

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Doris Johnson Hines
Administrative Law Judge**

In the Matter of

**CERTAIN BIO-LAYER
INTERFEROMETERS AND
COMPONENTS THEREOF**

Investigation No. 337-TA-1344

COMPLAINANT'S PRE-HEARING BRIEF

Complainant Sartorius BioAnalytical Instruments, Inc. (“Sartorius” or “SBAI” or “Complainant”) will adduce compelling evidence at the hearing in this Investigation that will show that Respondent Gator Bio, Inc. (“Gator Bio” or “Respondent”) has violated Section 337 by the sale for importation into the United States, importation into the United States, and/or sale in the United States after importation, of devices and components that infringe each of the patents asserted in this Investigation, namely U.S. Patent No. 7,394,547 (“the ’547 patent”), U.S. Patent No. 7,445,887 (“the ’887 patent”), U.S. Patent No. 7,728,982 (“the ’982 patent”), and U.S. Patent No. 8,305,585 (“the ’585 patent”) (together, the “Asserted Patents” or “Patents-in-Suit”).

I. Introduction

Sartorius is a United States corporation that is a global leader in the biopharmaceutical industry and the market leader in biolayer interferometry technology (“BLI”) with its Octet portfolio of products. Sartorius is a Delaware corporation with manufacturing facilities for the Octet portfolio in Fremont, California (with a future site in Ann Arbor, Michigan) and Shanghai, China. Sartorius AG, the parent company of Sartorius, was founded over 150 years ago in Germany as a precision mechanical workshop and 40 years later it became a family business. Since then, Sartorius AG has grown to become a leading international life science group focused on serving the biopharmaceutical sector from molecule development to large-scale production. In May 2020, Sartorius AG acquired selected life sciences businesses from Danaher Corporation which included the Octet BLI products—instruments and consumables—thus expanding its bioanalytics portfolio with innovative protein analysis instruments, biosensors, and reagents that allow customers to increase the efficiency of essential steps in the development of molecules, cell lines and processes.

The Octet BLI products were originally conceived of, developed, manufactured, and sold by FortéBio, Inc. (“FortéBio”)—a United States-based company headquartered in Fremont,

instrument is extremely consistent in providing titers and kinetics data and the consumables are affordable.” CX-00634C ¶ 680; CX-00069 at 2. This demonstrates that Tentarix has been using the Accused Products—a Gator Bio instrument with probes. CX-00634C ¶ 680. Moreover, Centivax reports that it was “working with a GatorPrime” and touted Gator Bio’s “consumables” (i.e., the biosensors or probes). CX-00634C ¶ 680; CX-00069 at 4. Accordingly, Centivax has been using a Gator Bio instrument with Accused Probes. CX-00634C ¶ 680; CPX-0022.

Additionally, Epfl reports that it used the Accused Products, specifically a Gator Bio instrument, and said that “the consumables are of excellent quality[,]” showing that Epfl has been using the instrument with the consumables. CX-00634C ¶ 681; CX-00069 at 5. Similar comments were made by, among others, Encodia (CX-00069 at 3) and University of Florida (CX-00069 at 9). CX-00634C ¶ 681. In sum, Gator Bio’s customers have been using the Accused Products—Gator Bio’s instruments with the Accused Probes. CX-00634C ¶ 681.

2. Gator Bio Infringes Claims 1, 16, 17, 20, and 21 of the ’547 patent

a) Claim 1

Sartorius and its experts will show that Gator Bio’s Accused Products satisfy each limitation in claim 1 of the ’547 patent. Claim 1 of the ’547 patent recites:

1. An assembly for use in detecting an analyte in a sample based on interference, comprising:

an optical fiber having a tip;

a first optical element adapted for coupling to a light source through a mechanical coupling that engages the first optical element with the fiber and provides an air gap between the first optical element and the fiber; and

second optical element attached to the first optical element, the second optical element commensurate in size with the fiber tip and adapted for coupling to the first optical element,

said second optical element comprising a transparent material, a first reflecting surface, and a second reflecting surface separated from the first reflecting surface by the transparent material, said first and second reflecting surfaces separated by at least 50 nm, wherein said first reflecting surface comprises a layer of analyte binding molecules, and an interference between light reflected into the fiber from said first and second reflecting surfaces varies as analyte in the sample binds to the analyte binding molecules.

For the reasons discussed below, Dr. Bailey will testify and the evidence will show that each of the Accused Products infringes claim 1 of the '547 patent.

(1) Preamble: “An assembly for use in detecting an analyte in a sample based on interference”

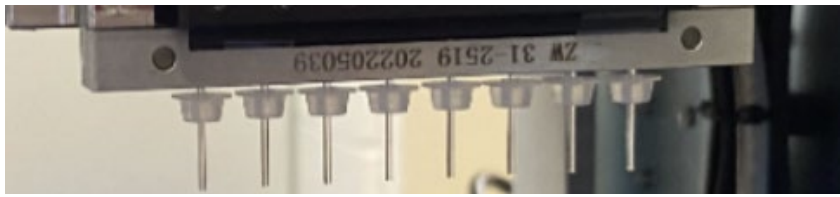
The evidence will show that each of the Accused Products practice this element. CX-00634C ¶¶ 83-86. Specifically, Dr. Bailey will opine that his analysis and testing, and Gator Bio’s own admissions and documents confirm that each of the Accused Products, including the First Redesign and the Second Redesign, satisfy the preamble.

