

GATOR-1068  
Gator Bio v. Sartorius Bioanalytical Instruments  
IPR2025-00633

1 JUDGE JOHNSON HINES: Okay.  
2 Mr. Santhanam?  
3 MR. SANTHANAM: Not from the Respondent.  
4 JUDGE JOHNSON HINES: Okay, Mr. Gennari.  
5 MR. GENNARI: No, Your Honor.  
6 JUDGE JOHNSON HINES: Okay.  
7 Can you call your next witness, then.  
8 MS. TURNER: Your Honor, may I approach the  
9 bench? I just have some courtesy binders for you.  
10 JUDGE JOHNSON HINES: Yes.  
11 MS. TURNER: Good afternoon, Your Honor. My  
12 name is Camille Turner, and I represent Complainant,  
13 Sartorius BioAnalytical Instruments, Inc., and I will be  
14 calling Mr. Tae Kang to the witness stand.  
15 JUDGE JOHNSON HINES: All right.  
16 Good afternoon. Before you sit down, can you  
17 raise your right hand, please.  
18 Whereupon--  
19 TAE KANG,  
20 having been first duly sworn, was examined and testified as  
21 follows:  
22 JUDGE JOHNSON HINES: Thank you very much.  
23 MS. TURNER: Just for some housekeeping,  
24 Mr. Kang, there should be binders on...  
25 Mr. Kang is the head of engineering team in

1 North America for Sartorius BioAnalytical Instruments.  
2 Mr. Kang will testify regarding the Octet instruments, and  
3 consumables, product development, projects, and their  
4 marketability.

5 His testimony will be relevant to domestic  
6 industry and public interest.

7 JUDGE JOHNSON HINES: Thank you. Please  
8 proceed.

9 DIRECT EXAMINATION

10 BY MS. TURNER:

11 Q. Good afternoon, Mr. Kang. Would you please  
12 spell and state your name for the record.  
13 (Clarification requested by the Realtime Stenographer.)

14 Q. Good afternoon, Mr. Kang. Would you please  
15 spell and state your name for the record.

16 A. My name is Tae Kang. T-A-E, K-A-N-G.

17 Q. What is your current occupation?

18 A. I'm head of engineering in North America for  
19 Sartorius BioAnalytical Instrumentations.

20 Q. How long have you been with Sartorius?

21 A. Collectively, 23 years.

22 Q. Before we get into your employment history,  
23 could you briefly summarize your educational background?

24 A. I have a BS in mechanical engineering,  
25 biochemistry and microbiology.

1 able to measure higher concentrations of AAV.

2 I think the dynamic range is actually shifted.

3 Q. Justin, you can please bring up Mr. Kang's  
4 deposition transcript at page 156, lines 5 through 9.

5 I asked you that same question, I said, "Is it  
6 true that Sartorius does not have a product currently on  
7 the market that is designed to detect AAV capsids on the  
8 same dynamic range as the Gator project; is that right?"

9 You said, "Not to the 5 times E6, no."

10 A. Yes.

11 Q. That was your testimony?

12 A. Yeah, that's true.

13 Q. So going back to AAV probes, the AAV probes --  
14 Sartorius's AAV probe detects what's called the capsid,  
15 which is the outer protein shell of the virus; is that  
16 correct?

17 A. Yes.

18 Q. If AAV capsids are empty, and they don't have  
19 genetic material in them, then they're not useful; correct?

20 A. That's right.

21 Q. Sartorius doesn't currently offer a product that  
22 identifies what percentage of AAV capsids have genetic  
23 material in them?

24 A. No, but that's in development at the moment.

25 Q. All right.

1 Tan, Gator Bio's CEO.

2 JUDGE JOHNSON HINES: Before you sit down...

3 Whereupon--

4 HONG TAN, PhD,

5 having been first duly sworn, was examined and testified as  
6 follows:

7 JUDGE JOHNSON HINES: Thank you. Good morning  
8 and welcome.

9 MR. SANTHANAM: Your Honor, may I begin?

10 JUDGE JOHNSON HINES: Yes. Thank you.

11 DIRECT EXAMINATION

12 BY MR. SANTHANAM:

13 Q. Good morning, Dr. Tan. Would you please  
14 introduce yourself and state your full name for the record?

15 A. Yes. My name is Hong Tan. H-O-N-G, T-A-N.

16 Q. Where do you work?

17 A. I'm currently at Gator Bio.

18 Q. What is your role at Gator Bio?

19 A. I'm the CEO.

20 Q. Where is Gator Bio located?

21 A. We are in Palo Alto, California.

22 Q. Tell us about some of your responsibilities.

23 A. Well, as a CEO, I interface with our investors,  
24 and I oversee the company's strategy. And I work with our  
25 team to develop the other product strategy and the

1 marketing strategy. And also, I need to make sure that  
2 these strategies are being executed.

3 Q. Dr. Tan, do you have any educational degrees?

4 A. Yes, I do.

5 Q. Tell us what those are.

6 A. I have a bachelor's degree in electrical  
7 engineering. And I have a master's degree in electrical  
8 engineering from Auburn University.

9 I have a PhD in electrical engineering, also  
10 from Auburn University, and also I have an MBA degree.

11 Q. Now, Dr. Tan, after you obtained your  
12 directorate, tell us at a high level the companies you've  
13 worked for.

14 A. Okay.

15 I -- when I -- actually, when I was working on  
16 my PhD degree, I worked at NASA, Goddard Space Center, not  
17 too far away from here.

18 Then I went to a company called Torrington  
19 Company as a software engineer. After Torrington, I moved  
20 into computer industry. I worked at companies like Iomega,  
21 Seagate, Maxtor, Caleb Technology, Conner Tech, et cetera.

22 Q. At some point, did you --

23 A. Well, actually, I have more. Sorry.

24 After that, I started my own company, first  
25 company called Wave Crossing. Then started second company

1 called ForteBio.

2 Q. Now, Doctor, I want to talk about your work at  
3 ForteBio.

4 When did you become involved with ForteBio?

5 A. Well, actually, you know, I founded a company --  
6 I started the company, and it was 2001.

7 Q. What was your role at ForteBio?

8 A. Well, first, you know, I was the CEO. Then we  
9 raised venture capital money, and then we hired a  
10 professional CEO, and I became CTO and the president of the  
11 company.

12 Q. What sort of products did you develop at  
13 ForteBio?

14 A. We actually developed bio-layer interferometry  
15 instruments and biosensors.

16 Q. At a high level, tell us what bio-layer  
17 interferometry is.

18 A. Okay.

19 Bio-layer interferometry, in essence, is a  
20 technology called refractometry interference spectroscopy,  
21 and this is -- it's called RIfS, R-I-F-S; right?

22 So it has many different ways to implement this  
23 technology. This technology first came from the  
24 semiconductor industry and optical thin film, you know,  
25 coating industry.

1           Then, you know, people started to use them in  
2 the biotech field, and so to use this interferometry to  
3 detect the molecular interactions in real-time.

4           So I believe we were the first one to  
5 commercialize the technology in the 2000s.

6       Q.     Why did you start calling the technology  
7 bio-layer interferometry or BLI?

8       A.     Well, it's very simply. You know, refractometry  
9 interference spectrometer actually is a very long name,  
10 right, for the bio -- you know, chemists and scientists to  
11 remember, it's very difficult. So I said, well, we needed  
12 to have an easy name, right, so everybody can remember. So  
13 that's why, you know, I came up with bio-layer  
14 interferometry.

15       Q.     Now, what did you do -- well, how long were you  
16 at ForteBio?

17       A.     I started the company in 20 -- 2001, and I left  
18 in August 2008.

19       Q.     What did you do after ForteBio?

20       A.     Actually, I worked with Bob Zuk to start a new  
21 company called ET Healthcare.

22       Q.     You mentioned Bob Zuk. He's the chief  
23 technology officer?

24       A.     Yes, yes. He's the CTO of Gator Bio right now.

25       Q.     Okay, and what did you do at this new company?

1       A.     Well, ET Healthcare is a diagnostics technology  
2 company. We invented, you know, a number of new  
3 technologies for advantaged, you know, diagnostic  
4 applications. And so, we commercialized the -- some of the  
5 technologies. And so, we are in the -- you know, a  
6 clinical diagnostics field, actually, which is, you know, a  
7 regulated market.

8       Q.     You mentioned you had to make some innovations.  
9 Were you successful in doing that at ET Healthcare?

10      A.     Yes. We actually invented, you know, very  
11 unique biosensor technology, and, you know, as I said, it's  
12 used for diagnostics. You know, it's a different  
13 application field.

14      Q.     Were those instruments bio-layer  
15 interferometers?

16      A.     No, they are fluorescence- and  
17 chemiluminescence-based systems.

18      Q.     Now, when did you start Gator Bio?

19      A.     I think it was 2017.

20      Q.     Tell us about some of the reasons behind  
21 starting Gator Bio.

22      A.     Yeah.

23             So, you know, I left ForteBio, and we -- you  
24 know, we focused on the diagnostics. And then, you know, a  
25 number of my old friends, you know, from, you know, my days

1 at ForteBio, they were the company CEO or they were very,  
2 you know, senior scientists, and they approached me and  
3 said, you know, you left this industry and the whole field,  
4 the biology field, right, and moved forward.

5 But, you know, the technology, BLI technology  
6 was still, you know, like ten years ago, old, okay, and,  
7 can you develop something for us to meet our new demands;  
8 right?

9 So I said, okay, let me do some study and  
10 understand the market landscape; right?

11 So that's how we started, and we actually talked  
12 to, you know, many people, you know, companies like Amgen,  
13 you know, et cetera, and then we learned, you know, there  
14 are many unmet demands in the market.

15 So we said, okay, we want to develop something  
16 much better than the first generation. So that's, you  
17 know, how we started and worked on the second generation or  
18 new generation BLI technology.

19 Q. Okay.

20 Were you able to apply any of the innovations  
21 from ET Healthcare to the BLI space?

22 A. Yes. Although, you know, the -- for ET, we  
23 focused on diagnostics and different technologies used  
24 fluorescence and chemiluminescence, but a lot of the  
25 fundamental science is the same.

1                   And engineering designs can be leveraged and  
2 implemented in the life science field, as well.

3           Q.     Now, Dr. Tan, I want to talk about the Gator Bio  
4 products, and -- and we're going to start with the probes.

5                   Before we go too far, have you prepared some  
6 slides to help walk us through the Gator Bio products?

7           A.     Yes, I have.

8           Q.     Do you believe those slides will be helpful in  
9 explaining your testimony today?

10          A.     Yes.

11                  MR. SANTHANAM: Your Honor, permission to put up  
12 RDX-2, which is Dr. Tan's demonstrative slides?

13                  JUDGE JOHNSON HINES: Yes, thank you.

14                  MR. SANTHANAM: And also permission to provide  
15 the witness a laser -- not a laser pointer, but a pointer  
16 that he can use?

17                  JUDGE JOHNSON HINES: Certainly.

18                  MR. SANTHANAM: Justin, let's put up slide 2.

19 BY MR. SANTHANAM:

20          Q.     Doctor, looking at the slide which references  
21 CX-276, RX-87 and RX-109C.3, looking at the images on this  
22 slide, could you please explain what we see here?

23          A.     Yes, I have three pictures here. The first one  
24 on the left side -- let me see the pointer.

25                  Okay. This one actually is the picture of our

1 fiberoptic biosensor. The middle picture here is a blowup  
2 of the portion of this biosensor.

3 This picture shows three rows of such biosensors  
4 in 96-well plate.

5 Q. Dr. Tan, are you familiar with the terms  
6 proximal and distal?

7 A. Yes.

8 Q. Okay.

9 Looking at the photo and the diagram on the  
10 left-hand side, can you tell us where the proximal portion  
11 of the probe is?

12 A. Yeah. Okay.

13 In this picture, this biosensor, fiber-optic  
14 biosensor, the proximal end is the top end. The distal end  
15 actually is the bottom end.

16 In this blowup diagram, the top actually, we  
17 call it the proximal and at the bottom we call it the  
18 distal.

19 Q. What is the proximal portion of the probe, the  
20 orange portion of the probe, what is that made of?

21 A. Well, actually, this piece, basically, as I  
22 said, is a part of this center piece here. It is made of  
23 optical fiber.

24 Q. Okay.

25 You also mentioned distal. Tell us about the

1 structures at the bottom portion of the probe.

2 A. Okay.

3 So you should be able to look at this middle  
4 picture.

5 The distal end, this is the surface of the  
6 optical fiber, and we coat a thin-film layer, optical layer  
7 basically on the surface. On top of the thin-film optical  
8 layer we have our surface chemistry adhered to it.

9 Q. Just so that we're all on the same page, which  
10 portion of the probe interfaces with the Gator instruments?

11 A. The top, the proximal end.

12 Q. What is the material that that portion is made  
13 of?

14 A. Optical fiber.

15 Q. Justin, can we put up RX-8 on the screen.

16 Dr. Tan, can you explain what we see here in  
17 RX-8?

18 A. Okay. This is the raw material optical fiber  
19 that we use to make these optical biosensors.

20 Q. Dr. Tan, does Gator Bio make its probes using  
21 anything other than optical fiber?

22 A. No, we do not.

23 MR. SANTHANAM: Your Honor, permission to  
24 approach the witness with an exhibit.

25 JUDGE JOHNSON HINES: Mm-hmm.

1 MR. SANTHANAM: I'm approaching the witness with  
2 what has been previously marked as RPX-2 for  
3 identification. Handing the witness the same.

