the participants who took the baseline had a positive baseline. Is that right?
A. Yes.
Q. If we could turn to the next slide, which is RDX 3-4. So we talked about the work flow earlier and the 490 women who had the positive baseline were then asked to have the confirmation test. Is that right?
A. Yes.
Q. And of those 490, 214 of the participants were found to have CHIP in the confirmation test, right?
A. Yes.
Q. And that means that those participants were -- were excluded from the next step because they had this other blood mutation and were unlikely to have cancer. Is that right?
A. Yes.
Q. And 142 of those 490 were excluded because the confirmation test did not find the same abnormality in the biomarkers as the baseline. Is that right?
A. Yes.
Q. And so then there were 134 participants who had two positive blood tests and no CHIP. Is that right?

A. Yes.

Q. So then let's turn to the next slide. So then as we talked about, those 134 participants were then evaluated by the multi -- the multidisciplinary review committee. Is that right?

A. I'm not sure all of them, but, yeah, most of them, yes.

Q. And for seven of them, the multidisciplinary review committee concluded that they did not recommend followup. Is that right?

A. Yes.

Q. And for 127 of them, the committee recommended imaging. Is that right?

A. Yes.

Q. And also of the 127, 116 had that full-body PET-CT scan that we talked about earlier. Is that right?

A. Yes.

Q. And 11 of them had other imaging.

A. Is that a question? Yes.

Q. Yes. I'm asking you questions because you're the witness, so thank you.

So, then, just turning to the next slide, which ends in -- which is RDX 3-6, so then just looking through the 116 who had PET-CT imaging, so of those, 63

showed in the imaging that they were not concerning for cancer. Is that right?

A. Yes.

Q. And 64 showed imaging that was concerning for cancer, right?

A. Yes.

Q. And of those 64, 26 patients or participants were ultimately found to have cancer, right?

A. No.

Q. How many were found to ultimately have cancer of the 64?

A. I do not know exactly, but most of them. I think the mistake you made in the question was 26 individuals were identified whose cancer was first detected by the block test, compared to being detected by systems of other means.

Q. So I just want to go back to the full flow chart which is in the DETECT-A paper. So if we could go back to RX 3419 and just look at the flow chart. So if you turn to -- I believe that it is -- just one moment.

If you turn to page 5, so it's 3419-5, to look at the full flow chart. So if you could zoom into the bottom that we were discussing with Dr. Langauer, maybe look a little bit further. So if you look just at the

bottom boxes on the left, so it says 64 with imaging concerning for cancer. Do you recall that we discussed that?

A. Yes.

Q. And then do you see that there's an arrow that goes out to the right where it says 38 found not to have cancer?

A. Yes.

Q. And it says 38, no further testing and cancer not observed. Do you see that?

A. Yes.

Q. And then when you go down, it says 26 cancers first detected by blood testing?

A. Yeah.

Q. And so the way that we are getting to 64 is 38 of those people don't have cancer and 26 of them do have cancer. Do you see that?

A. Yes.

Q. And so does that refresh your recollection about what we were talking about with the flow chart, that --

A. Yes, it --

Q. -- 26 of them had cancer?

A. Yes. It is just that the 64 with the imaging, there were two groups, one with PET-CT and the other

one with different imaging, 53 and 11. That gets you to 64.

Q. Right. But all of the 11 by other imaging, they have cancer, and then you have 15 that have cancer that's found through the DETECT-A protocol that has PET-CT, right?

A. That is correct.

Q. Right? So it's 53 that goes to the 15, and then the 11 goes to the 11, and then you have the 38 found not to have cancer, right?

A. Correct.

Q. Okay, good. Glad I understand it.

So let's go back to RDX 3-6. So I think as we just talked about -- and obviously this has a little bit less information -- but there were the 26 where they are first detected by blood testing, and of those 26, there are 15 that were managed according to the full DETECT-A protocol that has the PET-CT scan, right?

A. Correct.

Q. So of the 490 baseline positive blood tests, of those, there were 26 cancers that were actually detected. Is that right?

A. Correct.

Q. All right. So let's turn back to the Lennon paper where I think that you guys did some statistics

with -- with these analyses. So if we could turn to RX 3419-8 and take a look at just part of Table 2, because I think there are a lot of statistics in there.

So if you could look at the top left corner of Table 2 -- yeah, no, no, that's good. That's good. Okay, thank you.

So I'm just looking at the baseline blood tests for -- for right at this moment, because there are a lot of statistics in here. So we talked a little bit about positive predictive value, right?

A. Yes.

Q. And positive predictive value is when you have a positive test, you know, how many of those people, you know, actually have cancer from the positive test. Is that right?

A. Yes.

Q. And just from the baseline test alone, it was found that, you know, just around 5.9 percent had had cancer in the group that had a positive baseline test. Do you recall that?

A. Yes.

Q. And then let's take a look at specificity, and, again, this is just the -- just the baseline test. So with specificity, you look at -- again, you're comparing the -- the number of people -- actually,

strike that.

Can you describe what the calculation is for specificity that's here?

A. It's how often you get your result right, which means, like, you know, that's basically the ingress of the false positives.

Q. So at least in the baseline blood test, the specificity for the trial was 93.5 percent. Is that right?

A. Yes. We set it that way. It's not that that's what it was. We purposefully set it that way.

Q. Understood.

So let's look at the line that talks about sensitivity, which has a couple different lines. So I think the most relevant one is the top one, which is -- which is all included cancer types. Do you see that?

A. Yes.

Q. And so just looking at the denominator here, 96 is the number of cancers that were found in participants in the DETECT-A trial. Is that right?

A. Yes.

Q. And of those 96, 29 were found using the baseline blood test. Is that right?

A. Yes.

Q. And so that's how you get to about a 30 percent

sensitivity, right?

A. Correct.

Q. All right. So let's turn back to a different figure in Lennon, which is Figure 3.

A. Can I say something?

Q. Can I finish this and then you can say it?

A. Yeah. I just want to clarify something.

JUDGE CHAPPELL: Go ahead and clarify, sir.

THE WITNESS: The baseline test is only part of the test, and we intentionally set ourselves the specificity at this value to cast a wide net. This is a research component of that test in order to better understand the potential of the individual biomarkers. Therefore, we call this test here by design a two-draw test, because we drew the blood twice. This you do only in settings where you develop a test and want to understand some of it better.

The questions -- and I think I just want to be not misunderstood -- the blood test without confirmation here does not relate at all -- at all -- to the performance of CancerSEEK Alpha. It only relates towards the numbers as far as that first casting wide net research component of the test is concerned.

I think this is very important, because one

could be misled by assuming that this is -- has any relevance to the performance of CancerSEEK Alpha, which it doesn't.