First, the evidence will show that the Accused Products are an assembly that include, at least, each of the recited claimed elements. Second, the evidence will show that the Accused Products are for use in detecting an analyte in a sample based on interference. The Accused Products are instruments used to study biomolecular interactions utilizing biolayer interferometry (“BLI”). CX-00634C ¶ 85. As Dr. Bailey will explain “[i]n biolayer interferometry, biomolecular interactions are detected by measuring the interference pattern of white light reflected from the surface of a biosensor . . . Biolayer interferometry compares the interference pattern of white light reflected from an internal reference layer within a layer of immobilized biomolecules on the surface chemistry of the biosensor. Shifts in interference due to the accumulation of biomolecules are monitored in real-time to sensitively analyze and calculate rates of association and dissociation among target proteins with high precision. Only the interactions of bound biomolecules are

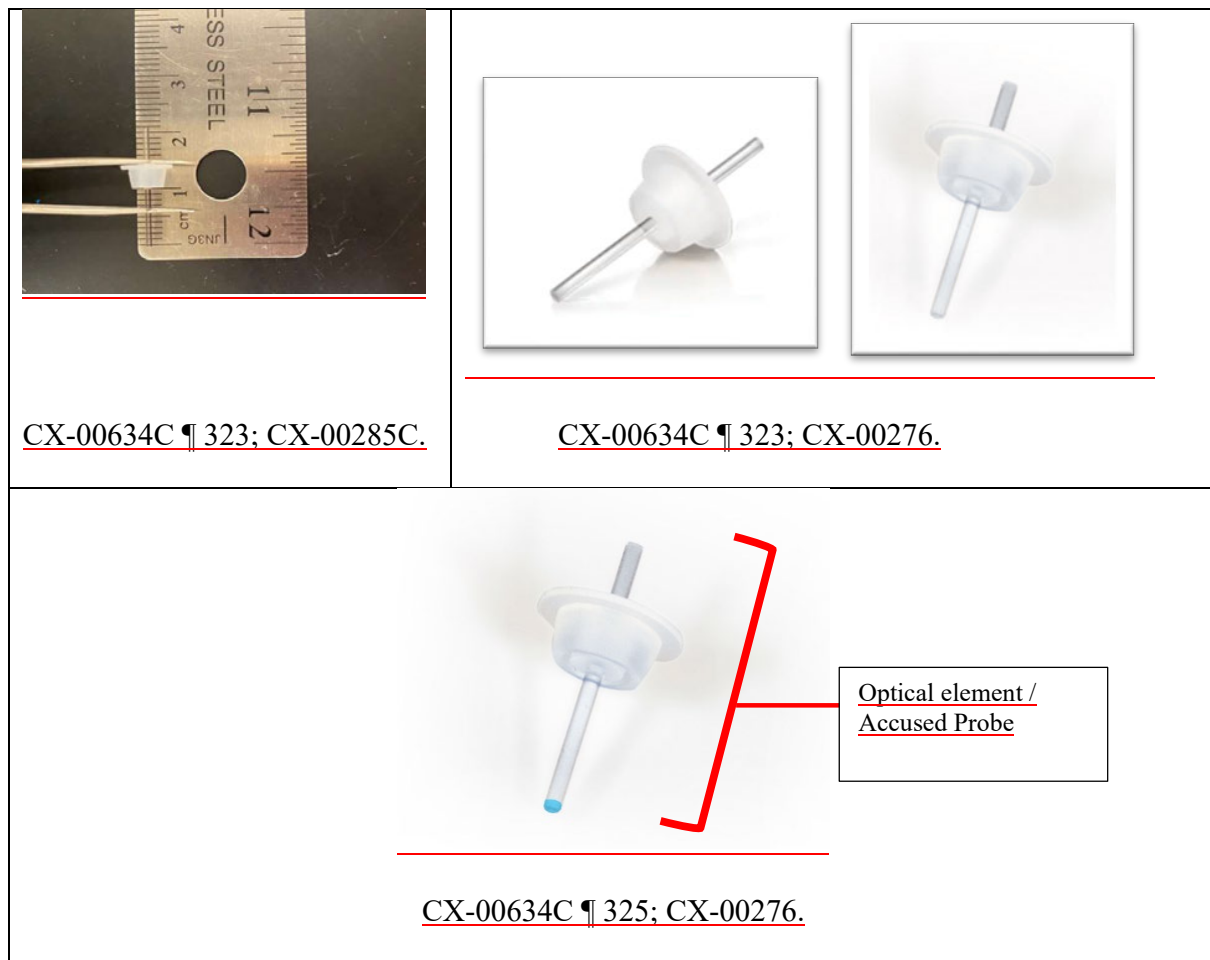
(3) “a first optical element adapted for coupling to a light source through a mechanical coupling that engages the first optical element with the fiber and provides an air gap between the first optical element and the fiber”

The evidence will show that each of the Accused Products practice this element. CX-00634C ¶¶ 55-81, 94-115. Specifically, the evidence will show and Dr. Bailey will opine that his analysis and testing, and Gator Bio’s own admissions and documents confirm that each of the Accused Products satisfy this limitation.

The evidence will show and Dr. Bailey will testify that the Accused Products include an optical element. CX-00634C ¶ 321. In the context of the claim language, the “optical element” is a section, or a component, of Accused Probes utilized by the instrument. CX-00634C ¶ 321. The Accused Probes are shown in the following images—first image the Accused Probes are attached to the Accused Products and in the second group of images the Accused Probes are detached from the Accused Products. CX-00634C ¶¶ 322-323.