4 I'm also going to hand the witness RPX-1. I  
5 handed you RPX-1. I'm going to hand you RPX-2.

6 JUDGE JOHNSON HINES: I'm sorry, the second one  
7 is RPX-2.

8 MR. SANTHANAM: Yes. That is RPX-2. This is  
9 RPX-1.

10 JUDGE JOHNSON HINES: All right.

11 BY MR. SANTHANAM:

12 Q. Doctor, looking at the tray that I handed you,  
13 RPX-2, could you please explain what that is.

14 A. Okay.

15 This is the -- we call it APS probes. They are  
16 the APS coated biosensors in a 96-well plate.

17 So it has 96 biosensors inside of here. So I  
18 can open up and so, Your Honor, you can see, we got 96 tips  
19 here.

20 Q. Dr. Tan, could you actually take one out and  
21 hold it up.

22 A. Oh, yeah. Yeah.

23 So it looks like this. It's just like --  
24 exactly like I showed on the picture.

25 Q. Your Honor, would you like to have one of those?

1 JUDGE JOHNSON HINES: No. I'm fine.

2 Thank you, though.

3 BY MR. SANTHANAM:

4 Q. So that we get a sense of dimensions, Dr. Tan,  
5 tell us, holding that up, and, Justin, can you also put up  
6 slide 2 on the screen.

7 Tell us holding up the probe --

8 A. Right.

9 Q. -- where is the optical fiber on the probe?

10 A. The piece I am holding right now. The center  
11 piece, not the -- you know, little section.

12 Q. Where is the surface chemistry on the probe?

13 A. At the bottom, the distal end.

14 Q. So that we get a sense of dimensions and  
15 proportions here, can you even see with the naked eye the  
16 optical layer and the surface chemistry on the probe?

17 A. No, you cannot because it's in the nanometer  
18 range and naked eyes cannot see that small layer.

19 Q. Okay.

20 Doctor, do all of Gator Bio's probes have this  
21 structure?

22 A. Yes.

23 Q. What is different between the probes?

24 A. The difference is at the bottom, the surface  
25 chemistry, and sometimes optical coating for different

1 applications, we probably have to use a different thin-film  
2 layer in order to accommodate the needs and for different  
3 assays we need to use different surface coating in order  
4 to, you know, conduct the assays in the right manner.

5 Q. We have heard this term surface chemistry used a  
6 couple of times. Can you explain what that is?

7 A. Yes. You know, I'm not a chemist, but in my  
8 mind, a surface chemistry is a generic term to describe the  
9 chemistry or chemical compounds we immobilized to the  
10 surface of the thin-film layer.

11 Q. Tell us, using the various surface chemistries  
12 on the Gator Bio products, what types of molecules and  
13 substances can you study?

14 A. I want to say virtually infinite. We can study  
15 antibodies, proteins, DNAs, RNAs, small molecule compounds,  
16 and even viral particles and bacterial particles.

17 Q. Doctor, I want to talk now about the Gator Bio  
18 instruments, and, Justin, can you put up CX-102, and let's  
19 blow up the center portion of that first page.

20 Doctor, first off, are the Gator Bio probes and  
21 kits used with instruments?

22 A. Yes.

23 Q. What are the instruments Gator Bio offers?

24 A. Well, actually, on the market right now, we have  
25 three models you can see in this slide here.

1                   And we -- a couple of weeks ago we announced two  
2 more models, but we have not started to ship yet.

3           Q.     Okay.

4                   Tell us what the Gator Prime, plus, and pro are?

5           A.     Yeah, Gator Prime actually, is our first  
6 instrument model we developed, and that we launched in  
7 2019.

8                   It has eight channels, can do eight parallel  
9 tests or assays. It uses eight spectrometers, so each  
10 channel has one spectrometer. So we can achieve high data  
11 rate. So that allows us to detect very fast binding event.

12                   So it can meet most of the applications in the  
13 field.

14                   The second one that Gator Plus, actually, is a  
15 step-up model of Gator Prime.

16                   Because when we launched Gator Prime, some  
17 customers approached us and said, well, you know, we  
18 actually want you to reduce the sample volume you used;  
19 right?

20                   Because Gator Prime can only work with 96-well  
21 plate, and each well needs probably 180 to 100 microliters  
22 of solution or samples; right?

23                   So they said, okay, too much. Can you reduce  
24 the volume? So then we developed the Gator Plus, so it can  
25 use 384-well plate; right?

1                   So which means we can reduce the amount of the  
2 sample we use to 40 microliters.

3                   So in addition to that, because we have, you  
4 know, we can use 384, which means more samples you are  
5 putting in the instrument, then people can walk away, you  
6 know, for a longer time.

7                   Then we need to have a much stable performance.  
8 So we improved the thermal control system to make the  
9 instrument much more stable.

10                  Then --

11           Q.     Well, tell us about the Gator Pro.

12           A.     Yeah. Gator Pro, then people approached us, and  
13 said okay, great products. Great technologies. I really  
14 want to use this for my high-throughput application. I  
15 have many, many samples; right? Your 8-channel is not  
16 sufficient.

17                  Okay. But I still needed high data quality  
18 because -- you know, the existing product on the market,  
19 you know, for so-called high-throughput, they really don't  
20 offer the high data rate when they switch to the  
21 high-throughput mode.

22                  So we said okay, let's design an instrument that  
23 can allow customers to use a high-throughput mode without  
24 sacrificing the data quality. That's how we, you know,  
25 came up with the Gator Pro. So it has 32 channel with 32

1 spectrometers, each channel has a spectrometer to work  
2 with.

3               So that way we can actually sample the -- I  
4 mean, collect the data at a very, very high sample rate.

5       Q.     Doctor, are the advantages conferred by having  
6 32 spectrometers, from your experience developing these  
7 products, can they be achieved through software  
8 improvements?

9       A.     No, they cannot, because you know, this is the  
10 basic, you know, control theory or a communication theory;  
11 right? We all learned that Shannon sample theorem; right?

12             Basically, you have to have enough information  
13 in order to reconstruct the data. This is a digital  
14 system. This is not analog; right?

15             So basically, we sample it. So you do have  
16 enough sample rate in order to reconstruct.

17             If you don't have the information, there's no  
18 way you can use software to reconstruct the assay  
19 information. So that's why we need a high frequency sample  
20 rate.

21       Q.     Doctor, are you aware whether Sartorius offers  
22 an instrument with 32 spectrometers?

23       A.     I have not seen that.

24       Q.     Now, Gator Bio has produced in this case, and we  
25 have heard testimony about a Gator Prime instrument.

1 Q. I want to switch gears a little bit, Justin, we  
2 can put that down. I want to talk about the range of  
3 probes and kits that Gator Bio offers and the applications  
4 for them.

5 Justin, let's put up CX-102 again. This time  
6 let's go to the second page and blow up the chart on the  
7 right.

8 Now, Doctor, have you seen this type of chart or  
9 something similar to it before?

10 A. Yeah. This is our product brochure.

11 Q. Okay.

12 Tell us about how many different probes and kits  
13 does Gator Bio offer?

14 A. We have probably a couple dozens of probes and  
15 kits.

16 Q. Okay.

17 Justin, let's go to CX-102. Blow out -- zoom  
18 out. Let's go to the second column.

19 Doctor, can you describe at a high level, the  
20 types of applications for which Gator Bio's probes and kits  
21 are used for?

22 A. Yeah. You know, as I mentioned before, you  
23 know, there are numerous applications; right? It really  
24 depends on, you know, the fields, you know, that the  
25 customer is in.

1 Over here, these are the four major areas that  
2 we currently serve; right? The first one is  
3 biotherapeutics. Basically, it's like biotech, biopharma  
4 industry, you know, for antibody therapeutic development,  
5 for -- you know, the proteins therapeutics, et cetera.

6 The second category over here that's the gene  
7 therapy. You know, we basically work on the AAV as our  
8 main product line, and this is really a critical and a new  
9 field for biotech and biopharma.

10 The third category here actually is the more  
11 traditional drug discovery and development including small  
12 molecule compounds and peptides, therapeutics, et cetera.

13 At the bottom category here is really for the  
14 other life science research, you know, universities, NIH,  
15 you know, et cetera, CDC; right? So for the life science  
16 research applications.

17 Q. Justin, let's zoom out and go back to the chart  
18 on the right on CX-102.

19 Doctor, among the probes and kits that Gator Bio  
20 offers, do any of them use horseradish peroxidase enzyme or  
21 HRP?

22 A. Yes. There are three kits here, actually, they  
23 use HRP as a label to amplify the signal.

24 So this is -- yeah, three.

25 Q. And can you tell us which specifically those

1 called SPR, surface plasmon resonance. But for many  
2 applications, you know, it is very difficult or impossible  
3 to find an alternative.

4 Q. Looking specifically at applications for -- gene  
5 therapy applications, are there any alternatives to the  
6 Gator Bio gene therapy products?

7 A. Well, I should say that we've provided solutions  
8 much better than some of the existing solutions out there.  
9 So I would not say there's a good way to replace what we  
10 offer here.

11 Q. Now, I want to talk a little bit about the  
12 market for BLI products. And having been at ForteBio, now  
13 at Gator Bio, do you have experience with the market  
14 landscape for BLI products?

15 A. Yes, I do.

16 Q. Okay.

17 Currently, who are the major companies that sell  
18 BLI products?

19 A. Two companies. One is Gator Bio. Another one  
20 is Sartorius.

21 Q. Are Gator Bio's instruments and probes  
22 interchangeable with Sartorius's instruments and probes,  
23 BLI instruments and probes?

24 A. No.

25 Q. Okay.

1                   So if a customer had a Gator Bio instrument and  
2 they didn't have access to the Gator Bio probes and kits,  
3 could they use one of Sartorius's probes and kits with the  
4 Gator Bio instrument?

5           A.     No.

6           Q.     Conversely, if a customer had, you know, Gator  
7 Bio's probes and kits, could they use those probes and kits  
8 with one of Sartorius's instruments?

9           A.     No.

10          Q.     Having worked, again, at two different companies  
11 developing BLI systems, would customers necessarily be able  
12 to switch from a Gator Bio BLI system to a Sartorius BLI  
13 system?

14          A.     For some customers, it is very difficult. For  
15 some customers, it is impossible.

16          Q.     And can you explain?

17          A.     Well, I'll give you some examples here.

18                  One, like for universities and government labs,  
19 and their research projects are really -- really are based  
20 on the grants and fundings; right?

21                  And so, these are expensive capital equipment.  
22 And once they acquired, you know, one technology, it is  
23 almost impossible for them to switch to another one, to buy  
24 another piece of equipment easily; right?

25                  For industry customers, if they develop drugs,

1 and this is a regulated environment, which means, you know,  
2 they have to, you know, record all the data and submit to  
3 the -- the history of the drug -- the whole drug design and  
4 development to FDA.

5           Once they adopted Gator, it would be very  
6 difficult, almost impossible for them to switch to another  
7 platform.

8           Q.     Are there any consumable probes and kits that  
9 Gator Bio offers that -- for which you know Sartorius does  
10 not offer a competing product?

11          A.     Oh, yeah.

12                 We have -- as I said, you know, this is really  
13 the next generation technology, and we solved a number of  
14 technical problems; right?

15                 For example, you know, the AAV kits, HS AAV I'm  
16 talking about, high sensitivity AAV, and high sensitivity  
17 AAV 9 and AAV ratio kits, Sartorius do not have.

18                 We have other probes, such as one probe that we  
19 call it SA XT. XT stands for extended. It has many folds  
20 of high sensitivity than what Sartorius can offer.

21                 We have another kit called Flex SA, which is a  
22 regenerable, reusable SA probe.

23                 This is also the only one probably in the world  
24 today, and Sartorius does not have.

25                 MR. SANTHANAM: Your Honor, at this point, I

1

2 BY MR. SANTHANAM:

3 Q. Justin, would you put up CX-55 on the screen.

4 And, Doctor, I'd like to now address some topics  
5 related to, you know, Gator Bio's business. We've put up  
6 here a spreadsheet from CX-55C.

7 Do you recognize this?

8 A. Yes.

9 Q. Can you tell us what CX-55C is?

10 A. Okay.

11 This is the spreadsheet of our sales at the end  
12 of last year, 2022.

13 Q. Does the spreadsheet identify Gator Bio's  
14 customers?

15 A. Yes.

16 Q. Has -- to your knowledge -- as Gator Bio's chief  
17 executive officer, do you have personal knowledge of Gator  
18 Bio's customers?

19 A. Yes.

20 Q. Has Gator Bio acquired new customers since the  
21 end of 2022?

22 A. Yes.

23 Q. Before we get into the specifics of what those  
24 -- who those customers are, can you explain at a high level  
25 the types of customers Gator Bio caters to?

1           A.     Yeah.

2                     We -- typically, we have three types. One is  
3 industry; right? Biotech company, biopharma, CRO, CDMO, et  
4 cetera.

5                     Then we have the second type is university labs,  
6 you know, public universities and private universities.

7                     The third type is government labs, government  
8 agencies.

9           Q.     Okay.

10                    And, Doctor, have you prepared a slide to  
11 illustrate some of these customers?

12          A.     Mm-hmm. Yes.

13          Q.     Justin, let's put up slide 6 from RDX-2.

14                    Without getting into the specifics of what each  
15 customer does, you mentioned that Gator Bio has some  
16 government customers.