BY MS. GOSWAMI:

Q. All right. CancerSEEK Alpha, as it was studied in the trial, had two blood tests and also a PET-CT scan, right?

A. Correct.

Q. So let's turn to Figure 3 in the article, which is RX 3419-9. And so I think we talked about these -- these cancers earlier, but if we look at the one on the left, those are the cancers that are first detected by blood testing.

If we could just zoom in on the -- and so these are the cancers that are in that 26 that we talked about from the DETECT-A work flow. Is that right?

A. Yes.

Q. And so here I think I'm counting them correctly. So there were cancers in ten organs that were found using the full DETECT-A work flow. Is that right?

A. Yes.

Q. And I think, just so I'm making sure I'm getting it all right for the record, so there's appendix, breast, colorectal, kidney, lung, lymphoma,

ovary, thyroid, and uterine cancers. Is that right?

A. Correct.

Q. And there's also carcinoma of unknown, primary. Is that right?

A. Correct.

Q. Okay. So then I think we -- I think you mentioned earlier that there were 96 cancers that were detected in the study generally, right?

A. Yes.

Q. And that's because, you know, participants in the study, they were also continuing to get standard of care screening. They were also continuing to see their primary care physicians, so they might show symptoms and so forth. Is that right?

A. Yes.

Q. So why don't we turn to -- I think the rest of this figure, which is the right side of the figure, to look at all cancers identified in the DETECT-A study. Do you see that?

A. Yes.

Q. And so there are -- there are three different colors that are here, and maybe we need to zoom out a little bit -- well, I guess we can see it. So it says, "Proportions of cancers first detected by blood testing, proportion of cancers first detected by

standard of care screening, and proportion of cancers first detected by other means." Do you see that?

A. Yes.

Q. And so the green and the maybe white or light blue, those are the cancers that were not first detected by blood testing, right?

A. Correct.

Q. And so there are a couple cancers here that are just in -- in green or -- actually, I guess just in light blue. So we see that that's sarcoma, stomach, pancreatic, neuro-endocrine, bladder, bile duct, and liver cancer. Is that right?

A. I think you meant gray instead of blue. Maybe you can repeat your --

Q. Oh, I can say gray. Sorry, maybe I'm just bad at the colors. So the ones that are in gray were not detected by the blood test. So that's sarcoma, stomach, pancreatic, neuro-endocrine, bladder, bile duct, and liver cancer. Is that right?

A. Correct.

Q. So we can take that down.

So with cancer screening, there's always a trade-off between sensitivity and specificity, right?

A. Yes.

Q. So you select specific biomarkers that could be

used to detect additional cancers, but you wouldn't want to include all biomarkers because then your specificity may go, you know, way down from the 99 percent that you're targeting. Is that fair?

A. Yes.

Q. And so part of the reason why there might be cancers that are not detected by CancerSEEK is because you wouldn't have included, you know, all possible biomarkers, right?

A. Correct, part of the reason. Part of the reason is also that they don't shed into blood or there might be other reasons as well. Correct, yes.

Q. Right. So there will, you know, necessarily be cancers that won't be detected by CancerSEEK, right?

A. Or by any liquid biopsy, yes.

Q. So, Dr. Langauer, you testified in an FTC investigational hearing in March of 2021. Is that right?

A. Yes.

Q. And before giving that testimony, you met with the FTC four times. Is that right?

A. You know, I believe so. I do not recall the number.

Q. And you didn't meet with the -- with any representatives of Illumina or GRAIL before providing

your testimony, right?

A. I believe that's correct, yes.

Q. And have you met with the FTC since your investigational hearing?

A. I do not recall.

Q. Okay. So just to -- if I may, Your Honor, there -- there are some questions that we think that because the third parties' in camera motion was projected may be provisionally in camera, so unfortunately, I think we will have to go back on the in camera record just for the end of my questions, because I don't want to run afoul of anything that's still provisionally in camera.

JUDGE CHAPPELL: It's 6:36.

How much redirect do you think you'll need, Mr. Mohr?

MR. MOHR: Your Honor, less than ten minutes.

JUDGE CHAPPELL: All right. So based on the request, we are going back 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, verify that there are no participants in the

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

MS. GOSWAMI: I don't -- I'm just looking through the list. I don't think I see anyone there who should be taken out into the waiting room.

MR. MOHR: And, Your Honor, aside from the two people who raised their hand, I do not see anyone else either.

JUDGE CHAPPELL: Go ahead, Scott.

SCOTT: Your Honor, I am just looking for Steve so I can move him. One second, please. I have got him here. Okay, Your Honor. The public line has been moved and those two individuals have been moved.

JUDGE CHAPPELL: All right. 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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SCOTT: One moment, Your Honor, as we move them back in.

Okay, Your Honor, the public line is back in and those two individuals are back.

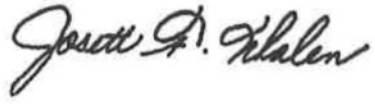
JUDGE CHAPPELL: All right. We have just finished the examination of this witness. Thank you, sir. You are excused. You may stand down.

We will continue with the Government calling your next witness tomorrow at 09:45. We're in recess.

(Whereupon, at 6:51 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

I, Susanne Bergling and Josett Whalen, do hereby certify that the foregoing proceedings were recorded by me via stenotype and reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that I am 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
August 25, 2021
9:52 a.m.
TRIAL VOLUME 2
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

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

APPEARANCES:
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C O N T E N T S

P R O C E E D I N G S

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JUDGE CHAPPELL: Do we have anything to address before you call your next witness?

MS. MUSSER: Not from complaint counsel, Your Honor.

JUDGE CHAPPELL: What's the mask update?

MS. MUSSER: I'm just going to be turning it over to my colleague and then we'll be mask-free the rest of the day.

JUDGE CHAPPELL: Okay. And that's within your guidelines?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right. Go ahead. Call your next witness.

MS. MUSSER: I'd like to introduce my colleague Nick Widnell, who will be calling our next witness on behalf of complaint counsel. Thank you, Your Honor.

JUDGE CHAPPELL: All right.

MR. WIDNELL: May it please the court.

Nicholas Widnell for complaint counsel, Your Honor.

Complaint counsel calls Dr. Matthew Rabinowitz.

And Your Honor, if I could just quickly

introduce Mr. Stephen Weissman, who is counsel for Dr. Rabinowitz.

JUDGE CHAPPELL: Okay.

MR. WEISSMAN: Thank you, Your Honor.

Steve Weissman. And with me today is general counsel, Daniel Rabinowitz, although I'll be representing Dr. Rabinowitz during the testimony.

JUDGE CHAPPELL: Okay.

I didn't hear -- when you called the witness, it was garbled, and I don't know if there's a connection problem.

Did everyone hear him clearly? I did not. I did not even hear the witness name.

Why don't we repeat that. Go ahead and call your next witness.

MR. WIDNELL: Sure. Yes, Your Honor.

Complaint counsel calls Dr. Matthew Rabinowitz.