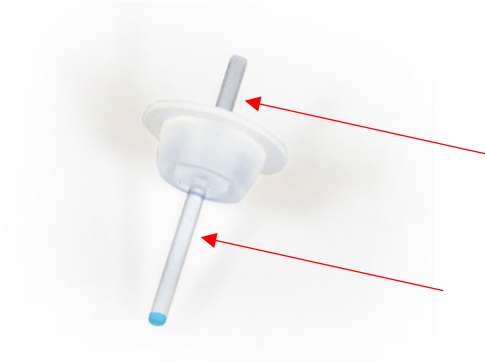


CX-00634C ¶ 322; CX-00285C.



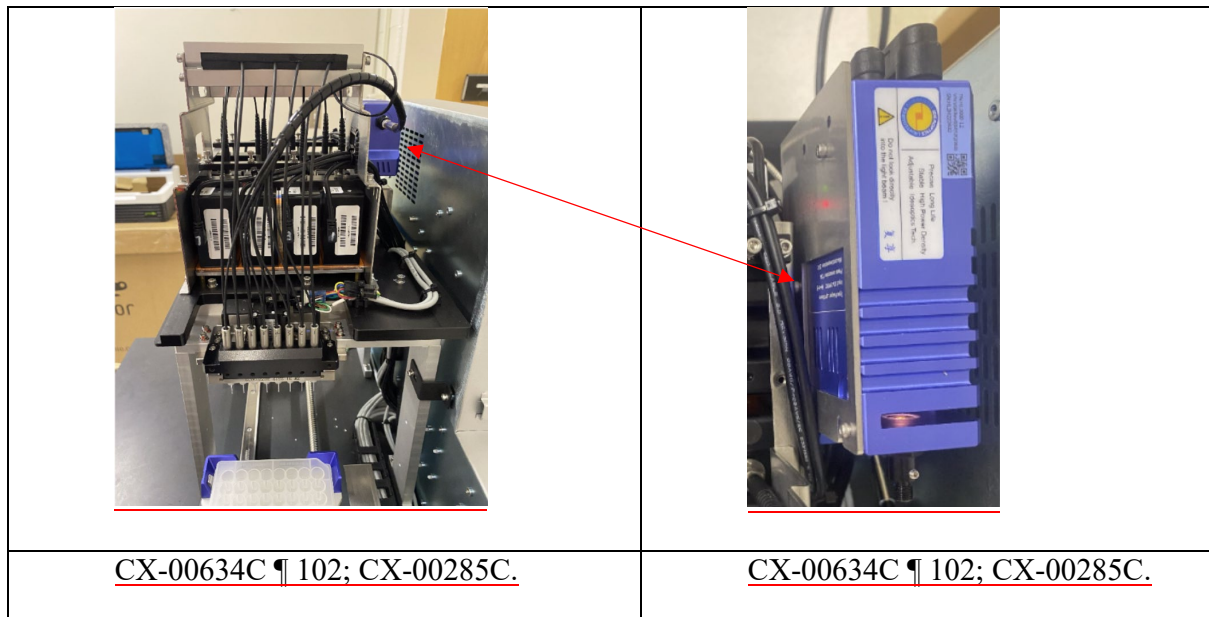
As the evidence will set forth and Dr. Bailey will testify, “Gator[®] probes are micro glass rods with the distal ends coated with proprietary optical layers and surface chemistries.” CX-00634C ¶ 98; CX-00102 at GATOR_SAR0003921. As Gator Bio’s documents further state, its probes “[have] two layers one is the optical layer and . . . the surface layer.” CX-00634C ¶ 98; CPX-0013 at 9:58.

In the context of the Asserted Claims, the optical element that includes a first optical element is illustrated below (CX-00634C ¶ 99):



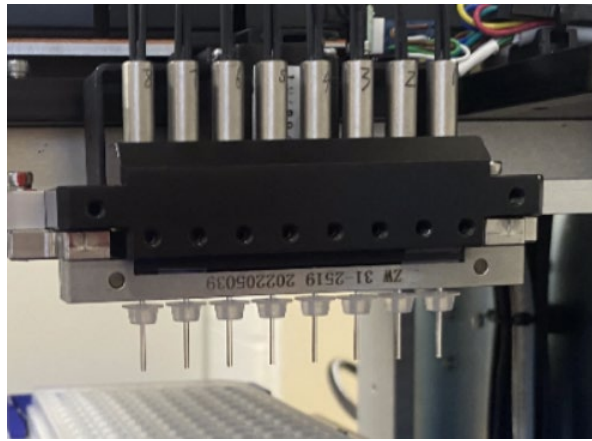
CX-00276

The evidence will show that the first optical element can be positioned to receive light from the light source, a lamp, that passes through the optical fiber. The blue box shown in the below image contains the light source that is located on the upper right hand portion of the Gator Bio instrument. CX-00634C ¶ 102. When the first optical element is attached to the Accused Products, specifically the GatorPrime instrument, it is coupled to the light source. CX-00634C ¶ 103.



The evidence will show that the Accused Products (and specifically the GatorPrime instrument) uses a fiber optic coupling mechanism for mechanically coupling the first optical element with the optical fiber, engaging and aligning the first optical element with the optical fiber in spatial proximity to one another. CX-00634C ¶ 106. Mechanical coupling firmly holds two components into spatial proximity relative to each other thus enabling a precise and controllable physical alignment. CX-00634C ¶ 105.

Below is an image of the fiber optic coupling mechanism that houses the optical fiber and aligns the optical fiber to engage the first optical element. CX-00634C ¶ 107.



CX-00634C ¶ 107; CX-00285C.

Dr. Bailey will explain that Gator Bio's documents illustrate (1) the straight coupling bracket mounted onto (2) the fabricated mounting plates with a V-bar groove affixed. CX-00634C ¶ 108.