17                    Can you identify who those customers -- some  
18 examples of those customers?

19          A.     Yeah.

20                    So this is a small portion of our customer list.  
21 And this one, USDA, that's government agency.

22          Q.     Any others?

23          A.     Well, actually, a lot of public universities,  
24 they run programs under government grants or contracts; and  
25 if so, you can see we have a few universities listed here.

1                   You can use one, two, three, you know, eight,  
2 right, so that's the meaning here.

3           Q.     I'm a little confused.

4                   Does the Gator Pro instrument have 32 fiber  
5 optic?

6           A.     Yes.

7           Q.     It does?

8           A.     Yes.

9                   In the instrument, it has 32 fiber optics and 32  
10 spectrometers, so they can read simultaneously in parallel;  
11 right?

12                   And so, if you really want to run  
13 high-throughput application, you can put 32 probes there,  
14 but some customers said, okay, I probably don't need that  
15 all the time; right? Sometimes I have a smaller number of  
16 samples. I may only want to run eight. I may run 12,  
17 right, 10.

18                   So they have the flexibility to format the assay  
19 how they want to run it.

20           Q.     When you sell a kit for the Gator Pro, is it the  
21 same kit that's for the Gator Plus and Gator Prime, so it's  
22 an 8-by-12 tray?

23           A.     Yes. They are identical.

24           Q.     So they would just add trays together to come up  
25 with -- so how would they run 32 channels simultaneously

1 with the 8-by-12 tray?

2 A. Oh. Many ways; right?

3 Some customers said, okay, I want to -- I don't  
4 want to do much. What I do is just place this 96 sensors  
5 in the machine; right?

6 So the machine will pick up 32, okay. So it  
7 depends on how they define. Okay, I want you to pick up in  
8 the middle section these, you know, four rows. Then the  
9 machine will go there and pick up, you know, 32 over here;  
10 right?

11 So it really depends on the user, you know, how  
12 they want to format the tests.

13 Q. Are the 32 channels, are they linear like the  
14 eight channels in the other machines? Are they 32 optical  
15 fibers in a row?

16 A. Well, actually, we have 32 fibers, basically.  
17 It's 4-by-8.

18 Q. Okay. So they're not all linear. It's in a --

19 A. Yeah, yeah. It's a 4-by-8, basically, yes.

20 Q. Okay.

21 What Sartorius instrument is comparable to --  
22 I'm sorry. Yeah.

23 What Gator Prime -- what Sartorius instrument is  
24 comparable to Gator's instruments?

25 A. Which model comparable?

1 Q. Yeah, which model of Sartorius's DI products?

2 A. Okay.

3 Q. Are there instruments that are comparable to the  
4 Gator instruments?

5 A. Right. Okay, I understand your question.

6 It is -- you know, there is actually -- first,  
7 you know, this is really a market or application -- it's  
8 application-driven product line; right?

9 So it depends on the application. It's not only  
10 the instrument. The instrument is just a piece of it;  
11 right? Just like a gun without bullets, it's useless;  
12 right?

13 So it depends on the applications; right?

14 Then you can talk about, you know, how they  
15 compare, okay.

16 Instrument that they have an 8-channel, we have  
17 an 8-channel.

18 So from outside, yes, they are the same, right,  
19 but if you look at inside, about the applications, how you  
20 use the instrument to do assays or to conduct tests, right,  
21 then that is the real differentiator; right?

22 So, for example, we have -- I just mentioned  
23 earlier, we have SA XT, which gives us, you know, many  
24 folds of higher sensitivity; right? That allow you to do  
25 many new applications.

1           Okay. For example, we have AAV kits, HS AAV, HS  
2 AAV9 and especially ratio kits, they do not have. So it  
3 doesn't matter they are 8-channel, you know, how many,  
4 16-channel. If they don't have that -- these applications  
5 or these biosensors or kits, then there's no comparison.

6           So when we actually, you know, talk about this  
7 technology or products, we really need to focus on  
8 applications.

9       Q.     Okay.

10           You're an inventor on the '547 Patent; correct?

11       A.     '547. That's the -- yeah, the older patent,  
12 yeah.

13       Q.     What is the purpose of the air gap in that  
14 disclosure of the '547 Patent?

15       A.     Well, at the beginning, you know, we used the  
16 standard SMA connector; right, and you know, this is a  
17 really screw-on kind of a connector, right.

18           Then we worried about the surface damage, you  
19 know, when you -- you know, put a sensor -- a fiber surface  
20 to the other fiber surface then you could have this  
21 rubbing, you know, scratching, right, and it will damage  
22 the other -- the surface of the fiber bundle. Because the  
23 fiber bundle is not removable. It's fixed in the  
24 instrument, right. Once you damage it, you know, you are  
25 going to have many troubles. You start to lose lights,

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22 the other -- the surface of the fiber bundle. Because the  
23 fiber bundle is not removable. It's fixed in the  
24 instrument, right. Once you damage it, you know, you are  
25 going to have many troubles. You start to lose lights,

1 right.

2           So, you know, more noise and loss of intensity,  
3 right. These are the problems with the air gap; right.

4           Also, there's another problem with the air gap  
5 is, you know, you want an 8-channel or 32-channel  
6 consistent; right. You don't want to one have a bigger air  
7 gap and another one have a smaller air gap, right. How do  
8 you do that? The easiest thing to do is basically to put  
9 them together, compact, right. Get rid of this air gap,  
10 then you don't have this problem.

11       Q.    You said that the purpose of the air gap  
12 initially was to prevent damage between the two optical  
13 fibers hitting each other?

14       A.    Yes.

15       Q.    But the -- you testified that the Gator  
16 products, the fibers touch each other?

17       A.    Yeah.

18       Q.    There's no air gap?

19       A.    Yes.

20       Q.    Now, how did you solve the problem of the damage  
21 between the two contacting?

22       A.    Right.

23           That is actually our invention. We filed a  
24 patent, you know, actually quite a few years ago for the  
25 diagnostics product I mentioned, right, because we use

1 fluorescence and chemiluminescence. And --

2 (Clarification requested by the Realtime Stenographer.)

3       A.     Fluorescence for diagnostics. Diagnostics  
4 systems, they use fluorescence and chemiluminescence. So  
5 they use fluorescence, and we have to shoot a laser beam  
6 from the bottom we use the same -- those -- from outside  
7 fluorescent system and the chemiluminescence system they  
8 use the same kind of biosensors, right. But what do we do  
9 with the diagnostic system is we shoot a laser from the  
10 bottom to the very tip of this probe; right.

11             Then we have a fluorescent material on the  
12 surface, and then we have a detector at the bottom, you  
13 know, it can be diodes or photomultiplier, you know, and  
14 OCCD (phonetic), and it collects the light, right. So it  
15 needs to be very precise, all right.

16             Any off-site is going to cause a precision  
17 problem, right. So we developed this mechanism, it's a  
18 V-groove. V-groove actually is also a typical optical  
19 fiber industry standard way to mount fiber, right, in a  
20 precise way.

21             So we used that concept, right.

22             So we can use a V-groove, combine it with this  
23 flexible silicon ring as a suspension to precisely engage  
24 the tip of this probe X, Y, Z, precisely.

25             So you can see in the video, we pushed this up,

1 right. Instead of we move around and scratch them and  
2 rotate them, right. So they only go in one direction,  
3 okay, push up; right.

4 Then we engage with a push-pin from the side, so  
5 which means they're sitting there. Then they're not going  
6 to, you know, wobble or, you know, rotate, right. So  
7 there's no scratch.

8 Q. Okay.

9 MR. GENNARI: Thank you. I have nothing  
10 further.

11 JUDGE JOHNSON HINES: All right.

12 Thank you.

13 Is there any redirect?

14 MR. SANTHANAM: Briefly, Your Honor, just --

15 REDIRECT EXAMINATION

16 BY MR. SANTHANAM:

17 Q. Now, Dr. Tan, you had in one of your answers,  
18 you referenced Sartorius's AAVX probes. Just so that we're  
19 all on the same page, did Gator Bio release its first  
20 generation AAVX probes before or after Sartorius's?

21 A. Yes. We launched this product before them, and  
22 we were the first one on the market.

23 Q. You also mentioned the antibodies on the AAVX  
24 probe.

25 Do you have a commercial -- do you obtain those

1 expert opinion. He's going to provide factual testimony  
2 about the use of products that he developed.

3 JUDGE JOHNSON HINES: The objection is  
4 overruled. I'll allow it.

5 Anything else we need to discuss?

6 MR. SANTHANAM: Not that we're aware of, Your  
7 Honor.

8 JUDGE JOHNSON HINES: Okay. Then please call  
9 the next witness.

10 MR. SANTHANAM: We call Robert Zuk.

11 JUDGE JOHNSON HINES: Please rise and raise your  
12 right hand.  
13 Whereupon--

14 ROBERT ZUK,  
15 having been first duly sworn, was examined and testified as  
16 follows:

17 THE WITNESS: I do.

18 JUDGE JOHNSON HINES: Thank you. Please be  
19 seated.

20 There's a microphone in front of you. Can you  
21 make sure that it's green?

22 THE WITNESS: It's green.

23 JUDGE JOHNSON HINES: Great. Thank you.

24 MR. SANTHANAM: May I begin, Your Honor?

25 JUDGE JOHNSON HINES: Yes.

1           It looks like there are binders that are being  
2 provided.

3           MR. SANTHANAM: Your Honor, Mr. Zuk may also be  
4 using a pointer during the course of his testimony.

5           JUDGE JOHNSON HINES: That's fine.

6           Please proceed, yes. Thank you.

7                                 DIRECT EXAMINATION

8 BY MR. SANTHANAM:

9           Q.     Mr. Zuk, would you please introduce yourself by  
10 stating your full name for the record?

11          A.     My name is Robert Zuk.

12          Q.     Tell us what your role is at Gator Bio.

13          A.     I'm the chief technology officer.

14          Q.     What are your responsibilities as chief  
15 technology officer?

16          A.     My responsibilities are to do the research and  
17 development of the Gator Bio fiber optic biosensors.

18          Q.     Now, do you have any educational degrees?

19          A.     Yes, I do. I have a BS degree from the  
20 University of California at Riverside in biology.

21          Q.     After graduating, can you tell us at a very high  
22 level the various companies that you've worked for?

23          A.     Okay.

24                 Well, it goes back to the '70s. I first worked  
25 at the Max Planck Institute for Biochemistry in Martinsried

1 for a couple of years.

2           Then I worked at the Scripps Clinic and Research  
3 Foundation in -- also for about two years. I went into  
4 private industry from maybe the late '70s to the mid-'80s.  
5 I was doing research in clinical assay development.

6           We launched a lateral flow device very similar  
7 to what the COVID home lateral flow devices are. We had  
8 several FDA-approved products.

9           In the late '80s, I was with a company called  
10 Molecular Devices. They had invented a ChemFET, which is a  
11 chemically-sensitive field-effect transistor, basically a  
12 computer chip that can measure chemistry.

13           They recruited me to design an analytical system  
14 using that technology, and we launched a product called  
15 Threshold for Life Science Research.

16           Early '90s, I was in a company called Metro  
17 Biosystems. It was a clinical diagnostic assay company,  
18 and we developed assays for bone metabolic markers. This  
19 was used in the diagnosis and management of osteoporosis  
20 for postmenopausal women. It was also FDA approved.

21           In the mid-'90s, I was with a company called  
22 First Medical, and we developed a centrifugal disk that  
23 assayed a panel of cardiac markers. This was used to rule  
24 in or rule out patients with a heart attack, and these are  
25 patients that were entering emergency rooms. This was also

1 FDA approved.

2 Late '90s, early 2000s, I went into the medical  
3 device arena, and I worked with a company called  
4 PharmaSonics. I was doing research. I teamed up with an  
5 ultrasound physicist. I was the biologist, and we  
6 developed methods to use ultrasound to enhance gene  
7 transfection for gene therapy.

8 Then in 2003, I met Hong Tan, and I started  
9 working with him as a consultant. And then when the  
10 company was funded in early 2004, I became a full-time  
11 employee there.

12 Q. Now, when you referenced a company working with  
13 Hong Tan, what was the name of that company?

14 A. Oh, ForteBio. Sorry.

15 Q. What was your title at ForteBio?

16 A. I was the VP of development.

17 Q. Tell us what you did at ForteBio.

18 A. Well, I did the research and development of the  
19 ForteBio sensors.

20 Q. About how long were you there at ForteBio?

21 A. I was there for four years.

22 Q. Tell us what you did after ForteBio.

23 A. Well, Hong and I left in 2008, and we founded a  
24 company called ET Healthcare. And our goal was to develop  
25 invitro diagnostics or immunoassay systems for the clinical

1 hospital market.

2 Q. Did you develop any instruments or technology at  
3 ET Healthcare?

4 A. Oh, yes.

5 We launched three -- I think at least three  
6 instruments, and we have over two dozen clinically-approved  
7 immunoassays.

8 Q. Now, I want to talk about your time at Gator  
9 Bio.

10 When did you start Gator Bio?

11 A. In 2017.

12 Q. Tell us about some of the reasons that went into  
13 founding Gator Bio.

14 A. Well, you know, we were focusing in that  
15 interim, nine years, we were focusing exclusively on the  
16 clinical diagnostics market and developing those products.

17 In that nine-year period, we realized that the  
18 biotherapeutics market had grown considerably. There were  
19 many FDA-approved products, but there was a problem in that  
20 all of the market or customer needs weren't being met by  
21 the -- some of the current analytical methods.