Did you hear me clearly this time, Your Honor?

JUDGE CHAPPELL: Yes. And now she'll swear the witness.

- - - - -

Whereupon --

MATTHEW RABINOWITZ

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

DIRECT EXAMINATION

BY MR. WIDNELL:

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

A. Matthew Rabinowitz, M-A-T-T-H-E-W R-A-B-I-N-O-W-I-T-Z.

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

A. Not to my knowledge.

Q. Could you briefly describe your educational background.

A. I did roughly a year of university in South Africa at the University of the Witwatersrand.

I then transferred to Stanford University, where I studied electrical engineering and physics. I completed my undergrad physics and a master's in electrical engineering. I then completed a Ph.D., also at Stanford, in electrical engineering with a minor in aero/astro, aeronautics and astronautics.

Q. Thank you.

And who is your principal employer?

A. Natera would be my principal employer, but I have other employers now as well.

Q. Okay. And when you say "Natera," is that

Natera, Inc.?

A. Yes.

Q. Okay. And can I just refer to that as "Natera" going forward?

A. Yes.

JUDGE CHAPPELL: Who are these other employers?

THE WITNESS: I am committed to Natera now as executive chairman roughly three days a week.

I also work for a company called Myome, where I'm the executive chairman.

I also work for a company Themba, which is my own Series C corporation, which is the repository of intellectual property that I develop outside of Natera.

And I'm on the advisory board or a board member of a range of other companies, Your Honor.

JUDGE CHAPPELL: All right.

BY MR. WIDNELL:

Q. And how long have you been executive chairman at Natera?

A. Since the beginning of 2019.

Q. And before that, what -- did you hold a position at Natera?

A. Yes. I was the CEO.

Q. And were you also the founder or cofounder of Natera?

A. Yes.

Q. What are your current responsibilities as executive chairman?

A. I oversee and work with the company on a range of issues. I work on the technology, the strategy, key business development decisions.

As chairman of the board, I coordinate a lot of the board activities and work with Steve during the board meetings. Steve is the CEO.

I'm involved in most of the key issues that Natera needs to decide or strategize about, but I'm not involved as the CEO is in a lot of the day-to-day issues, such as, you know, HR, talking to investors at the same level. A lot of the day-to-day operations fall to the CEO and the chief operating officer.

Q. Thank you.

And when you were CEO, what were your responsibilities?

A. A similar set of stuff, except I am on the hook for all of the day-to-day running of the company, and as the CEO, the buck ultimately stops with the CEO. As executive chairman, I have opinions, but I very rarely, if ever, overrule the CEO because ultimately he's

responsible for the day-to-day operations of the company.

Q. And I think you've already briefly described your other -- the other positions that you've had with other firms.

Have you had any academic positions?

A. I have, yes.

Q. What positions have you held?

A. I was a consulting professor at Stanford University for eight years in the School of Engineering. And more recently, I was visiting faculty at Harvard in the genetics department.

Q. Thank you.

Now, I'll note that this is the public session and the questions that I ask I've tried to design not to elicit sensitive or confidential information. That said, I'll ask you to please let me know if you feel like your answer would need to involve confidential or sensitive information that you're not comfortable divulging in the public session.

Is that okay?

A. Yes. Thank you.

Q. Okay.

Turning to Natera, could you describe what Natera does.

A. Natera does advanced genetic testing, in particular genetic testing that focuses on extracting information from small amounts of DNA.

We have become the leader I would say in the United States in women's health genetic testing, which includes our flagship test, which is the noninvasive prenatal test, where you can do a blood draw early in a woman's pregnancy rather than do invasive tests that are risky to the pregnancy, such as amnio and CVS.

It also involves a series of other tests like carrier screening where one screens an individual or couple for inherited genetic conditions, like cystic fibrosis, and a series of other tests in women's health.

We also offer a number of tests in oncology, of which the key test is called Signatera, which looks at minimal residual disease in the cancer setting, where we design a customized panel to track the particular mutations that are associated with a particular patient's cancer, and we can monitor that patient for recurrence of that cancer. We can usually detect recurrence of cancers up to one or two years before you see clinical symptoms, and that covers the main cancers.

We can also monitor responsive therapy in

treating cancer, including with immunotherapy.

We're involved in a number of pharmaceutical trials, including late-stage III pharmaceutical trials with multiple big pharma.

And then the third leg of our business is organ transplantation where we can monitor patients for rejection of kidneys and now heart and other organs coming down the pike where you can manage the therapy that the patient is receiving far better than you could in the past.

Q. Thank you.

Let me turn first to the noninvasive prenatal test that you offer, which I believe you said is Panorama. Is that correct?

A. It is Panorama, yes.

Q. And when did Natera first launch Panorama?

A. I believe that was 2013.

Q. And is Panorama -- does it analyze DNA?

A. It does. It looks at small traces of fetal DNA from the placenta or from the fetus that are in the mother's plasma.

Q. So -- and what does the test actually sample?

A. It samples a blood draw from the mother's arm, and it isolates plasma from that blood draw and then looks at the DNA that's free-floating in the plasma.

Q. And at the time that you launched or that Natera launched Panorama, were there other companies that were also providing NIPT or noninvasive prenatal tests?

A. Yes, there were.

Q. What companies were those?

A. The main companies in the United States were Verinata that then became Illumina, a company called Sequenom, and a company called Ariosa.

Q. And then turning to the oncology test that you offer, Signatera, when did you start offering Signatera?

A. That started commercially roughly two years ago, but that was in development along with a series of other oncology tests for about six years.

Q. Thank you.

And could you just describe the process for Signatera in terms of how you test for cancerous tumors?

A. Absolutely.

There are other tests that are associated with Signatera, and we run a number of different tests in the research setting or in the RUO setting where it's not commercially available, but I will just describe the process that is particular to Signatera in the

standard commercial setting.

We initially start with a sequence of a patient's tumor or a biopsy that's taken from that tumor, and we typically run a whole exome sequence, which is looking at a large set of genes, more than 20,000 genes, on the actual tissue sample.

And from that large analysis of genes or all of the regions of the DNA that will be turned into genes by enzymes we can identify the mutations that are particular to that patient's cancer and we can differentiate those mutations from what is present on the patient's germline sample, which is the sample that is not from the tumor.

Based on analyzing that exome sequence and a set of mutations that we see, we will build a customized assay for that particular patient. And typically that involves 16 variants that we target.

The variants are selected based on how accurately we can build primers to target those variants, our estimation of whether those variants are homogenous throughout the tumor tissue or are just representing a subportion of the tumor heterogenously, and various other characteristics that make those good variants to target to monitor that patient's cancer.

Having gone through a series of algorithms to

pick those particular variants, we will design a PCR assay, which is the acronym for polymerase chain reaction assay, which enables us to take a plasma sample from the patient and then amplify the regions that are particular to those variants that we want to track.