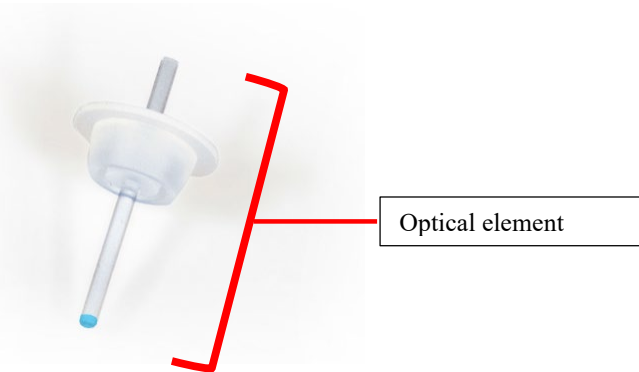
<u>Accused Probes</u> <u>roughness</u> <u>(nanometers)</u> <u>(Amine-reactive</u> <u>probes via</u> <u>profilometry)</u>				<u>Key:</u> <u>Ra: Average surface roughness</u> <u>Rq: Root-mean-squared surface</u> <u>roughness</u> <u>Rt: Maximum difference in height</u> <u>within sample</u> <u>(maximum gap imposed by single</u> <u>element)</u>
<u>Replicate</u>	<u>Ra</u>	<u>Rq</u>	<u>Rt</u>	
<u>1</u>	<u>4.8</u>	<u>6.0</u>	<u>37.2</u>	
<u>2</u>	<u>5.2</u>	<u>6.6</u>	<u>44.2</u>	
<u>3</u>	<u>6.7</u>	<u>8.2</u>	<u>45.3</u>	
<u>4</u>	<u>5.7</u>	<u>9.0</u>	<u>74.7</u>	
<u>5</u>	<u>19.1</u>	<u>21.3</u>	<u>79.8</u>	
<u>6</u>	<u>7.2</u>	<u>8.9</u>	<u>51.4</u>	
<u>7</u>	<u>6.1</u>	<u>7.7</u>	<u>58.2</u>	
<u>8</u>	<u>6.3</u>	<u>8.1</u>	<u>45</u>	
<u>Average</u>	<u>7.6</u>	<u>9.5</u>	<u>54.5</u>	
<u>Standard</u>	<u>4.7</u>	<u>4.9</u>	<u>15.4</u>	
<u>deviation</u>				

CX-00634C ¶ 81; CX-00286C.

(4) “second optical element attached to the first optical element, the second optical element commensurate in size with the fiber tip and adapted for coupling to the first optical element”

The evidence will show that each of the Accused Products practice this element. CX-00634C ¶¶ 116-124. Specifically, the evidence will show and Dr. Bailey will opine that his analysis and testing, and Gator Bio’s own admissions and documents confirm that each of the Accused Products satisfy this limitation. To the extent Gator Bio argues at the hearing that this limitation is not met, the argument is wholly unsupported and has been waived.

In the context of the claims, the optical element is illustrated below (CX-00634C ¶ 117):



CX-00276.

As the evidence will show and Dr. Bailey will explain, Gator Bio’s “biosensors [or Accused Probes] ha[ve] two layers,” specifically an optical layer and a surface layer. CX-00634C

¶ 118; CPX-0013 at 9:58.

Hong Tan confirmed the structure and components of Gator Bio’s Accused Probes:

Q. You see the next paragraph says: “Gator probes are micro glass rods with the distal ends coated with proprietary optical layers and surface chemistries”?

A. Mm-hmm.

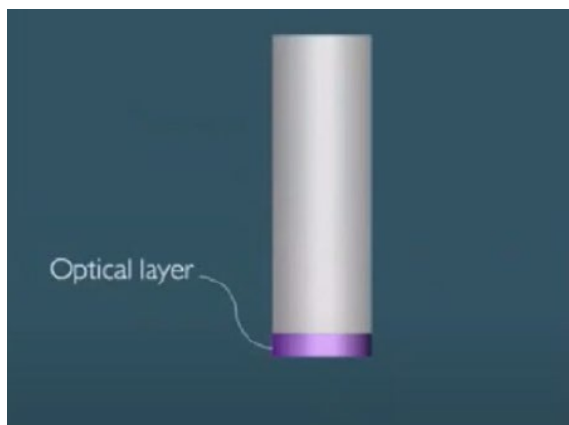
Q. Is that an accurate statement about Gator’s probes?

MR. VALENTINE: Object. Vague.

A. THE WITNESS: I think, yeah, that is --that is a description of the -- the probes.

CX-00634C ¶ 119; CX-00632C at 118:5-14.

As described above, the Accused Products, namely Gator Bio’s Accused Probes include a first optical element. CX-00634C ¶ 120. As explained by Gator Bio’s CEO Hong Tan, the evidence will identify the optical layer on the Accused Probes:



CX-00634C ¶ 121; CPX-0010 at 2:23-2:28. Dr. Bailey will testify that in the context of the '547 patent, the layer described by Gator Bio as the optical layer is the second optical element. CX-00634C ¶ 121.

The evidence will show and Dr. Bailey will explain that the second optical element is commensurate, or similar, in size with the optical fiber tip. CX-00634C ¶ 122. Dr. Bailey will testify that the second optical element has the same diameter as the first optical element, which is about 1.03936 mm or 1039 μm , as measured by optical microscopy, and also measured as 0.999 mm or 999 μm via caliper. CX-00634C ¶ 122.