22 Q. And -- go ahead.

23 A. Well --

24 Q. As part of the work that you did at Gator Bio,  
25 were you able to apply any of the --

1       A.     Oh, definitely. That was one of the reasons why  
2 we started --

3       Q.     If you can hold on and let me ask my question.

4       A.     Oh, sorry.

5       Q.     So as part of the work that you did at Gator  
6 Bio, were you able to apply any of the innovations that  
7 you'd had at ET Healthcare?

8       A.     Okay.

9             Well, we weren't idle during that nine-year  
10 period, and we have -- the company has almost 60 issued US  
11 patents on instrumentation and assay chemistry and  
12 biosensor applications, which we could apply to the Gator  
13 Bio fiber optic biosensors.

14       Q.     Now, Mr. Zuk, I want to go back to your time at  
15 ForteBio in the early -- in the 2000s.

16             When you were at ForteBio, did you do any  
17 research applying BLI or RfS to assaying enzyme activity?

18       A.     We did some work in that area.

19       Q.     Okay, and tell us about that.

20       A.     It was a project where we monitored the enzyme  
21 activity of really what are called large substrates. These  
22 substrates were polymers, and the BLI system is very good  
23 at monitoring the change in molecular size.

24             We looked at enzymes that would cleave polymers,  
25 make them smaller. And then we looked at enzymes that were

1 put -- we immobilize proteins or other chemical compounds  
2 that give binding -- what we call binding specificity. So  
3 it allows one to measure very specific analytes.

4 Q. Is the surface chemistry on the distal end of  
5 the Gator Bio probes the same or different across products?

6 A. They're different across every single biosensor  
7 because the applications and the analyte that those  
8 biosensors measure are different.

9 Q. Mr. Zuk, do you need some time to drink some  
10 water?

11 A. I'm fine, thank you.

12 Q. What types of molecules can you study with Gator  
13 Bio's probes and kits?

14 A. Large variety from very small molecular weights  
15 to proteins -- well, starting with drugs to proteins to  
16 large polymers, DNA molecules, viruses and even bacterial  
17 cells.

18 It's almost an infinite number of applications,  
19 and it's -- I am continually amazed at the creativity and  
20 ingenuity of the chemists that use these biosensors in the  
21 very novel assays that they design.

22 Q. I want to talk about the applications for Gator  
23 Bio's products.

24 Justin, would you put up CX-102. Let's go to  
25 the second page. Let's blow up the chart on the right.

1 Mr. Zuk, have you seen this table or something similar to  
2 it?

3 A. Yes.

4 Q. Tell us first off at the top, tell us what is  
5 meant as a full suite of applications.

6 A. Well, the -- we offer a panel of almost two  
7 dozen biosensors, and they all have different binding  
8 specificities and different applications. Customers will  
9 be interested in not just one application because they have  
10 many different projects, they have many different analytes.

11 So it's desirable to offer a wide what we call  
12 suite of applications for the customers.

13 Q. Looking at the chart on CX-102, do any of these  
14 products use horseradish peroxidase or HRP?

15 A. Yes, three of them do.

16 Q. Tell us which ones those are.

17 A. I think they're down here. HS AAV, HS AAV9 and  
18 AAV ratio.

19 Q. Aside from these three kits, the HS AAV, HS AAV9  
20 and ratio kits, do any of Gator Bio's other consumable  
21 probes and kits use HRP or any other enzyme?

22 A. They do not.

23 Q. Mr. Zuk, I'd like you to turn to your binder in  
24 front of you, and if you can look at a set of exhibits,  
25 RX-81 through 86.

1 Justin, let's put up slide 3 on the screen.

2 Without getting into the substance of the -- of  
3 these exhibits, 81 through 86, are you familiar with what's  
4 in these exhibits?

5 A. Oh, yes, they are a pre- -- excuse me,  
6 peer-reviewed scientific articles using the Gator Bio  
7 biosensors.

8 Q. As part of your duties at Gator Bio, do you  
9 review scientific articles relating to the Gator Bio  
10 products?

11 A. Well, it is part of my responsibilities to keep  
12 tabs on the publications in order to know how the customers  
13 are applying our biosensors. And also to understand some  
14 of their challenges so that we could maybe make improved  
15 biosensors, or biosensors with new applications.

16 Q. All right.

17 So I'd like to walk through some of these  
18 publications, and let's look at RX-81 first.

19 A. Okay.

20 Q. Can you tell us what RX-81 is?

21 A. Yes. That's an article published in clinica  
22 infectious diseases. Okay. The topic of the research was  
23 studying COVID-19 antibody avidity. Antibody avidity means  
24 that -- how tightly an antibody to COVID binds.

25 This group developed an assay for COVID-19

1 antibodies. They tested the immune response at early  
2 stages of the infection, and they found that the avidity  
3 was low, and then over time, the avidity increased.

4           So this was indication that the immune response  
5 to the COVID-19 infection had the process of what we call  
6 affinity maturation or maturation of the immune response.

7           Q.     Did the group use a Gator Bio product?

8           A.     Yes. They used one of our Gator Bio biosensors.

9           Q.     Tell us about the author's affiliations.

10          A.     These authors were from the University of  
11 California at San Francisco.

12          Q.     Do you know if this research was  
13 government-funded?

14          A.     Well, the University of California is a  
15 government institution, so it was.

16          Q.     Going a little bit of out of order, let's look  
17 at RX-84.

18                 Can you tell us --

19          A.     Okay, yes.

20                 RX-84, this was another scientific report.  
21 Okay.

22                 This also was in the COVID pandemic application,  
23 and the target of this group was to develop a therapeutic  
24 antibody to COVID-19.

25                 They essentially developed a whole panel of

1 antibodies that would bind to the virus, and they used one  
2 of our Gator Bio biosensors to characterize the panel of  
3 antibodies. Then they took the best-performing antibodies,  
4 and they used them in an animal preclinical study.

5 Q. Tell us about the authors' affiliations in  
6 RX-84.

7 A. This is Titong, et al., and they're with a  
8 biotech company, I believe, called Antibody Therapeutics.

9 Q. Let's look at RX-86.

10 A. Okay, RX-86 here.

11 Q. Tell us what that is.

12 A. This was related to the mRNA COVID vaccine. It  
13 was observed that -- or noted that individuals -- pregnant  
14 individuals used the vaccine at a much lower frequency  
15 compared to the general population. This group attributed  
16 the fact -- that fact to a concern about the safety and  
17 efficacy of the vaccine.

18 So this group developed an antibody to  
19 monitor -- or they have developed a Gator Bio assay to  
20 monitor the antibodies generated by the vaccine.

21 What they found was that pregnant individuals  
22 did have a very strong immune response, and that immune  
23 response and those antibodies were transferred to the  
24 infant, and they -- those infants were -- remained or were  
25 prevalent in the -- those antibodies were prevalent in the

1 infant for as long as 12 weeks.

2           Again, they used one of our Gator Bio  
3 biosensors.

4       Q.    Tell us about the authors' affiliations.

5       A.    The authors here were from the University of  
6 California San Francisco, and the NIH.

7       Q.    Now, let's turn to RX-82.

8       A.    Okay.

9       Q.    Tell us what that is.

10      A.    RX-82 studied the hemorrhagic fever virus. That  
11 particular disease has a 40 percent mortality rate. At  
12 this point in time, there is no effective vaccine.

13           So this group, they isolated antibodies from  
14 surviving patients, and they used the -- one of our Gator  
15 Bio sensors to characterize the binding of these antibodies  
16 to the hemorrhagic fever virus.

17      Q.    Tell us about the authors of that.

18      A.    The authors here were from the University of  
19 Maryland, University of Georgia, I believe the University  
20 of California Riverside, Centers for Disease Control, and  
21 the US Army at Fort Detrick.

22      Q.    Let's turn to RX-83.

23      A.    Okay. Down here.

24      Q.    And tell us what RX-83 is.

25      A.    Okay.

1           Well, this was a research study, okay, and it  
2 was using a novel biotherapeutic approach.

3           Antibodies have two binding sites, okay, and the  
4 binding sites bind the same antigen. The state of the art  
5 now is to develop a bi- or trispecific antibody.

6           In the case of bispecific, one binding site  
7 binds a different -- binds an antigen, and it could be a  
8 cancer cell. The second antibody binding site can bind  
9 another antigen, and it could be a cell from the immune  
10 system.

11           This group used a computer-aided design to  
12 predict or synthesize these bi- and trispecific antibodies,  
13 and they developed a large panel of antibodies, and they  
14 used the Gator Bio biosensors to characterize these  
15 antibodies that they developed.

16       Q.    Finally, tell us about the authors'  
17 affiliations.

18       A.    The authors here were also from a biotech  
19 company called Antibody Studio.

20       Q.    Okay.

21           Now, you had mentioned that -- as to a number of  
22 these articles, that they reflected government-funded  
23 research. Is it unusual for Gator Bio customers to be  
24 engaged in government-funded research?

25       A.    It's quite common.

1 Q. I'd like to focus on the Gator Bio products that  
2 are used for gene therapy.

3 Justin, we can put that down.

4 Before we go too far, Mr. Zuk, can you explain  
5 what gene therapy is?

6 A. Well, gene therapy, the ultimate goal is to have  
7 a -- to express a therapeutic protein in -- therapeutic  
8 protein in human cells or human tissues.

9 The way that is achieved with gene therapy is  
10 that one uses a virus, okay. The virus is what we call a  
11 vector. This virus will contain a segment of DNA that,  
12 once this virus infects or transfects a cell, it will cause  
13 that cell to express the DNA that the virus carried, and  
14 this DNA will have a sequence for a therapeutic protein.

15 Q. In this context, have you heard the abbreviation  
16 "AAV" before?

17 A. Oh, yes. It stands for adeno-associated virus,  
18 and it's a very commonly-used gene therapy vector.

19 Q. Have you come across the term "capsid" before?

20 A. Well, it's a virus, and you think after virus as  
21 a sphere, and it has a protein coat. The protein coat is  
22 called the capsid, and we often use that for referring to  
23 the virus.

24 Q. Now, Mr. Zuk, have you prepared some slides to  
25 help explain the Gator Bio products for gene therapy

1 Q. Has Gator Bio ever encouraged customers to use  
2 the first generation AAVX probe with the second generation  
3 HS AAV and HS AAV9 kits?

4 A. It has not.

5 Q. Justin, let's go back to RDX-3, and let's turn  
6 to slide 5.

7 Now, Mr. Zuk, I want to talk about the second  
8 generation HS AAV, and HS AAV9 kits.

9 At a high level, can you describe how these two  
10 kits work?

11 A. Okay. They're what we call a sandwich  
12 immunoassays, okay. There is a analyte binding molecule,  
13 in this case with specificity for the AAV capsid. It will  
14 bind the capsid.

15 Then there is a second antibody, which we term  
16 the signal or the detection antibody that will form a  
17 complex with any of the capsid captured on the surface.

18 Then, we have other binding events where we  
19 bring in the enzyme HRP.

20 Q. How is that different from the first generation  
21 AAVX and AAV9 probes?

22 A. Well, it doesn't have this secondary complex  
23 with the detection antibody and the HRP enzyme.

24 Q. What do the second generation HS AAV and HS AAV9  
25 kits measure?

1           A.     Well, they measure the AAV capsid at a much  
2 lower concentration. In this case, expressed as VP or ML,  
3 or viral particles per ML. They're much more sensitive  
4 than the AAVX and AAV9 label-free kits.

5           Q.     At any point during the use of these HS AAV and  
6 HS AAV9 kits, do you measure or assay the activity of HRP?

7           A.     No. It's merely used as a label to allow us to  
8 detect the formation of this immune complex, and quantify  
9 how many viral particles are in the sample.

10          Q.     At any point during the use of the HS AAV and HS  
11 AAV9 kits, do you measure a signal indicative of the  
12 activity of HRP?

13          A.     We do not. It just merely serves as a label.

14          Q.     If you wanted to assay the activity of HRP or  
15 measure a signal indicative of the activity of HRP, could  
16 someone use these kits, the HS AAV, HS AAV9 kits to do  
17 that?

18          A.     They are not suitable for enzyme activity  
19 measurements.

20          Q.     Now, are you aware of anyone who has ever tried  
21 to do that, to use these kits to assay enzyme?

22          A.     I'm not aware of that.

23          Q.     Mr. Zuk, are you familiar with what a dynamic  
24 range is?

25          A.     Yeah.

1 Q. What does that mean?

2 A. Well, it's a statement describing one aspect of  
3 the assays's overall performance. And the dynamic range  
4 gives the concentration of an analyte at very low levels  
5 out to very high levels.

6 The limits are determined by having a precision  
7 of plus or minus less than 10 percent.

8 Q. Without getting into the details, can you tell  
9 us generally how does the dynamic range of the first  
10 generation AAVX and AAV9 probes compare to the second  
11 generation HS AAV and HS AAV9 kits?

12 A. Well, the label-free assays, AAVX and AAV9,  
13 since they do not have the signal amplification element,  
14 their dynamic range is at much higher concentrations of the  
15 viral particles.

16 Q. Now, are there situations where the first  
17 generation probes can complement the second generation  
18 kits?

19 A. Yes. Absolutely.

20 Q. Okay. Tell us about that.

21 A. Well, it's -- these assays are intended to be  
22 used in the bioprocess and production of the AAV viral  
23 particles. This process can start at very low  
24 concentrations, and later stages in the process can be at  
25 very high concentrations.

1           So the two assays compliment each other, and  
2 they can give the user the opportunity of quantitation and  
3 measurements throughout the entire bioprocess range.