And Natera has I would say the world-leading expertise in being able to target these smaller amounts of DNA from putting many PCR primers in a single reaction well where we can capture single molecules that carry mutations associated with cancer.

We amplify the DNA and then sequence the DNA and can identify the level of the cancer that is present in that patient's plasma and use that with very high sensitivity and specificity to track whether their cancer is present, to track whether the cancer is recurring, to determine whether that cancer is responding to therapy, and to identify particular biomarkers that you might want to address therapeutically.

Q. And what you've just described is -- would you describe that as a minimal residual disease test?

A. Yes.

Q. Okay. And do you use the term "MRD" as well?

A. Yes. And it can be used in -- it can be used

in other contexts, but it is typically used in the minimal residual disease context.

Q. And what you've just described, is the -- is that a tissue biopsy or is that a liquid biopsy?

A. It's a liquid biopsy.

We start off with a tumor sample, which is a tissue component, but then the analysis by Signatera is a liquid biopsy from a blood sample.

And I should mention that we also offer testing which is pure liquid biopsy where we just analyze the blood sample to characterize the tumor as well and can build Signatera off that. We currently offer that in the research setting.

Q. So, Dr. Rabinowitz, I think you had just described that there's also a Signatera version that is an all-liquid biopsy?

A. Yes.

Q. And I think you said that -- well, in what setting is that liquid biopsy used, the all-liquid biopsy?

A. There are a few settings in which we do a liquid version of Signatera.

We have offered a version where you can just evaluate the plasma instead of getting an actual solid sample from the tumor and run a whole exome on the

plasma and see the mutations across a whole exome that are visible in the plasma as differentiated from the patient's germline genetic sample and build a customized assay to track particular mutations that are identified from that plasma assay, which is all liquid.

In addition, we in research use a test where we can target a panel of mutations, for example, for colorectal cancer, where that panel of mutations covers more than 90 percent of the disease load for all colorectal cancer cases. And by targeting that broad panel of mutations we can catch the presence or the level of colorectal cancer in that patient without requiring an up-front tissue sample.

Q. Now, without going into any competitively sensitive or confidential information, I want to ask about any future plans that you -- that Natera has for Signatera that at least it has publicly announced.

Are there future plans to modify or offer additional versions of Signatera?

A. Yes.

We have talked about a number of offerings.

We have talked about offering Signatera with a larger number of variants, which we also do in the research setting.

We have talked about offering Signatera of different types of panels, which we currently do in the research setting.

We talked offering it off the whole genome, off the tissue sample, which we also currently do in the research setting.

And we've also talked about other offerings which I would characterize as confidential at this point because those are competitively sensitive I would say.

Q. Are any of the offerings that you are contemplating or in the process of developing -- do any of them involve testing for asymptomatic cancer, to the extent that you can answer that?

A. Yes.

The panel that I described that we currently are using in research in Natera's lab for colorectal cancer is exactly that technology, when you're targeting a fixed panel of variants that we have developed based on our own database of many sequenced tumors and the publicly available databases, and that is the technology that one would use to look at asymptomatic screening for cancers as well.

So we have made mention of our capability to target asymptomatic screening, and for about five

years, maybe more, since the IPO, we have talked about our ability to look asymptomatically at cancers and the size of market, for example, in breast cancer, ovarian cancer and lung cancer and now colorectal cancer as well. But we haven't made statements to the public investor market of exactly when that would be released and exactly what technology we have developed to target that.

Q. Thank you.

I will ask you more questions about this when we go into the in camera session --

A. That would be great. Thank you.

Q. -- but I -- I don't want to put you in a position where it's difficult to answer the question.

A. Thank you.

Q. In your role as executive chairman, are you involved with decisions related to seeking regulatory clearance for Natera's products?

A. I am. I oversee some of the regulatory decisions and activities, but I'm less involved than I was as CEO in the direct regulatory engagement.

Q. Okay.

With respect to Signatera's currently planned liquid biopsy MRD test, is Natera working to obtain FDA approval? And again I'm asking for just public

information at this point.

A. Yes, we are.

Q. What is Natera -- what kind of FDA approval is Natera seeking?

A. We are involved in multiple companion diagnostic trials with the top ten big pharma, and in order to be acceptable as a companion diagnostic that would be used together with a therapeutic, whether that's chemotherapeutics or immunotherapy, one needs to have FDA approval in the oncology space, which would typically be a high-level, namely PMA, FDA approval.

So when we work with the pharmaceutical companies -- sorry?

I'll keep going.

When one works with the pharmaceutical companies, one needs to take one's assay through the FDA and have it comply with all of the FDA quality control standards and validation standards, typically for a PMA, which is the sort of highest level of FDA authorization.

Q. And I believe you mentioned that this was in the context of offering companion diagnostic tests. Is that correct?

A. Yes.

There are other reasons that FDA authorization is helpful, but it is absolutely necessary in the context of companion diagnostics.

JUDGE CHAPPELL: We need to pause for about 30 seconds. I have a technical issue. Just hang on.

(Pause in the proceedings.)

Okay. Go ahead.

MR. WIDNELL: Thank you, Your Honor.

BY MR. WIDNELL:

Q. Dr. Rabinowitz, I had asked about a companion diagnostic test.

Could you just briefly describe what a companion diagnostic test is.

A. It's a test that is used in combination with a particular drug or immunotherapy, where it enhances the outcomes or changes the utility of that therapy based on using the diagnostic alongside that therapy.

Q. Thank you.

And I believe prior to that you had said that Natera is seeking a premarket approval from the FDA or PMA.

Could you just briefly describe the advantages to obtaining a PMA.

A. Well, in the context of companion diagnostics, you can't offer them without having a PMA from the FDA,

so it's fundamental.

In terms of advantages, when you have FDA approval of your technology, you have a substantial marketing advantage relative to other companies that don't have FDA approval, even if the FDA approval is not necessary.

And also, if you want to offer your technology as a kit where, instead of offering it out of your central lab or setting up other labs to use your technology and get their own validation, which is quite an extensive process, you can just offer a kit, and then labs around the world can offer your test out of the box in a kitted form. And in order to do that, we need to have FDA approval.

Q. Thank you.

And with respect to the PMA that Natera is currently seeking, has Natera made any public announcements about its efforts to obtain FDA approval?

A. I believe we have spoken about the efforts alongside the pharmaceutical companies in various earnings calls.

And then we have also received breakthrough status from the FDA across multiple indications with Signatera, so that breakthrough status indicates that

we are working with the FDA and the FDA wants accelerated approval for what they consider to be key technology.

I can't hear you.

JUDGE CHAPPELL: Scott, do you know what happened there?

JADA: This is Jada, your other operator. Scott is handling another tech issue in a different room, but I can go ahead and try to help here.

JUDGE CHAPPELL: Are you aware of the problem, we lost one of the parties?