Dr. Bailey will testify and the evidence will show that in the First Redesign, the diameter of the recessed portion of the optical fiber tip is about 978 μm , as measured by optical microscopy. CX-00634C ¶ 123; CX-00284C. Thus, the second optical element of about 1039 μm is commensurate in size with the optical fiber tip of about 1007 μm . CX-00634C ¶ 123; CX-00269. Dr. Bailey will testify and the evidence will show that in the Second Redesign, the diameter of the recessed portion of the optical fiber tip is about 1146 μm , as measured by optical microscopy. CX-00634C ¶ 123; CX-00284C. Thus, the second optical element of about 1039 μm is commensurate in size with the fiber tip of about 1146 μm . CX-00634C ¶ 123.

The evidence will show and Dr. Bailey will explain, based on his visual inspection (previously discussed), that the second optical element is fused to the first optical element to form one structure (CX-00634C ¶ 124) and further that the second optical element is directly coupled to the first optical element (or Accused Probes) as they are a part of the same structure providing a continuous light path towards the distal end. CX-00634C ¶ 124.

(5) “said second optical element comprising a transparent material, a first reflecting surface, and a second reflecting surface separated from the first reflecting surface by the transparent material, said first and second reflecting surfaces separated by at least 50 nm, wherein said first reflecting surface comprises a layer of analyte binding molecules, and an interference between light reflected into the fiber from said first and second reflecting surfaces varies as analyte in the sample binds to the analyte binding molecules”

The evidence will show that each of the Accused Products practice this element. CX-00634C ¶¶ 125-140. Specifically, the evidence will show and Dr. Bailey will opine that his analysis and testing, and Gator Bio’s own admissions and documents confirm that each of the Accused Products satisfy this limitation. To the extent Gator Bio argues at the hearing that this limitation is not met, the argument is wholly unsupported and has been waived.

The evidence will show and Dr. Bailey will opine that the Accused Products, namely the Accused Probes contain a second optical element, or the optical layer, that is a transparent material. CX-00634C ¶ 126. Specifically, Gator Bio’s documents show that its Accused Probes are “micro glass rods with the distal ends coated with proprietary optical layers and surface chemistries.” CX-00634C ¶ 126; CX-00102 at GATOR SAR0003922. Dr. Bailey will explain and the evidence will show that Gator Bio’s documents identify that its Accused Probes comprise of either [REDACTED] [REDACTED] as the optical layer. CX-00634C ¶ 126; see CX-00134C; CX-00135C; CX-00272.

an induced-infringement analysis ordinarily assumes the presence of a third party (given that a party who directly causes infringement is ordinarily liable under Section 271(a)), the Federal Circuit left open the possibility that induced infringement under § 271(b) does not require the presence of a third party. At least one court has recognized this, and allowed a Section 271(b) inducement claim to proceed to discovery in view of *Promega*, where the patentee had not identified a third-party direct infringer. *Plano Encryption Techs., LLC v. Alkami Tech., Inc.*, No. 2:16-cv-1072-JRG, 2017 WL 8727249, at *4-5 (E.D. Tex. Sept. 22, 2017). Here, Gator Bio has “br[ought] about” and “cause[d]” infringement of the ’887 patent by (as explained below) practicing the claimed methods of that patent. Accordingly, Gator Bio has induced infringement of the ’887 patent.

1. Gator Bio Infringes Claims 8, 16, and 18 of the ’887 Patent

a) Claim 8

For the following reasons, Dr. Bailey will testify and the evidence will show that Gator Bio performs each step of claim 8 with Gator Bio’s Instruments and Probes.

Claim 8 of the ’887 patent recites:

8. A method for assaying enzyme activity, comprising:

providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber and provides an air gap between the first optical element and the fiber, the optical element including (a) a proximal reflecting surface and a distal reflecting surface separated by at least 50 nm, and (b) a layer of analyte binding molecules;

exposing the optical element to an enzyme substrate reacted or reacting with an enzyme, whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules, and wherein interference between a reflected beam from the proximal reflecting surface and a reflected beam from the distal reflecting surface varies as the enzyme substrate or portion thereof binds to the layer of enzyme binding molecules, the reflected beams coupled into the fiber; and

detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity.

JX-0002, cl. 8.

Dr. Forrest argues that “Sartorius assumes that it is sufficient that the accused probes can be used for purposes of assaying enzymatic activity but fails to identify any such actual use of the accused probes.” RX-0203 App’x C1 at 39; CX-00639C ¶ 316. To the extent Dr. Forrest argues that Sartorius has not identified “any actual use of the accused probes” to assay enzyme activity, Sartorius and its experts will show that individuals actually use the accused probes to perform the method recited in claim 8 of the ’887 patent. As explained further below, Sartorius and its experts will show that at least Gator Bio’s HS AAVX probes are used to infringe claim 8 of the ’887 patent. CX-00639C ¶ 316. For example, Mr. Zuk, Gator Bio’s chief technology officer, testified at his deposition that Gator Bio offers ELISA probes that use enzymes. CX-00633C at 80:10-81:4 (describing Gator Bio’s HS AAVX probe as “an ELISA for measuring AAV” and describing ELISA as “an enzyme immunosorbent assay”), 136:17-137:11 (Q. and ELISA probes use enzymes, right? A. Yes.); CX-00639C ¶ 316. Mr. Zuk further explained that the enzyme portion of these ELISA probes generate a detectable signal when it reacts with enzyme substrate. CX-00633C at 138:4-139:3; CX-00639C ¶ 316. Sartorius and its experts will show that these probes assay enzyme activity.