4       Q.     Again, before we jump ahead, have you prepared a  
5 slide to help explain the sensitivity and dynamic ranges of  
6 the gene therapy products Gator offers?

7       A.     Yes.

8       Q.     Justin, would you put up slide 6 in RDX-3.

9           Mr. Zuk, walk us through the dynamic range of  
10 the second generation HS AAV kit and the first generation  
11 AAVX probe.

12      A.     Okay.

13           So for the second generation HS AAV, the range  
14 is 5 times 10 to the 6th to 5 times 10 to the 10th, viral  
15 particles per mL. First generation is 1 times 10 to the  
16 9th, to 1 times 10 to the 13th viral particles per million.  
17 For an overall combined range of 5 times 10 to the 6th to 1  
18 times 10 to the 13th VP per mL.

19      Q.     And similarly can you walk us through the second  
20 generation HS AAV9 kit and the first --

21 (Clarification requested by the Realtime Stenographer.)

22      Q.     I'm going to ask you to slow down, Mr. Zuk. I  
23 know you're nervous.

24      A.     I have that tendency.

25      Q.     Can you walk us through the dynamic range of the

1 second generation HS AAV9 kit and the first generation AAV9  
2 probe?

3 A. Yes, I can.

4 Q. Okay.

5 A. The second generation is 1 times 10 to the 7th,  
6 to 1 times 10 to the 9th, VP per mL.

7 First generation, AAV9, is 3 times 10 to the  
8 9th, to 1 times 10 to the 13th, viral particles per mL for  
9 an overall combined range of 1 times 10 to the 7th to 1  
10 times 10 to the 13th VP per mL.

11 Q. Mr. Zuk, is there a gap in the dynamic range  
12 where the HS AAV kit ends and where the AAV9 probe works?

13 A. You mean for this gap here.

14 Well, no, this -- there's actually no gap, okay.

15 The first generation kit can detect down to 1  
16 times 10 to the 9th. It's just that the precision isn't  
17 quite as good.

18 Also, if one wants to measure at 1 times 10 to  
19 the 9th at high precision, they can use the second  
20 generation kit.

21 Q. Now, to your knowledge, does Sartorius offer any  
22 gene therapy products -- products for gene therapy  
23 applications?

24 A. I believe they have launched something somewhat  
25 similar to our first generation AAVX kit.

1           Q.     To your knowledge, are you aware of any  
2 Sartorius products that are tailored to the AAV9 serotype?

3           A.     No.

4           Q.     Are you aware of any combination of Sartorius  
5 products that offers the same, combined dynamic ranges as  
6 the Gator Bio gene therapy products?

7           A.     I'm not aware of any.

8           Q.     I want to talk about how these products fit into  
9 the overall picture.

10                     Justin, can you put up slide 7?

11                     First off, Mr. Zuk, would you explain the  
12 various stages in the development and manufacture of gene  
13 therapies?

14           A.     Okay.

15                     So bioprocess people, okay, they use the term  
16 upstream and downstream. Upstream is the very early stage  
17 where it's the initial production of the AAV capsid. Those  
18 concentrations are very low. As the bioprocess continues,  
19 the -- they go to what they call the mid-stage where the  
20 concentration of the virus capsid increases. Then they go  
21 to the late stage, which is at the maximum level, or which  
22 they call the actual product production levels which is the  
23 downstream process.

24                     At that point, they begin the purification of  
25 the AAV virus.

1 Q. Where did the Gator Bio first generation probes  
2 and second generation high sensitivity kits fit into this  
3 picture?

4 A. Well, the HS assays, because of their high  
5 sensitivity can be used for the early stage, and even up to  
6 some portion of the mid-stage.

7 The first generation can measure from mid-stage  
8 to late stage. The fact that these two methods can be used  
9 in conjunction is that the same instrument can be used  
10 throughout the stages in the AAV production.

11 Q. And how do Gator Bio's gene therapy application  
12 products compare to potential non-BLI alternatives?

13 A. Okay.

14 Well, the most common alternative is ELISA down  
15 here. It's known to be a sensitive method. It's not quite  
16 as sensitive as our second generation HS kit.

17 It has a relatively narrow range, okay. This  
18 method is mostly a manual protocol, so it's labor  
19 intensive. Also, if one wants to assay samples at a higher  
20 concentration, the user has to dilute the samples into the  
21 ELISA concentration range. So that adds to the labor, and  
22 also it's a source of error.

23 Q. What about fluidic disc?

24 A. Fluidic disc, we use that -- they're in it  
25 reference to a company called Gyros (phonetic). They have

1 a centrifugal disc that can measure the AAV viral  
2 particles.

3 But you can see here, they're nowhere near  
4 sensitive, and they are restricted to mid-stage and late  
5 stage samples.

6 Q. How labor intensive is it to use the fluidic  
7 disc?

8 A. This one is automated, but it does have some  
9 instrument issues in terms of maintenance. But its primary  
10 limitation is the narrow, or it doesn't have the  
11 sensitivity that our HS assays have.

12 Q. Tell us what AUC is.

13 A. AUC stands for analytical ultracentrifugation.  
14 It takes a capsid sample, and subjects it to very high  
15 g-forces. They can monitor the sedimentation rate, and  
16 then it can also derive a concentration of the viral  
17 capsid.

18 But as you can see here, it's not sensitive at  
19 all. It's only used for a final product that's been  
20 purified. It's also very labor intensive and very  
21 expensive.

22 It's listed here because historically, it was  
23 the first analytical method that was used.

24 Q. Are you familiar with something called surface  
25 plasmon resonance or SPR?

1           A.     Yes, I am.

2           Q.     Is SPR an alternative to Gator Bio's gene  
3 therapy products?

4           A.     Not really. The SPR uses what we call a  
5 microfluidic flow cell that has very narrow and very small  
6 capillary channels. These bioprocess samples, okay, often  
7 will contain cellular debris.

8                     In the SPR flow cells will have a tendency of  
9 clogging with these bioprocess samples.

10                    So they're not suitable at all.

11                    JUDGE JOHNSON HINES: Mr. Kanter.

12                    MR. KANTER: Again, the witness is providing  
13 expert testimony about what are suitable alternatives,  
14 testifying about other methods not at issue in this case.  
15 I think that's inappropriate for a fact witness.

16                    JUDGE JOHNSON HINES: Mr. Santhanam, can you lay  
17 some foundation, please.

18                    MR. SANTHANAM: Sure.

19 BY MR. SANTHANAM:

20           Q.     Mr. Zuk, during the course of your work at Gator  
21 Bio, as you develop products, do you look at potential  
22 alternatives to the Gator Bio products that are being  
23 developed?

24           A.     Absolutely, because we want to do comparison  
25 studies to ensure that we have a better-performing

1 analytical system. So it's always on our mind.

2 Q. Do you take into account how potential  
3 alternatives to BLI might be used by customers in  
4 developing your products?

5 A. Absolutely, because, one, the customer will want  
6 to compare the sensitivity, precision, the tolerance for  
7 crude samples, and they want to do a comparison between our  
8 biosensors and a competitive product.

9 Q. Mr. Zuk, have you been involved in the process  
10 of --

11 JUDGE JOHNSON HINES: Excuse me, Mr. Kanter.

12 MR. KANTER: Yeah, I'm sorry, Your Honor. I  
13 believe we're going to maintain that objection.

14 I think he's testifying not about what Gator Bio  
15 believes is a suitable alternative, but what is a suitable  
16 alternative. So that, I think, strays beyond giving fact  
17 testimony and his own personal opinion and trying to  
18 testify about scientific topics, for which an expert report  
19 should have been disclosed in this case.

20 JUDGE JOHNSON HINES: You know, I think  
21 notwithstanding him not saying it's his belief, the  
22 testimony would necessarily be that.

23 So I'll overrule the objection.

24 MR. KANTER: Thank you, Your Honor.

25 BY MR. SANTHANAM:

1 Q. Now, Mr. Zuk, have you been involved in the  
2 process for seeking premarket approval for FDA products?

3 A. Many of the projects in the course of my career  
4 have been FDA approved.

5 Q. Do you know if gene therapies are regulated by  
6 the FDA?

7 A. Oh, yes. Very much so.

8 Q. As you developed the Gator Bio products for gene  
9 therapy applications, did you consider the regulatory  
10 environment in which customers develop gene therapy  
11 products?

12 A. It is a critical and major consideration for us,  
13 because since the customers will be using our products in a  
14 regulated environment, we need to consider the quality of  
15 the engineering and the reliability of the instrument.

16 Customers will have demands on specific  
17 software, and each of our biosensors that we offer to  
18 customers, we need to provide a certificate of analysis,  
19 because they're very much concerned about lot-to-lot  
20 reproducibility. They need to have consistent performance.

21 Q. You worked at -- worked with two sets of BLI  
22 systems; one at ForteBio and one now at Gator Bio.

23 Are you familiar with the challenges in  
24 switching systems?

25 A. For customers who are in a regulated

1 environment, okay, it's extremely difficult for them to  
2 switch if they have already validated an analytical method.

3           And the reason for that is that they will have  
4 to approach the FDA and get the FDA's opinion on the  
5 significance of that switch. In many cases, they may have  
6 to repeat some of the development studies. And even in the  
7 worst case, they may have to repeat the clinical trial.

8           So it is very difficult to switch.

9           Q.     Mr. Zuk, I want to switch gears a little bit and  
10 talk about the Gator Bio ratio kit.

11           What specifically does the ratio kit measure?

12           A.     It measures the ratio between empty AAV capsids  
13 and what we call full capsids.

14           An empty capsid is defined as a viral capsid  
15 that has no genetic material, and a full capsid is a capsid  
16 that contains the full complement of its genetic material.

17           Q.     How is the ratio of empty to full important?

18           A.     Well, it's critically important because this is  
19 a biologic, okay? The manufacturer of these gene therapy  
20 products is several orders of magnitude more complicated  
21 than, say, a conventional drug, because it's inherently  
22 variable.

23           In the production of the AAV capsid, there is a  
24 percentage of empty capsids. This has several impacts.

25           If a product has a high concentration of empty

1 capsids, the potency or what we call the efficacy of that  
2 therapy will be much reduced.

3           Also, if they have to load a dose, a higher  
4 amount of viruses, these viruses do have safety issues.  
5 Okay.

6           In some cases in the past, it's been reported  
7 that individuals can undergo organ failure, or there are --  
8 it's known that the AAV has what we call pre-existing  
9 antibodies, because the AAV is not that much different than  
10 influenza.

11           If the patient has preexisting antibodies, it  
12 can cause an immune response and tissue damage. So there  
13 is a serious safety issue.

14           The other -- the third part of it is, is that  
15 the FDA is concerned about efficacy and safety but also  
16 reproducible manufacturing. So the challenge for the  
17 developers, okay, is that they have to demonstrate that  
18 they can produce this product in a reproducible manner for  
19 the FDA.

20       Q.     Justin, can you put up CX-104.

21           Let's blow up the diagram there.

22           Mr. Zuk, at a high level, can you tell us how  
23 the ratio kit works?

24       A.     Yes.

25           It's a three-step protocol, and it uses two

1 or measure a signal indicative of HRP activity, could they  
2 use the ratio kit to do that?

3 A. They could not.

4 Q. Are you aware of anyone who has ever tried?

5 A. No.

6 Q. Now, Mr. Zuk, does the ratio kit use an AAVX  
7 first generation probe?

8 A. Yes, it does. It's used for this affinity  
9 capture step.

10 Q. Can a customer purchase a standalone first  
11 generation AAVX probe and run the ratio assay?

12 A. No, because the ratio kit has a proprietary  
13 reagent, and of course, we have the second biosensor probe  
14 to measure DNA.

15 Q. To your knowledge, has any customer purchased a  
16 standalone AAVX probe, first generation probe, and tried to  
17 carry out the ratio assay?

18 A. No.

19 Q. Does Gator Bio encourage that?

20 A. No.

21 Q. To your knowledge, does Sartorius offer any  
22 product that does what the ratio kit does?

23 A. No.

24 Q. Are there other acceptable alternatives to the  
25 Gator Bio ratio kit?

1           A.     Oh, there are on the market, there's maybe four  
2     or five methods, okay, but these other methods, okay, do  
3     not have this affinity capture step. So they're limited in  
4     their application. Primarily, they're used for samples  
5     that are downstream at the end of the bioprocess. Okay.

6                     Our product is unique because it can span the  
7     entire upstream-to-downstream range of testing  
8     requirements.

9           Q.     Now, Mr. Zuk, I want to go back and focus on the  
10    HS AAV and HS AAV9 kits, and we're going to leave the ratio  
11    kit for now.

12                    Justin, would you go back to slide 5 in RDX-3.

13                    I want to focus, Mr. Zuk, on the two diagrams  
14    that we see here on the left of the screen.

15                    Focusing on the left diagram, does that show a  
16    probe before or after substrate is introduced?

17           A.     This shows the slide here, okay, the -- the  
18    diagram here is right after all the binding steps, and it's  
19    before the substrate is introduced.

20           Q.     Okay.

21           A.     This -- okay.

22           Q.     Before the substrate is introduced, is the  
23    enzyme already bound on the probe?

24           A.     Yes, it is. You can see here in the  
25    illustration, it's bound.

1 Q. At the moment that the probe is introduced to,  
2 say, a substrate solution, is there an enzyme in the  
3 solution?