JADA: That is correct.

Can you confirm the name?

JUDGE CHAPPELL: Josett, do you have his name?

THE REPORTER: I do, Your Honor. It's Nicholas Widnell with the FTC.

JUDGE CHAPPELL: There he is.

MR. WIDNELL: I'm back on. My apologies, Your Honor. I don't know exactly what happened, but it appears our phone connection got disconnected, so hopefully we should be back on and okay.

JUDGE CHAPPELL: Okay. Did you finish your answer to the last question?

THE WITNESS: I think so, Your Honor.

Nick, did you hear my answer?

BY MR. WIDNELL:

Q. I did not, but I could actually see it on realtime.

So you described I believe the breakthrough device.

Could you just describe what the breakthrough device program offers in terms of advantages.

A. When a technology is needing FDA approval or a company is working with the FDA, the FDA can grant breakthrough designation, which says that the technology is important, key technology which can substantially impact healthcare in the United States, and that will accelerate the processes of approval for that technology.

So that is a way that the information about Natera's engagement with the FDA with Signatera for various indications has been made public, because those breakthrough designations are public.

Q. Thank you.

And when we were talking about the potential different products that -- or innovations for Signatera that Natera is currently considering, I believe you -- you described an asymptomatic cancer test as one of them. Is that correct?

A. Yes.

Q. Has Natera assessed whether or not an asymptomatic cancer test would require FDA approval?

A. We have.

We have several conversations with FDA consultants on an ongoing basis, and our regulatory team involves people who are very close to the FDA or in some case have worked with the FDA as reviewers, so this is an ongoing process. And the answer is almost certainly an asymptomatic screen would require FDA approval.

Q. And why is that?

A. Because --

Q. To the extent that you can answer, I should --

THE REPORTER: One at a time.

THE WITNESS: Yes, I can talk about this. This is nonproprietary.

An asymptomatic screen which is offered to the general population typically involves more FDA oversight versus a test that is used in the context where a patient is already diagnosed with cancer.

When a patient is already diagnosed with cancer, there's a lot of involvement with doctors, and those tests can be offered out of a CLIA lab, which is the standard regulation in the United States, which is not requiring FDA oversight.

Natera, for example, is certified with CLIA, CAP and New York State, which are non-FDA bodies. But when you start to offer a test to the general population and at that level of broad screening, the FDA typically gets involved. And in this case, it's almost a certainty that they would want to have that asymptomatic screening test which could be offered population-wide go through a PMA.

BY MR. WIDNELL:

Q. Thank you.

I believe you described at least for your NIPT and Signatera tests that Natera effectively analyzes DNA.

Does Natera use a DNA sequencer to analyze DNA for those tests?

A. Yes.

Q. And what sequencer, to the extent you're comfortable saying in the public session, does Natera use?

A. For our commercial testing we use Illumina. We have performed research testing on a series of other sequencers, but Illumina is the only one that we offer commercially.

Q. And could you briefly describe the function the Illumina NGS sequencer performs for Natera for those

tests.

A. You want me to describe how it works at a high level?

Q. Precisely.

A. Okay.

Sequencing is a way of taking many fragments of DNA and telling you exactly what those fragments are made of, in other words, what nucleotides, A, C, T or G, go into those fragments. And when one does next-gen, high-throughput sequencing, one is sequencing millions of fragments and producing billions of data points.

For example, you know, one can do a run which has a hundred billion data points which is the information on what nucleotide, A, C, T or G, is on a particular sequence and what the sequence of nucleotides on each fragment is.

The way this works at a high level is you prepare the DNA. You put on sequencing adapters. It's basically a library preparation where you take the DNA that you've extracted from the sample -- Nick, if you're talking, I can't hear you. Should I keep going?

JUDGE CHAPPELL: We've lost him again. Hold on.

(Pause in the proceedings.)

SCOTT: I don't know if the FTC can hear me on their ends -- this is Scott with OpenExchange -- but you've muted the actual phone. I don't know if that's intentional or not.

MS. MUSSER: This is Susan from the FTC. If you could bear with us, Your Honor, I think we're just trying to figure out the tech issues, and we'll be back as soon as we can. We have tech support in here now. Our apologies. We're working on it.

JUDGE CHAPPELL: What are you anticipating? One minute? Ten minutes?

MS. MUSSER: I think five minutes, Your Honor, if that works. Could we just take a quick break. I just want to make sure that we can solve this and not have this happen again to disrupt the court.

JUDGE CHAPPELL: All right. Let's go ahead and take an unscheduled break. Let's -- we'll reconvene at 10:35.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Did you fix your technical problems, Complaint Counsel?

MR. WIDNELL: I believe we have. We've

effectively taken the phone line out of the process so that we're entirely doing audio through the computer, which hopefully should resolve this. I am very sorry for the inconvenience, Your Honor.

JUDGE CHAPPELL: Josett, can you hear him okay? The volume seems low.

THE REPORTER: It is a little low.

MR. WIDNELL: I can adjust that through the settings in Zoom. Let me see if that...

(Pause in the proceedings.)

Is this any better?

JUDGE CHAPPELL: Josett, is that okay?

THE REPORTER: I think so.

SCOTT: Yeah, I hear him perfectly fine, Your Honor. This is Scott.

JUDGE CHAPPELL: All right. Well, let him know if he needs to be louder or lean closer to the microphone.

Go ahead with your next question.

MR. WIDNELL: Thank you.

BY MR. WIDNELL:

Q. So, Dr. Rabinowitz, before this interruption, I believe you were describing how the NGS sequencer works for Natera's products?

A. Sure.

I was just saying that you extract the DNA from a target sample, and you then prepare the DNA for sequencing such as by attaching onto the tips of the DNA fragments sequencing adapters that allow the DNA to work with a particular sequencer.

You then hybridize the DNA onto a flow cell that is a part of the sequencing system. The DNA attaches to the substrate of the flow cell which has oligos or fragments of matching DNA that are designed to hybridize to the adapters that you've attached to the target DNA.

And once the DNA is hybridized onto the flow cell, a process is then undertaken called sequencing by synthesis, where you will add a particular nucleotide to the reaction, and the DNA that's attached onto the flow cell will be built up next to a matching fragment of DNA where the nucleotide that is added matches the nucleotide that is on that fragment that is attached to the substrate.

You design it in such a way that only one nucleotide can be added in each cycle, and the nucleotides have a fluorescent marker associated with them.

So, after each cycle, you add a nucleotide and you then take a photograph so that at each position

where the DNA has hybridized you can see what nucleotide attached to that piece of DNA.

Over a series of cycles where you keep adding a single nucleotide and keep taking photographs you will see the colors that the nucleotide is showing with a fluorescent tag indicating what the series of nucleotides is that makes up each fragment that is hybridized onto the flow cell.