Q. How – and how does ELISA allow for this kind of measurement?

A. It serves as a label that can be detected by any – many – multiple types of instrumentation.

Q. Could you explain how this – how that’s a label? I think you’ve used – you used the term “label.”

A. A label?

Q. Yes.

A. It’s a component of a reagent that will generate a detectable signal.

Q. How – how is that signal generated?

[Objection]

Sartorius and its experts will show that an example of a specific method for assaying enzyme activity was performed by Gator Bio and detailed in a Gator Bio YouTube presentation hosted by Robert Zuk, as well as other materials published by Gator Bio. CX-00634C ¶ 248. For example, the Gator Bio YouTube presentation hosted by Mr. Zuk disclosed a method that included the use of Gator Bio's AAVX Probe that utilizes a CaptureSelect™ anti-AAVX antibody immobilized on the AAVX Probe, which binds to viral AAV capsid and is then exposed to a second reagent—a capture select antibody that is linked to the enzyme HRP. CX-00634C ¶ 248. After an immune complex is formed between the anti-AAVX antibody on the AAVX Probe, the capsid being analyzed, and the HRP linked antibody, the Probe is then dipped in a substrate solution and enzyme activity is monitored due to HRP's enzymatic oxidation of the substrate. CX-00634C ¶ 248. Through its enzymatic activity, HRP causes the oxidized substrate to precipitate or bind onto the biosensors producing a change in optical thickness. CX-00634C ¶ 248. The precipitated substrate will be locally deposited onto the first reflective surface, including the layer of analyte binding molecules, because of its close proximity as ensured by specific biomolecular interactions. CX-00634C ¶ 248; CX-00265; CPX-0019.

(2) “providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber and provides an air gap between the first optical element and the fiber”

Sartorius and its experts will show that Gator Bio performs the method wherein an optical element is coupled to a light source via a mechanical coupling that engages the optical element with an optical fiber and provides an air gap between the optical element and the fiber. CX-00634C ¶ 249.

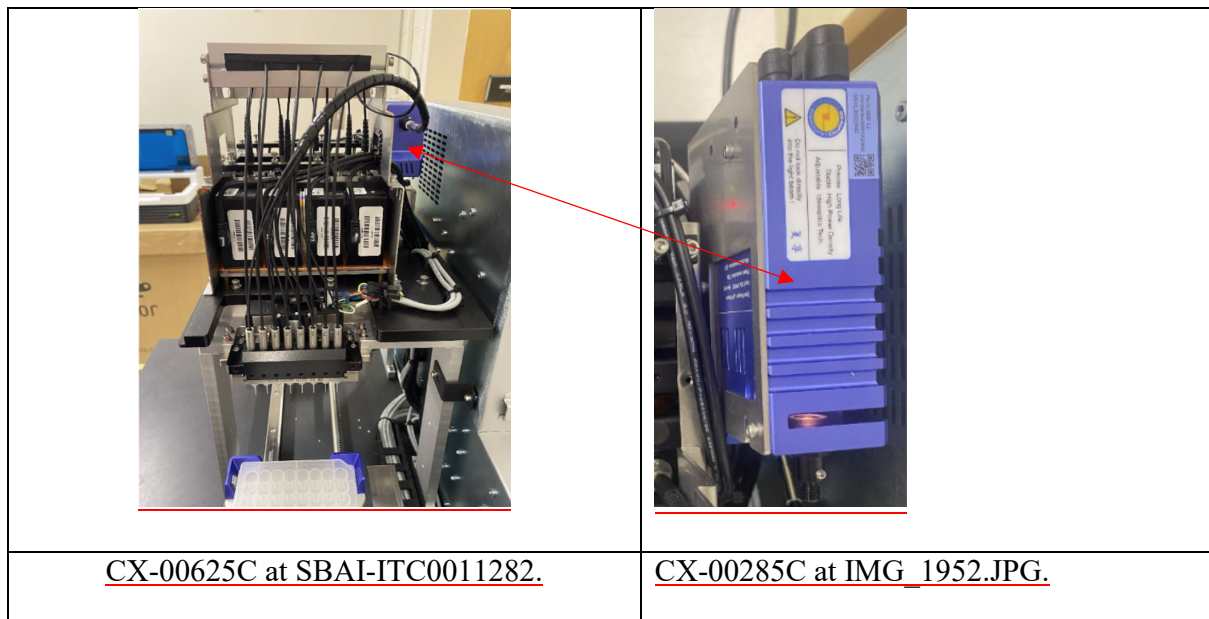
(a) An Optical Element

The evidence will show that Gator Bio's probes comprise an optical element for the same reasons provided in Section VI.C.2.a.3 with respect to Gator Bio's infringement of claim 1 of the '982 patent.

(b) A Light Source

Sartorius and its experts will show that the First Redesign includes an optical element coupled to a light source. The optical element can be positioned to receive light from the light source (i.e. a lamp), which passes through the optical fiber. CX-00634C ¶ 256.

Light from the lamp is directed through twelve excitation fibers that, along with a collection fiber, make up each optical fiber. CX-00634C ¶ 257. The blue box containing the light source is located on the upper right hand portion of the instrument in the image on the left below.



Accordingly, when the optical element is attached to GatorPrime instrument, it is coupled to the light source. CX-00634C ¶ 258.