4 A. No.

5 Q. Is there any substrate reacted or reacting with  
6 an enzyme in the solution?

7 A. No.

8 Q. Now, what is the analyte that these -- and we  
9 can zoom back out.

10 What is the analyte that these kits, the HS AAV  
11 and HS AAV9 kits, detect?

12 A. It detects the AAV capsid, and the reported  
13 results are viral particles per ML.

14 Q. What is the analyte binding molecule in the  
15 probes that binds the virus capsids?

16 A. It's the antibody here that has specificity for  
17 the -- it's immobilized on the probe tip, and it has  
18 specificity for the AAV capsid.

19 It's a commercial product with the trade name of  
20 CaptureSelect, and it's offered by Thermo Fisher  
21 Scientific.

22 Q. When you obtain these antibodies from Thermo  
23 Fisher Scientific, are they marketed as binding HRP  
24 substrate?

25 A. No.

1 Gator Bio, you call the next witness?

2 MS. MORTAZAVI: Not from our side, Your Honor.

3 MS. ASCARRUNZ: Not for Gator Bio.

4 MR. GENNARI: No, Your Honor.

5 JUDGE JOHNSON HINES: Can you call the next

6 witness?

7 MS. ASCARRUNZ: Yes, Your Honor.

8 This is Veronica Ascarrunz. We're calling Tom

9 Vander Veen as our next witness. May I approach with some

10 binders?

11 JUDGE JOHNSON HINES: Yes.

12 Thank you.

13 Whereupon --

14 THOMAS VANDER VEEN PhD,

15 having been first duly sworn, was examined and testified as

16 follows:

17 JUDGE JOHNSON HINES: Be seated and welcome.

18 THE WITNESS: Thank you.

19 MS. ASCARRUNZ: Thank you, Your Honor. I think

20 maybe we have a couple of points of business for this

21 witness before we proceed.

22 One is I believe that Complainants had some

23 objections to his demonstratives and exhibits that Your

24 Honor may wish to address before we go forward with the

25 witness.

1 I'll let them speak to that.

2 MS. MORTAZAVI: If all of the changes that we  
3 discussed yesterday have been made to the slides, we have  
4 no further objections. I understand you've added some  
5 exhibits that weren't previously disclosed. I don't know  
6 what those are yet, so if you want to make a  
7 representation, consider it, but I -- you have just handed  
8 me a binder with some new exhibits not previously  
9 disclosed.

10 JUDGE JOHNSON HINES: Okay.

11 Let's do one thing at a time. I think the first  
12 question was do there continue to be objections to the  
13 demonstratives?

14 MS. ASCARRUNZ: Not to the demonstratives, Your  
15 Honor.

16 JUDGE JOHNSON HINES: Okay.

17 MS. ASCARRUNZ: Secondly, Dr. Vander Veen is one  
18 of the witnesses who we are taking out of turn because he  
19 has testimony tomorrow in another investigation. So we  
20 think timing-wise, we are accurate with respect to the  
21 estimates that we should be fine, and able to complete  
22 today, but I just wanted to make Your Honor aware of that  
23 in case things start to get tight. But I think we should  
24 be okay on that.

25 JUDGE JOHNSON HINES: All right.

1                   So is the request then that Mr. Vander Veen  
2 finish today?

3                   MS. ASCARRUNZ: Yes, Your Honor.

4                   JUDGE JOHNSON HINES: Okay.

5                   Let's try to do that.

6                   MS. ASCARRUNZ: Perfect.

7                   Secondly, Dr. Vander Veen is a rebuttal expert.  
8 It's a little bit of an awkward situation in that the  
9 expert he is rebutting has not yet testified. So just  
10 wanted to make Your Honor aware of that as well.

11                  JUDGE JOHNSON HINES: Sure.

12                  No, I understand that.

13                  MS. ASCARRUNZ: Ready to proceed?

14                  JUDGE JOHNSON HINES: Yes.

15                                 DIRECT EXAMINATION

16 BY MS. ASCARRUNZ:

17           Q.     Good afternoon, Dr. Vander Veen.

18           A.     Good afternoon.

19           Q.     Can you state your full name for the Court?

20           A.     Thomas D. Vander Veen.

21           Q.     Where do you work, Dr. Vander Veen?

22           A.     I'm employed at Epsilon Economics.

23           Q.     Could you tell us what you do at Epsilon  
24 Economics?

25           A.     I'm managing director as well as vice chairman

1 of the firm. I provide economic analysis and strategy work  
2 inside and outside of litigation.

3 So the non-litigation work involves valuation of  
4 intellectual property or market analyses and those sorts of  
5 things related to buying and selling of assets, for  
6 example.

7 Then I also provide testimony in intellectual  
8 property and international trade matters.

9 Q. Thank you. Did you prepare anything to help you  
10 with your testimony today?

11 A. Yes. I have a set of demonstratives.

12 Q. Could you look in your binder. It should be a  
13 small binder labeled RDX-004C.

14 A. I have it.

15 Q. Are these the demonstratives you referenced?

16 A. Yes.

17 MS. ASCARRUNZ: Your Honor, may we post the  
18 demonstratives up on the screen?

19 JUDGE JOHNSON HINES: Yes.

20 MS. ASCARRUNZ: Justin, if you could put up  
21 RDX-002.

22 BY MS. ASCARRUNZ:

23 Q. Dr. Vander Veen, let's start with your  
24 background. Could you tell us what your educational  
25 history is?

1           A.     I have a bachelors degree in economics and  
2 mathematics from Calvin College. I have a master's degree  
3 in economics and a PhD in economics. My graduate degrees  
4 are from Brown.

5           Q.     Are you a member of any professional  
6 associations?

7           A.     Yes. I'm a member of the American Economic  
8 Association, the Licensing Executives Society, and in the  
9 past I have also developed and taught courses on valuation  
10 techniques for LES.

11                   And then I'm an associate member of the  
12 International Trade Commission Trial Lawyers Association.

13          Q.     Could you describe your work experience after  
14 graduate school?

15          A.     Yes. So, actually, during and after graduate  
16 school, I taught economics, and though I see it's actually  
17 not listed on this slide, this started after my teaching  
18 stint at Skidmore College.

19                   I worked at the International Trade Commission  
20 on the Staff of Commissioner Copeland. I was here for a  
21 little bit over four years advising him on trade and other  
22 matters that came before the Commission at the time.

23                   Then for the last 20 years or so, I have been  
24 working as an economic consultant for a number of different  
25 organizations, but doing work largely consistent of how I

1 described it at the beginning.

2 Q. Have you served as an expert witness before in  
3 court?

4 A. Yes. I have served as a witness in district  
5 court and arbitration and here at the ITC.

6 Q. About how many times have you served as an  
7 expert witness?

8 A. Probably approaching 100. Over 20 years.

9 Q. Have you ever been qualified as an expert?

10 A. Yes, I have.

11 Q. Could you explain the relationship between your  
12 educational and professional background and the work that  
13 you've done for this case?

14 A. Yes.

15 Well, certainly my economics background has  
16 informed my work. My experience in working as an economic  
17 consultant over the last 20 years has certainly informed my  
18 work here. I have provided testimony and done analyses on  
19 a number of ITC cases related to domestic industry, public  
20 interest, remedy, bond and so forth.

21 Q. Okay.

22 If I could ask you to turn in your binder to  
23 RX-0198.

24 Do you recognize that document?

25 A. Yes. That's a copy of my CV that was submitted

1 with my reports in this case.

2 Q. Does it accurately reflect your educational and  
3 professional experience?

4 A. Yes, it does.

5 MS. ASCARRUNZ: Your Honor, at this time, Gator  
6 Bio tenders Dr. Vander Veen as an expert in the field of  
7 economic and financial analysis.

8 JUDGE JOHNSON HINES: Any objection?

9 MS. MORTAZAVI: No objection, Your Honor.

10 MR. GENNARI: No objection, Your Honor.

11 JUDGE JOHNSON HINES: So tendered.

12 MS. ASCARRUNZ: Thank you.

13 BY MS. ASCARRUNZ:

14 Q. Dr. Vander Veen, could you describe generally  
15 what your assignment was for this investigation?

16 A. Yeah, in this investigation, I was asked to  
17 evaluate the public interest factors, economic prong of the  
18 domestic industry, and bond, and within that context,  
19 respond to opinions put forward by Dr. Schwartz.

20 Q. Justin, if you could put up the next slide.  
21 Could you summarize what your opinions were that you  
22 reached in this case?

23 A. Yes, so at a high level, it's my conclusion that  
24 the proposed remedy would have an adverse impact on the  
25 public interest. That Sartorius and Dr. Schwartz have not

1                    Could you explain what your opinion is in that  
2 regard?

3            A.     Yes.   So here we have heard testimony from Dr.  
4 Tan and Mr. Zuk regarding the uses of these biosensors and  
5 instruments. They're used in applications that relate to,  
6 of course, a host of things and drug development and  
7 related to disease and other health research.

8            Q.     Okay.  
9                    Why don't we go to your slide 8.  
10                  What are you expressing on this slide?

11          A.     Yes.  
12                  So as I mentioned, the accused products are used  
13 for research, and we heard a lot of testimony this morning  
14 regarding that.

15                  There's also issues that come up because of the  
16 validation, the need to revalidate the systems. We heard  
17 testimony this morning regarding that.

18                  Then as well as the lack of available  
19 substitutes from Sartorius for at least some of these  
20 systems.

21          Q.     Okay. We'll address each of these points, but I  
22 want to ask you, what is your understand of who the  
23 consumers are that are purchasing these products.

24          A.     So it's a range of entities, but they are  
25 primarily research institutes, and it can include US

1 government, academic institutes including state and private  
2 universities as well as private industry, who is doing  
3 research in these areas.

4 Q. Justin, could I ask you to put up slide  
5 RDX-002C.006.

6 Do you recognize what this is, Dr. Vander Veen?

7 A. Yes. So this is a slide that Dr. Tan, I  
8 believe, discussed earlier today.

9 Q. What does it reflect?

10 A. It provides a sampling of Gator Bio customers.

11 MS. ASCARRUNZ: At this point, Your Honor, we  
12 can go back on the public order record.

13 JUDGE JOHNSON HINES: All right.

14 (Whereupon, the trial resumed in open session.)

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1 O P E N S E S S I O N

2 BY MS. ASCARRUNZ:

3 Q. Justin, could you put up RDX-003.003.

4 Dr. Vander Veen, do you recognize what's up on  
5 the screen right now?

6 A. Yes, this was a slide that Mr. Zuk discussed  
7 earlier today.

8 Q. What does it reflect?

9 A. So it's a number of research studies that have  
10 been conducting -- have been conducted using Gator Bio  
11 instruments and biosensors.

12 Q. How, if at all, do these research studies inform  
13 your opinion?

14 A. Well, I also referenced them in my report, and  
15 in the context of the research that's ongoing in the health  
16 and disease areas, but also that it's being conducted by  
17 research institutes including universities, US government,  
18 as well as private industry.

19 Q. Are you aware of the affiliations or funding for  
20 these research studies?

21 A. I mean, to the extent they're disclosed in the  
22 studies, yes.

23 Q. Justin, if you could put up Dr. Vander Veen's  
24 next slide, slide 9.

25 What are you showing here, Dr. Vander Veen?

1           A.     So this is information similar to what Mr. Zuk  
2     discussed in terms of these research studies, and it shows  
3     the various affiliations of the authors, and you can see it  
4     includes universities, private industry, government  
5     entities, then and as well as some of the funding that  
6     underlay the research, including US Department of Energy  
7     contract, and NIH work.

8           Q.     Just as an example, what is the affiliation  
9     funding for RX-0085C?

10          A.     85C?

11          Q.     Correct.

12          A.     It's the University of California San Francisco,  
13     the University of Utah School of Medicine and Gator Bio.

14          Q.     Your slide 8 had mentioned in the second bullet  
15     point, validation of a new BLI system.

16                     What were you referring to?

17          A.     So we heard testimony from both Dr. Tan and  
18     Mr. Zuk about the adverse impact that the exclusion order  
19     would have if an entity needed to change out its  
20     instruments.

21                     One of the issues is that some of these are  
22     related to studies on drug development and they have other  
23     validation elements in the study. If they would have to  
24     change the system, it would require revalidating, and that  
25     revalidation could take extensive time, and cost.

1 Q. How does that relate to the statutory public  
2 health and welfare factor?

3 A. Well, it's another adverse impact that would  
4 exist on the users of these systems, if they have to switch  
5 it out. It may mean that there would be delays in their  
6 work or inability to complete their work.

7 Dr. Tan also talked about how some of these  
8 instruments are purchased by -- through grant money, and  
9 they may not be able to replace an instrument because of a  
10 lack of funding.

11 Q. Apart from the testimony you heard in the  
12 courtroom today and yesterday regarding this issue, did you  
13 -- do you have any other evidence for this validation  
14 concern?

15 A. I've also seen it in documents produced by  
16 Sartorius, including their annual report.

17 Q. Why don't we put up their annual report, which  
18 is CX-0139, which should also be in your binder if you need  
19 to reference it.

20 How does this relate to the validation concern?

21 A. There was a statement in the annual report about  
22 potential risks to customers of -- if they're unable to  
23 replace a system.