And there are various techniques, by the way, for amplifying the DNA that is attached to the flow cell so that instead of just looking at one fragment, once that fragment has attached, you will replicate that fragment so you look at a whole cluster of copies of that fragment so you can get a clearer signal out.

And the ability to get a clear signal out is contingent on how dense you can make the flow cell, in other words, how many fragments of DNA you can hybridize and take pictures of as you are building up that matching copy nucleotide by nucleotide and get a good signal to figure out, you know, what DNA is there with very high density, which Illumina is, you know, by far the leader in.

Q. And just sort of order of magnitude -- I'm not looking for a very specific number, but roughly how many fragments are there on a flow cell for Illumina's

sequencer?

A. Well, it depends on which sequencer you use, but if you say that a sequencer can generate like a hundred billion data points, the flow cell is actually more than that now, but just using very rough numbers, and each fragment is roughly, say, a hundred bases, that would be about a billion or more fragments that hybridize initially and then get amplified in clusters.

Q. And would you describe that as reads per count, the number that you just were discussing?

A. That would be related to the number of reads that are on a flow cell. Yes.

Q. Are there specific -- to the extent that you're comfortable answering this, and please let me know if you aren't, but are there specific attributes for -- and this is really ideally at a high level -- are there specific attributes that Natera finds to be important for its DNA sequencers that it uses for its tests?

A. Yes.

The protocol that is typically undertaken with Natera's tests that target tiny amounts of DNA is we will extract the DNA from samples such as the plasma, we will then produce a library where you are making

multiple copies of the initial fragments or strands of DNA that are in the sample, and then we run that multiplex PCR assay that I was describing earlier, where you target particular regions of the DNA and in a single reaction you will amplify up all the regions that are particularly interesting.

Having amplified that up, you then run the amplified product on the sequencer to see what DNA you've got there.

When we put it on the sequencer, we are very concerned that the sequencer give us accurate information about those regions that we've targeted, so the sequencer has to be very accurate in saying what series of nucleotides constitute each fragment, and the sequencer needs to be stable.

In other words, we need to model the noise of the sequencer very precisely so that we can calibrate out that noise and kind of squeeze the last bit of blood out of the turnip by modeling the noise processes very precisely.

If the sequencer is accurate sometimes, not accurate sometimes, and has a variable noise model or run-to-run instability, that creates major issues.

In addition, we care about uniformity.

In other words, all the regions of DNA that we

want to look at should have a similar amount of sequencing. When you amplify a particular region of DNA, you want to get many reads that cover as many fragments as possible that come from that particular region of the chromosome.

If you have lack of uniformity in the sequencer, you'll get a lot of information about one region of the chromosome and much less information about another region, and the result of that is you have to do a whole lot more sequencing, because you want to get a minimum amount of coverage and the coverage is largely the richness of the data that you can get about what's going on at that particular region of the chromosome.

And then I think the last thing I'll mention is just the amount of data that you can generate. You know, especially for the oncology tests, you want to do as much sequencing as your costs will allow, because the more sequencing you do, the broader the things that you can look at, the better you are at capturing single molecules, and the better the sensitivity and specificity of your test.

So the more sequencing that one can do, the better performance of the test, especially in the oncology context, where you want to go down to sort of

single-molecule detection levels.

MR. WIDNELL: Thank you.

Your Honor, the remainder of my direct examination covers subject matter that Natera has identified as being proprietary and competitively sensitive, including subject matter discussed in transcripts and documents that have been granted in camera status pursuant to the court's orders on August 19 and August 25.

Therefore, I respectfully request to move in camera at this time for the remainder of my direct examination.

JUDGE CHAPPELL: All right. At this time we're going to go into in camera session.

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

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

If there is anyone who is not authorized to be in an in camera session, you are to instruct that person to use the Raise Hand function in the Zoom screen. OpenExchange will then move that person into a

waiting room.

Go ahead.

(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.)

JUDGE CHAPPELL: Scott, you don't need to connect the phone call. We're just going on the record to take a break.

SCOTT: Understood.

JUDGE CHAPPELL: What you can do, though, is when I announce the time we're reconvening, you can pass that time on to them and let them know at that time when we reconvene we will be in public session.

SCOTT: I will do that.

MR. WIDNELL: Your Honor, can I ask a quick question?

JUDGE CHAPPELL: Yes.

MR. WIDNELL: We got a different headset which I'm using now. Is this any better?

JUDGE CHAPPELL: It is better from my end.

MR. WIDNELL: Does this solve the problem from your perspective?

JUDGE CHAPPELL: It does.

MR. WIDNELL: Thank you, Your Honor.

JUDGE CHAPPELL: Josett, can you hear him okay?

THE REPORTER: Yes.

JUDGE CHAPPELL: Anyone have a problem hearing him now?

MR. MARRIOTT: I can hear him fine.

MR. WEISSMAN: Your Honor, I do have a question, though, when you allow me to ask it.

JUDGE CHAPPELL: Go ahead.

MR. WEISSMAN: I'm just wondering whether the examination of Dr. Rabinowitz is completed or whether there's going to be more after lunch on the public record, just so we -- he can plan his day.

JUDGE CHAPPELL: Mr. Marriott, do you have further --

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

JUDGE CHAPPELL: Oh, I was not under that impression.

So your entire cross was in camera.

MR. MARRIOTT: Correct.

JUDGE CHAPPELL: All right. You're finished with the witness.

MR. MARRIOTT: I am.

JUDGE CHAPPELL: We've had redirect and nothing further, so a very good question, Mr. Weissman.

And with that -- and we are on the public record at this time; right, Josett?

THE REPORTER: Yes, Your Honor.

JUDGE CHAPPELL: Okay.

So with that, Dr. Rabinowitz, you are excused. You may stand down.

THE WITNESS: Thank you very much.

JUDGE CHAPPELL: All right. At this time we're going to take our lunch break. We will reconvene at 3:35.

We're in recess.

(Whereupon, at 2:28 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(3:41 p.m.)

JUDGE CHAPPELL: We are back on the record. Call your next witness.

MR. STEBINGER: Thank you, Your Honor. Nicolas Stebinger for Complaint Counsel.

Complaint Counsel calls Mr. Christopher Della Porta, director of growth strategy for GRAIL.

Whereupon--

CHRISTOPHER DELLA PORTA

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

DIRECT EXAMINATION

BY MR. STEBINGER:

Q. Good afternoon, Mr. Della Porta.

A. Good afternoon.

Q. Would you please spell your first and last name for the record.

A. Christopher, C-H-R-I-S-T-O-P-H-E-R, Della Porta, D-E-L-L-A, P-O-R-T-A.

Q. Thank you.

Now, you're currently employed by GRAIL, correct?