Sartorius and its experts will show that the Second Redesign includes an optical element coupled to a light source. CX-00634C ¶ 259. The Second Redesign differs from the First Redesign

(2) Gator Bio Infringes Claim 18 of the '887 Patent

Sartorius and its experts will show that Gator Bio's activities with the Gator Bio Instruments (as represented by the GatorPrime) and probes satisfy each limitation in claim 18 of the '887 patent. Claim 18 of the '887 patent recites:

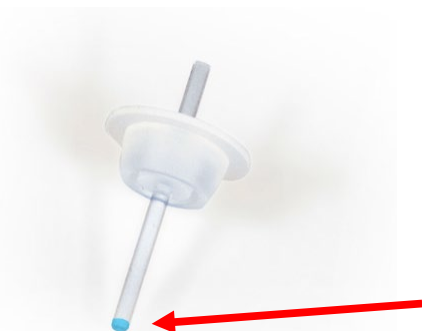
18. The method of claim 8, wherein the optical element is a first optical element, and wherein the method further comprises providing a second optical element positioned between the proximal reflecting surface of the first optical element and the fiber, the second optical element being coupled to the light source via the mechanical coupling that engages the second optical element with the fiber and provides an air gap between the second optical element and the fiber, and wherein the first optical element is coupled to the second optical element at the proximal reflective surface.

As described in Section VIII.C.1.a, Sartorius and its experts will show that Gator Bio practices each limitation of claim 8. Sartorius and its experts will also show that Gator Bio practices each additional limitation of claim 18 based on the following reasons.

(a) The Optical Element is a First Optical Element

Sartorius and its experts will show that Gator Bio performs the method of claim 8 wherein the optical element is a first optical element. CX-00634C ¶ 288.

The Gator Bio Probes are comprised of two components—including a first optical element. CX-00634C ¶ 289. The first optical element is the surface chemistry, shown in the below illustration as a blue tip.



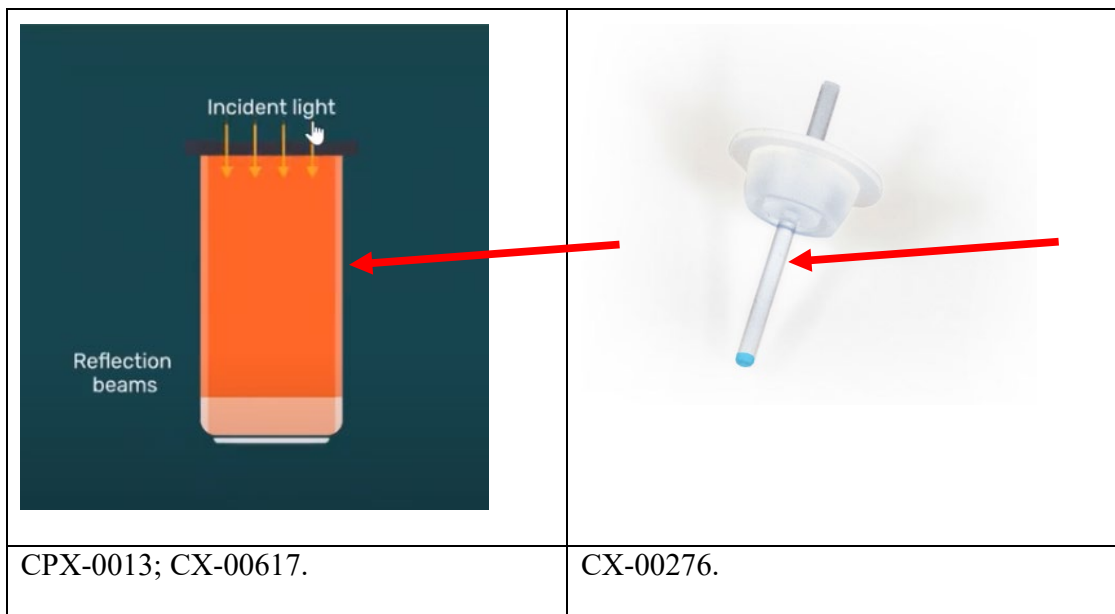
CX-00276.

(b) A Second Optical Element Positioned Between the Proximal Reflecting Surface of the First Optical Element and the Fiber

Sartorius and its experts will show that Gator Bio performs the method of claim 8 wherein a second optical element is positioned between the proximal reflecting surface of the first optical element and the fiber.

In the images of Gator Bio's biosensors provided below, the second optical element positioned between the proximal reflecting surface of the first optical element and the fiber is shown as orange in the image on the left and colorless in the image on the right. CX-00634C

¶ 291.



(c) The Second Optical Element Being Coupled to the Light Source Via the Mechanical Coupling that Engages the Second Optical Element with the Fiber and Provides an Air Gap Between the Second Optical Element and the Fiber

Sartorius and its experts will show that Gator Bio performs the method of claim 8 wherein the second optical element is coupled to the light source via the mechanical coupling that engages

the second optical element with the fiber and provides an air gap between the second optical element and the fiber.

(i) A Mechanical Coupling

Sartorius and its experts will show that Gator Bio's Instruments and Probes include a second optical element coupled to a light source via a mechanical coupling that engages the second optical element with an optical fiber. CX-00634C ¶ 293. The evidence will show that Gator Bio's Instruments and Probes satisfy this limitation of claim 18 of the '887 patent for the same reasons provided in Section V.C.2.a.3 regarding Gator Bio's infringement of claim 1 of the '547 patent, which is incorporated by reference.