24 Q. You don't happen to recall where in the report?

25 A. It's -- I think it's page 26 or 27.

1 Q. Why don't we go to -- let's start with page 27,  
2 Justin.

3 You will have to zoom in.

4 A. 27 is the bottom paragraph. Yes. Okay. I see  
5 the paragraph.

6 Q. Okay. Same question.

7 How does this relate to the validation concern  
8 you have been discussing?

9 A. Yes. So you can see here in this paragraph,  
10 there's a statement that says, "Because health authorities  
11 validate production processes as an integral part of an  
12 application for approval of a new medical drug, the  
13 components initially validated can be replaced only at  
14 considerable expense once they have been approved."

15 So that's reflecting the same validation concern  
16 that Dr. Tan and Mr. Zuk were discussing.

17 Q. Okay.

18 Your slide 8 had a third bullet point that said,  
19 "Lack of available substitution for the accused products."

20 Could you explain what you meant there.

21 A. Yes. So there again, in the testimony this  
22 morning from Dr. Tan and Mr. Zuk, you heard that Sartorius  
23 does not have substitutes for the suite of AAV biosensors  
24 that Gator Bio provides or the Gator Pro instrument.

25 Q. How does that relate to the statutory public

1 health and welfare?

2 A. Again, there are applications that, if there  
3 were an exclusion order, there are applications where  
4 researchers can -- the consumers of the products would be  
5 unable to obtain certain types of biosensors or  
6 instruments, and would then adversely impact their ability  
7 to conduct the research.

8 Q. Okay.

9 Why don't we go to your slide 11. Did you  
10 identify in reaching your opinions in this case any  
11 concerns regarding substitutions for the instruments?

12 A. Yes.

13 This was discussed earlier today in terms of the  
14 Gator Pro instrument.

15 Here, this is a instrument that has 32 channels,  
16 and based on the testimony I heard this morning, Sartorius  
17 does not have a comparable instrument that has -- that can  
18 do 32 channels. They have a version that has 16  
19 spectrometers, but not the 32.

20 Q. Apart from Sartorius and Gator Bio, are there  
21 any other manufacturers of BLI products that could provide  
22 available substitutes?

23 A. I understand that Gator Bio and Sartorius are  
24 the only two providers of BLI technology products.

25 Q. So that we can avoid jumping back and forth on

1 the confidential record, I'm going to skip your second  
2 public interest factor and go to the third, which is  
3 competitive conditions in the United States.

4 Did you reach an opinion on that issue?

5 A. Yes, I did, and that there would be an adverse  
6 impact on the competitive conditions.

7 Q. Why don't we go to your slide 13.

8 Could you tell us what you're showing here.

9 A. Yes.

10 So the first point is related to the fact that  
11 there are essentially only 2 providers of BLI technology  
12 products. So if there were an exclusion order that  
13 eliminated the Gator Bio products from the market, we would  
14 be left with only one, so there would be obviously no  
15 choice left for customers.

16 And then some of this is, you know, related to  
17 the testimony we heard today in terms of the inability for  
18 customers to obtain certain biosensors. And one of the  
19 issues, of course, is that the biosensors and the  
20 instruments are not interchangeable. So a Gator Bio  
21 instrument cannot be used with a Sartorius instrument or a  
22 Sartorius consumable cannot be used with a Gator Bio  
23 instrument.

24 So the order would mean that there would be this  
25 lack of competition then remaining.

1           Q.     So if Sartorius were to succeed in obtaining the  
2 remedy it seeks in this case, what would be the competitive  
3 landscape in the United States?

4           A.     We would be left with one supplier.

5                   MS. ASCARRUNZ: I think, Your Honor, at this  
6 point, we need to go on the confidential record of both  
7 parties because there will be some intermingling.

8                   JUDGE JOHNSON HINES: All right. We're on the  
9 confidential record.

10                   (Whereupon, the trial proceeded in confidential  
11 session.)

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1                   Good morning. Can you raise your right hand.

2   Whereupon--

3                   RYAN BAILEY, PhD,  
4   having been first duly sworn, was examined and testified as  
5   follows:

6                   JUDGE JOHNSON HINES: Thank you. Good morning.

7                   MS. TURNER: Plaintiffs call Dr. Ryan C. Bailey.  
8   Dr. Bailey is a professor in the Department of Chemistry at  
9   the University of Michigan. Dr. Bailey will testify  
10   regarding infringement, domestic industry and Sartorius's  
11   biosensors compared to Gator Bio's biosensors with  
12   respect --

13                  JUDGE JOHNSON HINES: You need to slow down.  
14   You might just want to ask the witness the questions, it's  
15   his testimony, instead of providing an introduction  
16   yourself.

17                  MS. TURNER: Oh, okay. No problem.

18                  JUDGE JOHNSON HINES: Thank you.

19                                 DIRECT EXAMINATION

20   BY MS. TURNER:

21           Q.     Would you please state and spell your full name  
22   for the record.

23           A.     Yes.

24                   My name is Ryan Bailey. R-Y-A-N, B-A-I-L-E-Y.

25           Q.     What is your profession?

1 A. Yes.

2 Q. To your knowledge, Doctor, Sartorius does not  
3 offer a ratio kit; correct?

4 A. They do not offer one.

5 As I walked through, they actually teach how  
6 they could use their products to develop their own, but  
7 correct, they do not offer one.

8 There's -- Tae Kang, I believe -- no, never  
9 mind. Sorry. Something else.

10 Q. Sartorius does not offer, to your understanding,  
11 a ratio kit; correct?

12 A. I understand that one's under development, but  
13 they do not offer it.

14 Q. Sartorius does not offer, to your understanding,  
15 any probes or kits that are dedicated to the AAV9 serotype;  
16 correct?

17 A. That's actually -- I would not agree with that.  
18 Sartorius shows that their AAVX probes can be  
19 used for AAV9.

20 Q. Doctor, let me see if I can clarify that for  
21 you.

22 You're not aware of any product that Sartorius  
23 offers that is dedicated and specific to the AAV9 serotype;  
24 correct?

25 A. Correct, because they'd have no need to do it,

1 because they show they can detect AAV9.

2 Q. Now, let's go to CDX-1.95.

3 Now, Doctor, you also testified about this slide  
4 on direct examination; is that right?

5 A. That's correct.

6 Q. You talked about how important dynamic range is,  
7 in your view; is that right?

8 A. That's right.

9 Q. In fact, it's one of the most important  
10 considerations in your view; is that right?

11 A. It's among the most important.

12 Q. Okay.

13 Doctor, you looked at the dynamic ranges of  
14 various kits of Sartorius and Gator Bio kits; is that  
15 right?

16 A. That's correct.

17 Q. You didn't, as part of your analysis, Doctor --  
18 you haven't done any analysis of the concentrations of  
19 virus capsids that are measured at various stages of the  
20 gene therapy development process, did you?

21 A. No, I did not.

22 Q. You haven't provided any analysis in this case  
23 about what the dynamic ranges might be if you combine two  
24 or more kits; correct?

25 A. Can you please ask the question again?

1 Q. Yeah.

2 You haven't done any analysis in this case to  
3 see what the dynamic range would be if you combined two or  
4 more kits; correct?

5 A. Well, I believe as we exchanged about in my  
6 deposition, I think it's inappropriate to do  
7 apples-to-oranges comparison of two kits versus one.

8 You can ask these questions, if you'd like.

9 Q. Doctor, again, my question was quite simple.  
10 You haven't done any analysis in this case to  
11 determine what the dynamic range would be if you combined  
12 two or more kits; correct?

13 A. No, because I think it's scientifically  
14 inappropriate to do so.

15 Q. Now, Doctor -- we can put that down, Justin.

16 You're not aware of any two products from  
17 Sartorius that you could combine to achieve a dynamic range  
18 between 1 times 10 to the 7 and 1 times 10 to the 13 virus  
19 particles per milliliter; correct?

20 A. That is correct.

21 Q. Doctor, you are not aware of any Sartorius  
22 biosensors that are -- that can be combined to -- for a  
23 combined dynamic range between 1 times 10 to the 7 to 1  
24 times 10 to the 13 virus particles per milliliter for AAV9  
25 serotype viruses; correct?

1 A. That's correct.

2 Q. Okay.

3 And, Doctor, based on your own calculations, you  
4 acknowledge that the Gator Bio HS AAV9 kit is 62- to  
5 85-fold more sensitive than the Sartorius product  
6 offerings; correct?

7 A. That's correct.

8 MR. SANTHANAM: No further questions at this  
9 time, Your Honor.

10 JUDGE JOHNSON HINES: Thank you.

11 Mr. Gennari, do you have any questions?

12 MR. GENNARI: I do.

13 JUDGE JOHNSON HINES: Should we do them before  
14 lunch or after lunch?

15 MR. GENNARI: After lunch. Thank you.

16 JUDGE JOHNSON HINES: Okay. Then we are going  
17 to at least go back on the public record, and we will break  
18 for lunch now, and I will see you all at about 1:40.

19 (Whereupon, at 12:37 p.m., a lunch recess was  
20 taken.)

21 (Whereupon, the hearing resumed in open  
22 session.)

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1 follows:

2 DIRECT EXAMINATION

3 BY MR. SANTHANAM:

4 Q. Good morning, Dr. Schaafsma.

5 Would you please introduce yourself and state  
6 your full name for the ALJ.

7 A. Sure.

8 David Schaafsma. My last name is spelled  
9 S-C-H-A-A-F-S-M-A.

10 Q. Tell us where you work.

11 A. I am the president of California Optical  
12 Engineering, Inc.

13 Q. What do you do at California Optical  
14 Engineering, Inc.?

15 A. We provide technology and product development  
16 services to the med tech and biotech industries largely in  
17 the area of optical systems.

18 Q. Doctor, without getting into the details, would  
19 you tell us what you are here to testify about?

20 A. Yeah.

21 I have been retained by counsel for Gator Bio to  
22 come and give opinions on the patent at issue here.

23 Q. Now, Doctor, before we dive in to your opinions,  
24 I'd like to start by talking a little bit about your  
25 background and qualifications.

1                   Have you prepared some slides to help assist  
2 with your testimony today?

3           A.     Yes.

4           Q.     Do you believe those slides will be helpful?

5           A.     Yes.

6           Q.     Justin, let's put up slide 2 of Dr. Schaafsma's.

7                   JUDGE JOHNSON HINES: Mr. Santhanam, is there an  
8 RDX number for this?

9                   MR. SANTHANAM: Yes. It should be RDX-6, but  
10 that will be added to the demonstrative, Your Honor.

11                   JUDGE JOHNSON HINES: Thank you.

12 BY MR. SANTHANAM:

13          Q.     Doctor, can you tell us, do you have any  
14 educational degrees?

15          A.     I do. I have a bachelor's in physics from  
16 Whitman College.

17                   I have a master's in physics from Brown.

18                   And I have a directorate in physics from the  
19 University of Colorado at Boulder.

20          Q.     What was your area of research while you were  
21 getting your directorate?

22          A.     I did research on thin films, particularly  
23 optical devices, some like what we're talking about here.  
24 Quantum optics, and that type of optical devices,  
25 generally.

1 Q. Let's go to slide 3.

2 Doctor, can you describe for us your industry  
3 experience?

4 A. Yeah.

5 I have been doing technology and product  
6 development for over 30 years for a wide range of  
7 customers.

8 Before that, I actually ran a small group at a  
9 fiber-optics company in California called Ipitek, where I  
10 ran the fiber sensors group, and we developed a number of  
11 different types of fiber-optic sensors, including some  
12 biosensors.

13 Q. What did you do before that?

14 A. Before that, I was at NRL, where we did research  
15 on infrared fiber optics, some of which were used for  
16 biosensor applications.

17 Before that, I worked for the Bureau of  
18 Standards, NIST, in the area -- part of that was my PhD  
19 work, but generally, in the area of thin-film optics,  
20 including things like simulating reflectants and  
21 interference in thin films.

22 Q. You mentioned NRL, does that stand for US Naval  
23 Research Laboratory?

24 A. Yes, it does.

25 Q. When you said the Bureau of Standards, were you

1 referring to the National Institutes of Standards and  
2 Technology?

3 A. I was, yes.

4 Q. Tell us about your experience working with  
5 biosensors.

6 A. Right.

7 So, particularly, I'm pointing to the time at  
8 Ipitek where we developed a range -- we research and  
9 developed a range of different biosensors, some of which,  
10 as I have said, have relevance to the issue here.

11 And we did both label-based technologies, as  
12 well as label-free technologies.

13 Q. What's the difference between the two, between  
14 labeled and label-free?

15 A. So I'll give me nonbiochemist interpretation.

16 The -- in all of these types of sensors, there  
17 is some selective binding event, molecules that selectively  
18 bind with each other, antibody, antigen, nucleotides, DNA,  
19 that sort of thing.

20 We looked at a number of those type of sensors  
21 where, if you have this binding event, and then you have  
22 another molecule that comes along that enables you to  
23 detect it, so that could be a fluorescent molecule or  
24 something like that, that's what we call labeling that  
25 interaction. So you read out the label from the binding

1 event.

2           When you have a change that you can detect  
3 that's just based on that binding event itself, that's what  
4 was called label-free or nonlabeled techniques.

5       Q.     Do you have experience with label-free  
6 biosensors?

7       A.     Yeah. As a matter of fact, we did some research  
8 into different types of label-free technologies. It was  
9 very much the buzz word at the time.

10      Q.     Justin, can you put up RX-214.

11           Tell us what this is, Doctor.

12      A.     This is the first page of my CV.

13      Q.     Does your CV accurately describe your  
14 educational and professional experience?

15      A.     Yes, it does.

16           MR. SANTHANAM: Your Honor, at this time, we  
17 tender Dr. Schaafsma as an expert in fiber-optic systems  
18 and optical biosensors.