A. Correct.

Q. Your current title is director of growth

strategy?
A. Yes.
Q. You've been director of growth strategy since September of 2020?
A. Yes.
Q. Before that, your title was associate director of product marketing?
A. Yes.
Q. Before that, you were senior manager of product marketing.
A. Yes.
Q. Prior to that, you were product marketing manager.
A. Yes.
Q. Product marketing manager was the title you held when you joined GRAIL, right?
A. Yes.
Q. And that was in 2016?
A. Yes.
Q. First I want to talk with you about your role in connection with GRAIL's growth strategy. As GRAIL's director of growth strategy, you report to GRAIL's chief commercial officer, correct?
A. Yes.
Q. And that is Gautam Kollu?

A. Yes.
Q. Now, GRAIL has a growth strategy team, right?
A. Yes.
Q. And you actually founded GRAIL's growth strategy team.
A. Yes.
Q. GRAIL's growth strategy team reports to you.
A. Yes.
Q. You're involved with planning for the growth strategy team?
A. Yes.
Q. One purpose of the growth strategy team is to develop new channels for the sale of Galleri, right?
A. Yes.
Q. Just so that we're all on the same page, what is Galleri?
A. Galleri is GRAIL's multicancer early detection test.
Q. Thank you.
So developing new channels means strategically evaluating potential customers for Galleri, correct?
A. Yes.
Q. This role of the growth strategy team is by design exploratory, right?
A. Yes.

Q. But beyond just exploring, GRAIL's growth strategy team also -- sorry. GRAIL's new channels work also involves actually approaching potential partners for the sale of Galleri, right?

A. In certain cases, yes.

Q. And so potential sales channels for Galleri include physicians, correct?

A. Yes.

Q. A subset of physicians, concierge physicians, right?

A. Yes, within the physicians group.

Q. Another channel is health systems?

A. Yes.

Q. Now, GRAIL has a separate health systems team, right?

A. Yes.

Q. It's separate from the growth strategy team.

A. Yes.

Q. The health systems team is responsible for establishing relationships with health systems, right?

A. Yes.

Q. A health system is a healthcare delivery organization, correct?

A. Yes.

Q. Often it will have hospitals, clinics, and

physicians associated with it, right?
A. Yes, that's right.
Q. Providence St. Joseph is an example of a health system, right?
A. Yes, I would say so.
Q. Providence St. Joseph is often referred to as Providence for short, right?
A. Yes.
Q. And GRAIL has secured a partnership with Providence, right?
A. Yes.
Q. So Providence has agreed to offer Galleri to its patients.
A. Yes.
Q. And GRAIL's health system team is also in conversations with other potential health system partners.
A. To my knowledge, yes.
Q. All right. Another channel for the sale of Galleri is employers, right?
A. Yes.
Q. The employer channel includes self-insured employers, right?
A. Yes.
Q. And so self-insured employers are employers

that are responsible for the healthcare costs of their employees, right?

A. To my understanding, yes.

Q. And GRAIL has an employer partnership team tasked with establishing relationships with employers, right?

A. Yes.

Q. That team is separate from the growth strategy group.

A. Yes.

Q. It's a subteam within the market access group.

A. Yes.

Q. You also have worked on securing deals with customers in the life insurance channel.

A. Yes, the early stages of that.

Q. Another potential channel for the sale of Galleri is imaging manufacturers?

A. We explored it. It's unlikely that it's a channel for sale, but potentially other types of partnerships.

Q. And what sorts of partnerships?

A. Comarketing is one example.

Q. Other examples?

A. None at the moment.

Q. Okay. So GRAIL's growth strategy group has

explored comarketing arrangements with imaging manufacturers.

A. Is exploring, yes.

Q. All right. And so those are some examples, but there are other potential sales channels for Galleri, right, that the growth strategy group is exploring or has explored?

A. Yes.

Q. Okay. We will come back to that in a bit.

Now we talked about groups other than the growth strategy team that are responsible for establishing customer relationships for GRAIL. One of them is GRAIL's sales team, right?

A. Yes.

Q. There are about 30 to 40 people on GRAIL's sales team.

A. Yes.

Q. The sales team is involved with direct sales to physicians.

A. Yes.

Q. And we also referenced the market access team. GRAIL's got a market access team, right?

A. Yes, it does.

Q. And the market access team is responsible for the relationships with employers, payers and health

insurers, right?
A. Yes.
Q. Now, like the growth strategy team, the sales team, the market access team also are within GRAIL's commercial group, right?
A. Yes.
Q. And so they also report to Chief Commercial Officer Gautam Kollu, correct?
A. Yes.
Q. All right. Now I want to move to some of your work in connection with the launch of Galleri. First of all, GRAIL has launched Galleri for sale in the United States, right?
A. Yes.
Q. That was in May of 2021?
A. Yes.
Q. GRAIL had a launch readiness team in connection with the launch of Galleri, right?
A. Yes, it did.
Q. The launch readiness team was a cross-functional team.
A. It was.
Q. And I think we will be hearing those words "cross-functional" a bit. So to be clear, cross-functional, that means that the team has

representatives from different functions within GRAIL, right?

A. Yes, that's right.

Q. Functions is how GRAIL refers to business divisions within the company, right?

A. Yes. That's one way to define it, yes.

Q. So, for example, there's the commercial function?

A. Yes.

Q. What are examples of other functions within GRAIL?

A. Clinical development, operations, legal.

Q. Thank you.

You yourself were the facilitative lead for the launch readiness team, right?

A. Yes, that's how I would describe it.

Q. And so you managed the other team members in their cross-functional roles.

A. I didn't manage what they were doing or their objectives, but I brought them together for information-sharing.

Q. All right. Now, talking about the launch of Galleri, the growth strategy team itself was also involved with tasks relating to the launch of Galleri, right?

A. Yes.
Q. In particular, the growth strategy team was tasked with securing initial concierge physician customers.
A. Yes.
Q. What are concierge physicians?
A. They are physicians who in general have a membership fee for access for their patients, and some take insurance, some do not, and so they have smaller numbers of patients typically and tend to be early adopters of new products that their patients are interested in.
Q. So concierge physicians tend to be early adopters of new products that their patients are interested in, right?
A. That's what we learned from market research with them.
Q. Okay. And I think you read my mind. Your team conducted market research with concierge physicians, right?
A. We did in 2020, yes.
Q. All right. And the point was to try to assess their interest in Galleri before Galleri's launch, right?
A. Yes.

Q. The research included interviews with concierge physicians, right?

A. Yes.

Q. And these interviews with concierge physicians were -- they took place at the direction of GRAIL's chief commercial officer, Gautaum Kollu, right?

A. Yes.

Q. And you yourself participated in some of these interviews.

A. Some, yes.

Q. And based on the market research that your team did, you believed that concierge physicians were likely to adopt Galleri.

A. Some of them, yes.

Q. And we will come back to that in more detail in a few moments.

And so in addition to market research, your team pursued deals with concierge physicians, right?