(ii) An Air Gap

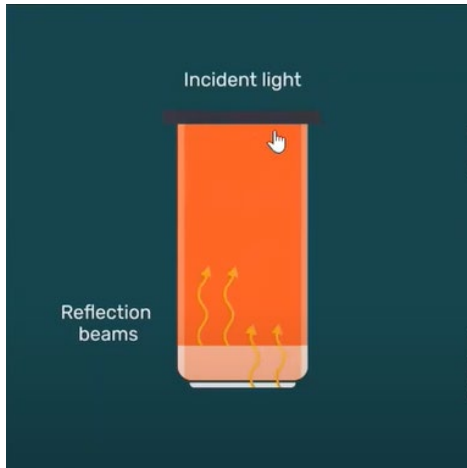
Sartorius and its experts will show that Gator Bio's Instruments and Probes have a mechanical coupling between the second optical element and metal housing surrounding the tip of the optical fiber that results in an air gap. CX-00634C ¶ 300. An air gap is a void or a space containing air. The evidence will show that Gator Bio's Instruments and Probes satisfy this limitation of claim 18 of the '887 patent for the same reasons provided in Section V.C.2.a.3 regarding Gator Bio's infringement of claim 1 of the '547 patent, which is incorporated by reference.

(d) Wherein the First Optical Element is Coupled to the Second Optical Element at the Proximal Reflective Surface

Sartorius and its experts will show that Gator Bio's Instruments and Probes have a first optical element coupled to a second optical element at the proximal reflective surface. CX-00634C ¶ 303.

As shown in Gator Bio's "Strategies for Accurate, Easy and Fast Quantitation of AAV Serotypes" YouTube video, at 10:29, the beams of light (shown in yellow) reflect back from the

proximal and distal reflective surfaces. CX-00634C ¶ 304. The distal (first) reflective surface is below the peach and grey layer and the proximal (second) reflective surface is at the interface between the peach layer and the orange layer.

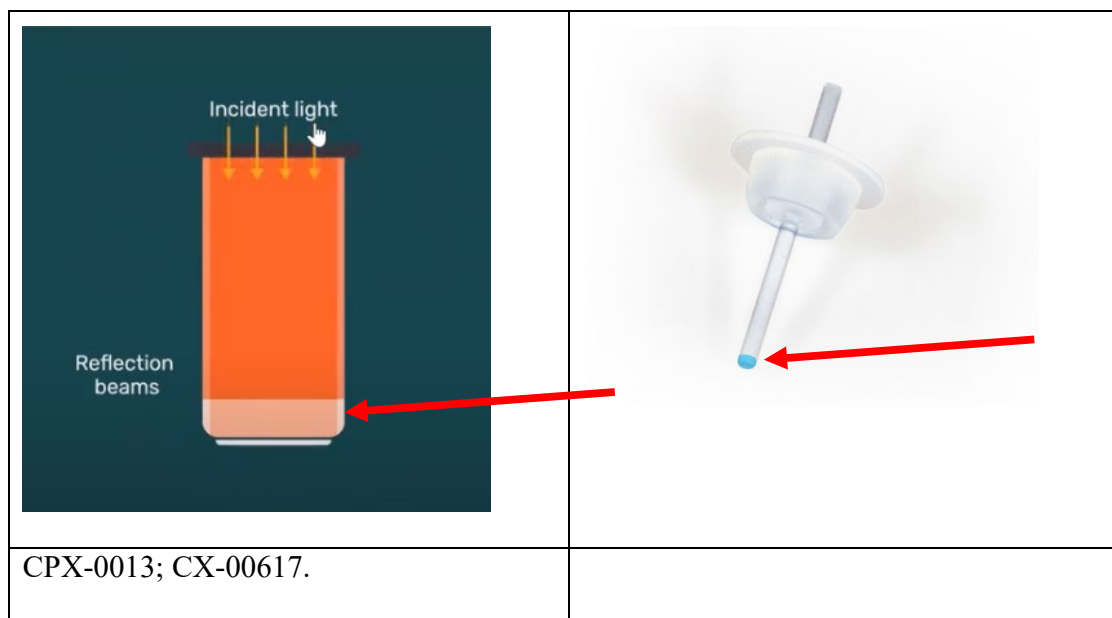


CPX-0013; CX-00617.

The diagrams of Gator Bio's probes provided below show the second optical element positioned between the proximal reflective surface of the first optical element and the fiber is shown in orange on the left and colorless on the right. CX-00634C ¶ 305.

A diagram showing a cross-section of a probe. At the top, a dark blue horizontal bar represents the proximal end. Below it is a large orange rectangular area. A white hand cursor icon points to the top of this orange area, with the text "Incident light" above it. At the bottom of the orange area is a thin, light-colored layer. From this layer, three yellow wavy arrows point upwards into the orange area, with the text "Reflection beams" to the left. The entire diagram is set against a dark teal background.	A photograph of a probe. It has a grey handle with a white ring. A thin, clear fiber extends from the handle. A red arrow points from the left towards the fiber. The fiber has a small blue tip.
CPX-0013; CX-00617.	CX-00276.

The first optical element is shown in peach on the right and blue on the left.



Thus, the first optical element is coupled to the second optical element at the proximal reflective surface. CX-00634C ¶ 307.

D. Domestic Industry – Technical Prong

1. Sartorius’s Domestic Industry Products Satisfy the Limitations of Claims 8, 16, and 18 of the ’887 Patent

Sartorius and its experts will show that Sartorius instructs individuals to use, and individuals do use, Octet instruments and biosensors to practice claim 8 of the ’887 patent, which recites:

8. A method for assaying enzyme activity, comprising:

providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber and provides an air gap between the first optical element and the fiber, the optical element including (a) a proximal reflecting surface and a distal reflecting surface separated by at least 50 nm, and (b) a layer of analyte binding molecules;

exposing the optical element to an enzyme substrate reacted or reacting with an enzyme, whereby the enzyme substrate or a

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Respectfully submitted,

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