19           JUDGE JOHNSON HINES: Is there any objection,  
20 Mr. Kanter?

21           MR. KANTER: No objection.

22           MR. GENNARI: No objection.

23           JUDGE JOHNSON HINES: Thank you.

24           So tendered.

25 BY MR. SANTHANAM:

1 Q. Were you familiar with those methods?

2 A. Yes.

3 Q. Bottom line, Doctor, what is your opinion  
4 regarding whether Sun alone or in combination with Yu  
5 renders Claim 8 of the '887 Patent obvious when you apply  
6 the same reasoning that Sartorius does with respect to  
7 infringement and domestic industry?

8 A. Yeah.

9 I think that either Sun or -- Sun in combination  
10 with Yu does render the claim obvious.

11 Q. What is your opinion regarding whether Claim 8  
12 of the '887 Patent would have been obvious based on the  
13 claimed subject matter of the '547 Patent?

14 A. Well, once again, I think the '887 incorporates  
15 the '547 to serve as the device that they will use for the  
16 measurement, as a known device. It's being used for a  
17 known measurement, enzyme activity was known. I knew some  
18 of the people who worked for me to measure it.

19 So I think it represents an obvious application  
20 of a known device to a known measurement.

21 Q. Now, Dr. Schaafsma, I want to focus your opinion  
22 on whether Sartorius -- switching gears -- whether  
23 Sartorius offers an alternative to Gator Bio's 32-channel  
24 Gator Pro instrument.

25 Have you looked into that?

1 A. I have, yes.

2 Q. Okay.

3 Have you prepared some slides to help us walk  
4 through this?

5 A. Yes, I have.

6 Q. Let's go to slide 96.

7 Referencing here CX-102, Doctor, tell us how  
8 many spectrometers does the Gator Pro instrument have.

9 A. I think you can see over here in the column for  
10 the Gator Pro, it calls out that it has 32 spectrometers.

11 Q. From your experience and testimony earlier in  
12 this case from Dr. Tan, what significance does having 32  
13 spectrometers have?

14 A. Right.

15 From my experience, I can tell you that the  
16 number of spectrometers is basically what's going to limit  
17 the data rate, the bandwidth in this case.

18 So -- and we've heard Dr. Tan testify that, you  
19 know, sometimes that data rate is required for high-rate  
20 kinetics interactions. Things that have short time scales.

21 So more spectrometers buys you more bandwidth  
22 with which to make those measurements, and fundamentally,  
23 you have a higher Fidelity measurement when you can do  
24 that.

25 Q. Let's go to slide 97, referencing CX-476 at

1 Table 1.

2 Doctor, tell us how many spectrometers do  
3 Sartorius's highest throughput instruments have?

4 A. You can see here, both, the RH16 and the RH96  
5 have 16 spectrometers.

6 Q. Now, to your understanding does Sartorius have  
7 any instruments with 32 spectrometers?

8 A. I have not seen any such instruments, no.

9 Q. If you look at the Sartorius Octet RH96, how  
10 many simultaneous reads do they say that instrument can do?

11 A. They say it can do 96 simultaneous reads, over  
12 here.

13 Q. How is it possible to do 96 simultaneous reads  
14 using 16 spectrometers?

15 A. So the term "simultaneous" I think is used a  
16 little loosely here.

17 My understanding is that this machine is  
18 basically optically multiplexed. So they're literally  
19 multiplexing a set of optical signals into a set of  
20 spectrometers several at a time, 16 at a time in this case,  
21 right.

22 So my understanding is that this is a --  
23 basically a time division multiplexing kind of scheme.  
24 It's like a -- you know, a data time share. I'm looking at  
25 a set of 16, and I'm not looking at the rest of them at

1 that particular moment in time.

2 Q. How does multiplexing affect the data  
3 acquisition?

4 A. Well, as I have mentioned, I mean, basically,  
5 anytime you have a time division scheme like this, you're  
6 essentially decimating the data rate per channel, if you  
7 will.

8 There's only so much time that you allot to that  
9 channel, so you have less bandwidth available for it.

10 Q. Based on your review of the materials in this  
11 case, and Dr. Tan's testimony from earlier this week, do  
12 you have any opinion as to whether the use of 32  
13 spectrometers in the Gator Pro has any practical  
14 consequences?

15 A. Right. I think I mentioned, I think we heard  
16 Dr. Tan describe some of these applications.

17 Basically, if you need a lot of high rate  
18 kinetics information, right, where the speed of the  
19 acquisition, the number of channels and the Fidelity are  
20 important, then 32 spectrometers buys you significant  
21 advantage over 16.

22 MR. SANTHANAM: Your Honor, I pass the witness.

23 JUDGE JOHNSON HINES: Thank you.

24 Mr. Kanter.

25 MR. KANTER: Your Honor, may I approach?

1 ago.

2 MR. HERSTOFF: Your Honor, my colleague, Conrad  
3 Stumpf, will be conducting the cross-examination under the  
4 NEXT program.

5 JUDGE JOHNSON HINES: Terrific, thank you.

6 MR. STUMPF: Your Honor, Conrad Stumpf here.

7 I'd just like to remind the Court of what we  
8 discussed in the first day of the hearing with respect to  
9 assignor estoppel and his validity arguments. Sartorius  
10 BioAnalytical Instruments objects to Dr. Forrest providing  
11 opinions with respect to the invalidity of the '887 Patent.

12 JUDGE JOHNSON HINES: Thank you.

13 Mr. Day, I see there are binders, so why don't  
14 we get those distributed first.

15 Good afternoon, Dr. Forrest.

16 THE WITNESS: Good afternoon, Your Honor.

17 Whereupon--

18 LAIRD FORREST, PhD,  
19 having been first duly sworn, was examined and testified as  
20 follows:

21 JUDGE JOHNSON HINES: Thank you very much.

22 Please be seated.

23 Mr. Day.

24 DIRECT EXAMINATION

25 BY MR. DAY:

1 Q. Good afternoon, Dr. Forrest.

2 A. Good afternoon.

3 Q. Please introduce yourself to the Administrative  
4 Law Judge.

5 A. Yes.

6 My name is Laird Forrest, L-A-I-R-D,  
7 F-O-R-R-E-S-T. I'm a professor at the University of  
8 Kansas.

9 Q. What are you here to talk about?

10 A. I'm here to give my opinions regarding the  
11 validity or invalidity of Claim 8 of the '887, and also my  
12 opinions about domestic industry, and about infringement of  
13 Gator -- or Gator Bio's infringement, potentially, of that  
14 claim.

15 Q. Have you prepared any demonstrative exhibits to  
16 assist in your testimony today?

17 A. Yes, I have.

18 Q. Justin, can you please bring up RDX-5, the  
19 demonstrative exhibits.

20 A. Yes, that is.

21 Q. What administrative note --

22 MR. DAY: Your Honor, we expect the majority of  
23 this examination will take place on the public record.  
24 These slide have only been marked as an abundance of  
25 caution. We will proceed on the public record for this

1 examination. There are one or two slides where we will  
2 need to go briefly on the Sartorius confidential record.

3 JUDGE JOHNSON HINES: Thank you.

4 BY MR. DAY:

5 Q. Justin, please bring up slide RDX-2.

6 Dr. Forrest, can you please describe your  
7 education to the Administrative Law Judge?

8 A. Yes. I have a bachelors of science in chemical  
9 engineering from Auburn. A master's in chemical  
10 engineering also -- well, from the University of Illinois,  
11 and then I also have a PhD in chemical and biomolecular  
12 engineering from the University of Illinois.

13 After that I completed a couple of post-docs one  
14 of them at Wisconsin pharmaceuticals, but then also in  
15 pharmacokinetics at Washington State.

16 Q. Have you been involved in any businesses outside  
17 of academia?

18 A. Yes. I founded several startup companies  
19 related to my research. A couple are in drug development.  
20 One works with esters that we call substrates that are  
21 involved in certain biological processes such as the Krebs  
22 cycle, another one in cancer drugs. I also have been  
23 involved in a couple of companies that are developing  
24 biomedical devices, one for helping bone fractures break,  
25 and another one that is involved in ultrasound imaging, and

1 clearing of vascular clots.

2 I'm also on the scientific board of advisers of  
3 a company called Exogenesis that actually has a USDA -- or  
4 US, pardon me. FDA approved medical device in the US.

5 Q. Have you published any work related to your  
6 education and professional experience?

7 A. Yes. I have just over 100 peer-reviewed papers,  
8 and a similar number of abstracts, posters, and talks that  
9 I have given.

10 Q. How does your professional experience relate to  
11 the subject matter of this case?

12 A. Well, much of my work involves working with  
13 biochemical processes either we're trying to treat diseases  
14 or we're trying to understand them.

15 That involves a lot of work developing  
16 BioAnalytical assays and utilizing various tools that are  
17 necessary to measure these biochemical processes.

18 Q. Justin, can you please bring up RX-215.

19 Dr. Forrest, do you recognize RX-215?

20 A. Yes. That is my current CV.

21 MR. DAY: Your Honor, at this time, Gator Bio  
22 asks that Dr. Forrest be recognized as an expert in the  
23 field of biochemistry.

24 JUDGE JOHNSON HINES: Mr. Stumpf, any objection?

25 MR. STUMPF: No objection, Your Honor.

1 JUDGE JOHNSON HINES: Mr. Gennari?

2 MR. GENNARI: No objection.

3 JUDGE JOHNSON HINES: So tendered.

4 BY MR. DAY:

5 Q. Turning to slide 3, Dr. Forrest, what were you  
6 asked to do in this case?

7 A. I was asked to opine on certain matters. One  
8 was about the infringement by Gator Bio of the '887 Patent.  
9 Another one was whether Sartorius has technical domestic  
10 industry for the '887 Patent.

11 Then on Claim 8 of the '887 Patent, whether it  
12 was valid. Then finally, what harm, if any, an exclusion  
13 order would cause to the public.

14 Q. What conclusions did you reach?

15 A. Well, first, Gator Bio does not infringe on the  
16 '887 Patent, and that Sartorius has not shown that it has  
17 technical industry for the '887 Patent.

18 Also, Claim 8 of that same patent is invalid.

19 Finally, exclusion order would cause harm, both,  
20 to third parties and the public.

21 Q. Let's turn to slide 4 and talk a bit about the  
22 technical background of the '887 Patent.

23 Dr. Forrest, what is an enzyme?

24 A. Well, we've heard these described several times,  
25 and quickly, they're proteins generally, that convert a

1 so it can be very important to only measure this particular  
2 serotype in a sample, and having a kit that can measure 1  
3 to 10 all at the same time, it's just not adequate.

4           Also, these universal kits can respond  
5 differently to each one. So when you're dealing with one  
6 like AAV9, it's very useful to have a specific kit.

7           Then, finally, Gator Bio has an AAV Ratio kit,  
8 and Sartorius doesn't have an equivalent.

9           A problem I've often had in early development of  
10 AAVs is that if you don't get that mixture of the DNA  
11 plasmas just right, you can end up with a lot of viral  
12 plasmids that have no DNA in them, because you put one  
13 plasmid in there to make the capsid, the packaging, and you  
14 put another one in there that causes your fermentation cell  
15 line to make the genetic material that goes into them, and  
16 you have to have that tuned just right to get active  
17 viruses that will actually work.

18           If you have a lot that don't work, well, it  
19 won't be effective to the patient. You can't just give  
20 them more because the concentration of AAVs is critical.

21           In fact, I almost changed PhD topics back in the  
22 late '90s, because I just started my PhD, and suddenly, it  
23 came in the news that this young man at the University of  
24 Pennsylvania had actually died because they gave him too  
25 much AAV. So it was the first death in a human trial with

1 gene therapy. So it's critical to have your concentration  
2 and your quality of these just right.

3           There are alternatives to these Ratio kits.  
4 When I was doing a lot of AAV, 10-plus more years ago, we  
5 used some techniques like cell titering, which can take  
6 over a week to do, and it takes a lot of training, so it's  
7 very difficult.

8           You can potentially use TEM, but it --  
9 transmission electron microscopy, but it's very subjective,  
10 and it also depends on the serotype, how well you can do  
11 it.

12           You can use analytical ultracentrifugation. But  
13 that, again, takes a lot of setup. It's very hard to do.

14           You know, none of these compare to a 30,  
15 35-minute assay or an hour-long assay in either the quality  
16 there and how quickly you can do it.

17       Q.     Finally, turning to the last group of issues  
18 you've identified in that slide, can you explain what  
19 consequences the relief that Sartorius is asking for would  
20 have on existing users of accused Gator Bio products?

21       A.     Well, first, because the probes are not  
22 interchangeable, they would have to go get a Sartorius  
23 instrument. It's very expensive. I'm an academic lab, and  
24 we have to write new instruments often into grants years  
25 before, and it can take years to get a grant. So it could

1 CERTIFICATE OF REPORTER

2 TITLE: In the Matter of Certain Bio-Layer Interferometers  
3 and Components Thereof

4 INVESTIGATION NO: 337-TA-1344

5 HEARING DATE: Friday, November 3, 2023

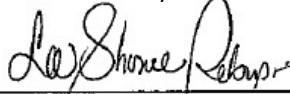
6 LOCATION: Courtroom C

7 NATURE OF HEARING: Evidentiary Hearing

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9 transcript is a true, correct and complete record of the  
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10 Date: November 4, 2023

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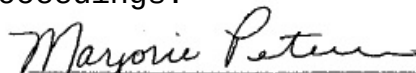
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