A. Yes.

Q. Before reaching out to concierge physicians to try to conclude these deals, the growth strategy team did some preparation, right?

A. Yes.

Q. The team was trained by the -- by GRAIL's medical affairs and science liaison teams, right?

A. To a certain extent, yes.
Q. To get up to date on the latest publications, right?
A. Yes.
Q. Relating to GRAIL -- to Galleri. Excuse me.
A. To Galleri, yes.
Q. And the growth strategy team also developed a slide deck that described Galleri, right?
A. Yes.
Q. To establish commercial relationships with concierge physicians, the growth strategy team started out with simple cold calls, right?
A. Yes, that was one way. The other was introductions.
Q. And in the end, your growth strategy team successfully executed deals with a number of concierge physicians.
A. Yes, around 15 or so.
Q. Right, about 15, including the two largest concierge networks in the United States, right?
A. Yes.
Q. Representing over 500,000 patients.
A. Yes. At their maximum, yes.
Q. Okay. I'm going to come back to the growth strategy work in a few moments, but now I'd like to

talk briefly about your background in GRAIL's competitive intelligence work.

So, first of all, GRAIL has a cross-functional competitive intelligence team, right?

A. Yes.

Q. And the competitive intelligence team was at one time called the CIA team.

A. Yes, it was.

Q. You were previously a member of the competitive intelligence team.

A. Yes.

Q. And you were actually tasked with forming the competitive intelligence team.

A. One of a few, yes.

Q. And so you did establish GRAIL's competitive intelligence team.

A. I was a part of that, yes.

Q. All right. That was in 2018.

A. Yes, I believe so.

Q. For a time, you were the co-lead of GRAIL's competitive intelligence team.

A. Yes.

Q. The other co-lead was a GRAIL employee named Vasiliki Demas. Is that right?

A. That's right.

Q. Ms. Demas also goes by Vicki?
A. That's right.
Q. Okay. During your time with the competitive intelligence team, sometimes you would devote as much as 50 percent of your time in a given week to competitive intelligence tasks.
A. In a given week, yeah. I would say, averaged over the year, it was probably more like 5 percent, something like that. It was very spikey.
Q. Spikey. But at times, as much as half of a given week to be devoted to competitive intelligence work.
A. Yeah, maybe one or two weeks a year, something like that.
Q. All right. And you yourself were involved with collecting commercial information during your time with the competitive intelligence team.
A. Yes.
Q. As co-lead of the competitive intelligence team, you also had a facilitative role.
A. Yes.
Q. As co-lead of the competitive intelligence team, you also responded to specific requests for information from leadership.
A. Yes.

Q. You were involved with GRAIL's competitive intelligence team until the first half of 2021, correct?

A. More -- more like the end of 2020, but roughly, yes.

Q. Well, 2020 or 2021?

A. I would say January of 2021.

Q. All right. And so when you transitioned away from the competitive intelligence team -- well, backing up -- sorry.

When you founded the competitive intelligence team, it had about five people on it.

A. Roughly, yes.

Q. And when you transitioned away from the competitive intelligence team in the beginning of 2021, there were about ten people on the team, right?

A. Yes.

Q. Now, talking about the team's role, the competitive intelligence team's role was to monitor industry developments that were relevant to GRAIL, right?

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

Q. So you would survey the scientific landscape in the context of cancer screening and related technologies.

A. Yes.
Q. You would also survey the commercial landscape in the context of cancer screening and related technologies.
A. To the extent it existed, yes.
Q. While you were co-lead of the competitive intelligence team, it produced various work product, right?
A. Yes.
Q. Some of that work product was shared within GRAIL.
A. Yes.
Q. Examples of that work product would be updates from conferences, right?
A. Yes, that's one example.
Q. Could include profiles of particular companies of interest?
A. Yes.
Q. Could include profiles of technologies of interest?
A. Yes.
Q. The work product would also include slides or presentations?
A. Yes.
Q. Reports?

A. Yes.
Q. Sometimes you would create work product specifically for GRAIL's chief commercial officer, Gautum Kollu.
A. Yes.
Q. And Mr. Kollu you would occasionally take the competitive intelligence team's slides to share with GRAIL's board of directors.
A. That's my understanding. I didn't have any personal experience with that, but yes.
Q. The competitive intelligence team's work product would also be used by the finance teams at times?
A. To my knowledge, they would receive it, some of the products. I didn't have experience with them using it or how they used it.
Q. The competitive intelligence team's work product would also go to the -- to GRAIL's investor relations team.
A. Yes. They were on the receiving list.
Q. Because of these various uses of the competitive intelligence team's work product, the accuracy of the information was important to the competitive intelligence team.
A. Yes. Accuracy was important to the extent we

could verify things.

Q. Well, accuracy was one of the competitive intelligence team's goals.

A. Yes.

Q. The competitive intelligence team also tried to present information that was up to date.

A. Yes, to the extent that was possible.

Q. Thank you.

And, Your Honor, at this time I plan to address information that Respondents had previously designated for in camera treatment, and I understand that the Court has denied Respondent -- particularly GRAIL's request for in camera treatment, but I wanted to bring it to the Court's attention just in an abundance of caution.

JUDGE CHAPPELL: All right. Let me make sure I follow this. It was requested but denied?

MR. STEBINGER: That's correct, Your Honor. I believe yesterday you entered an order denying GRAIL's request for in camera treatment.

JUDGE CHAPPELL: Were they also invited to file another one if they would like?

MS. RATHBUN: Yes, Your Honor. We will be filing another one on August 27th. This is Anna Rathbun for GRAIL.

JUDGE CHAPPELL: All right. To be safe, we will go ahead and treat it as in camera for now.

MS. RATHBUN: Thank you, Your Honor.

JUDGE CHAPPELL: So at this time we will 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 into public session.

I need the lead or questioning counsel for each party to view the list of participants on the Zoom screen and verify there are no participants in the courtroom who should not be there. If there is anyone who is not authorized to be in an in camera session, you will instruct that person to use the raise hand function on the Zoom screen. Open Exchange will then move that person into a waiting room.

MR. STEBINGER: I'm sorry. I believe I still see Ms. Song on the list.

MS. RATHBUN: Ms. Song is in-house counsel for GRAIL. We are fine with her remaining for the in-house portion of Mr. Della Porta's testimony.

JUDGE CHAPPELL: All right. Have both sides looked over the list?

MS. RATHBUN: Yes, Your Honor, and it looks good to me. It looks like everyone who should leave

has left or is about to leave.

SCOTT: We just need to get one more person moved, Your Honor.

JUDGE CHAPPELL: All right.

SCOTT: And they have been moved, and the public line is out.

JUDGE CHAPPELL: And the phone call has been muted, the call-in line?

SCOTT: The public line is in isolation, yes. It's suffering in silence.

JUDGE CHAPPELL: All right. We're 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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