PUBLIC VERSION

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN BIO-LAYER INTERFEROMETERS AND COMPONENTS THEREOF**	**Inv. No. 337-TA-1344**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Doris Johnson Hines

(March 8, 2024)

Appearances:

For Complainant Sartorius BioAnalytical Instruments, Inc.: Jonathan A. Herstoff, Camille Y. Turner, Sheila Mortazavi, Kaitlin Farrell, Jason Kanter, Audrey R. Sparschu, Nisha Gera, Conrad D. Stumpf, and Patrick Lavery of HAUG PARTNERS LLP, New York, New York.

For Respondent Gator Bio, Inc.: Hari Santhanam of PERKINS COIE LLP, Chicago, Illinois, Veronica S. Ascarrunz and Michelle Yocum of PERKINS COIE LLP, Washington, DC, James F. Valentine, C. Wendy Wang, Bingjie Li, and Hessam Seyed Gharaviram of PERKINS COIE LLP, Palo Alto, California, and Evan S. Day of PERKINS COIE LLP, San Diego, California.

For the Office of Unfair Import Investigations: Margaret D. Macdonald, Anne Goalwin, Paul A. Gennari, U.S. International Trade Commission, Washington, DC.

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This is the final Initial Determination in the matter of *Certain Bio-Layer Interferometers and Components Thereof*, Investigation No. 337-TA-1344, pursuant to the Notice of Investigation, 87 Fed. Reg. 73329 (Nov. 29, 2022), 19 C.F.R. §§ 210.10(b) and 210.42(a)(1)(i).

I. INTRODUCTION

A. Procedural History

Sartorius BioAnalytical Instruments, Inc. filed a Complaint on October 25, 2022, (EDIS Doc. ID 783025), and filed an Amended Complaint on November 14, 2022, (EDIS Doc. ID 784399). The original Complaint and Amended Complaint allege violations of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain bio-layer interferometers and components thereof that allegedly infringe certain claims of U.S. Patent No. 7,394,547, U.S. Patent No. 7,445,887, U.S. Patent No. 7,728,982, and U.S. Patent No. 8,305,585.

The Commission instituted this investigation on November 23, 2022, to determine "whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 3–6, and 11–21 of the '547 patent; claims 1–5, 7–14, and 16–18 of the '887 patent; claims 1, 3–6, and 11–35 of the '982 patent; and claims 1, 3–6, and 11–19 of the '585 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337." 87 Fed. Reg. 73329.

The plain language description of the accused products in the Notice of Investigation defines the scope of the investigation. 19 C.F.R. § 210.10(b)(1). They are described as "biolayer interferometers, biosensors, and kits containing biosensors and reagents." 87 Fed. Reg. 73329.

[redacted]

The Notice of Investigation named Gator Bio, Inc. as the sole respondent. *Id*. The Office of Unfair Import Investigations is also a party to this investigation. *Id*.

The presiding Chief Administrative Law Judge set the target date for this investigation at 15.5 months. Order No. 6 (Jan. 5, 2023) (EDIS Doc. ID 787371).

Gator Bio moved to terminate this investigation in part as to certain instruments that contain a "registration plate" based on a consent order stipulation and proposed consent order. Motion Docket No. 1344-003 (EDIS Doc. ID 788334). The presiding Chief Administrative Law Judge granted Gator Bio's motion. Order No. 8 (Initial Determination), *unreviewed by* Comm'n Notice (Mar. 23, 2023) (EDIS Doc. ID 793045). The Commission subsequently issued a Consent Order directed to Gator Bio instruments with a registration plate. (EDIS Doc. ID 793046).

In February 2023, the presiding Chief Administrative Law Judge issued a Notice reassigning this investigation to me. Notice to the Parties (Feb. 27, 2023) (EDIS Doc. ID 791317).

The Commission terminated the investigation as to claims 20 and 29–31 of the '982 patent, claims 1–5, 7, 9–14, and 17 of the '887 patent, and claims 5, 6, and 15 of the '547 patent based on withdrawal of the complaint as to those claims. Order No. 14 (May 15, 2023) (EDIS Doc. ID 796446), *unreviewed by* Comm'n Notice (Jun. 9, 2023) (EDIS Doc. ID 798167). The '547, '982, and '585 patents were subsequently terminated from the investigation in their entirety based on the withdrawal of the complaint as to those patents. Order No. 26 (Jun. 29, 2023) (EDIS Doc. ID 799541), *unreviewed by* Comm'n Notice (July 20, 2023) (EDIS Doc. ID 800587).

Following briefing and a claim construction hearing, I issued a claim construction order, Order No. 16 (EDIS Doc ID 797546), and a supplemental claim construction order, Order No. 22 (EDIS Doc ID 799288), finding claims 8, 16, and 18 of the '887 patent indefinite under 35 U.S.C. § 112. Following Sartorius's unopposed motion for summary determination, I found claims 8, 16,

[redacted]

and 18 of the '887 patent invalid for indefiniteness and terminated the investigation. Order No. 27 (Initial Determination) (EDIS Doc. ID 799657). The Commission reviewed Order No. 27, reversed the finding of invalidity, and remanded the investigation to me for further proceedings consistent with its determination. Comm'n Remand Order (Aug. 16, 2023) (EDIS Doc ID 802510); *see also* Comm'n Op. (Aug. 24, 2023) (EDIS Doc. ID 803150).

Thereafter, I conducted a case management conference after which, based on the parties' availability for an evidentiary hearing, I extended the target date to June 6, 2024. Order No. 29 (Aug. 24, 2023) (EDIS Doc. ID 803144), *unreviewed by* Comm'n Notice (Sept. 22, 2023) (EDIS Doc. ID 804705). I subsequently extended the target date to July 8, 2024. Order No. 41 (Feb. 6, 2024) (EDIS Doc. ID 813422) *unreviewed by* Comm'n Notice (Mar. 4, 2024) (EDIS Doc. ID 815405).

Claims 16 and 18 were terminated based on withdrawal of the complaint as to those claims. Order No. 37 (Oct. 26, 2023) (EDIS Doc. ID 806972), *unreviewed by* Comm'n Notice (Nov. 27, 2023) (EDIS Doc. ID 809229). Claim 8 of the '887 patent is the only claim remaining.

In accordance with Ground Rule 11.2, (Order No. 10) (EDIS Doc. ID 792151), the parties filed pre-hearing briefs. Sartorius Pre-Hearing Br. (EDIS Doc. ID 798402); Gator Bio Pre-Hearing Br. (EDIS Doc. ID 798385); and Staff Pre-Hearing Br. (EDIS Doc. ID 804363). The evidentiary hearing was held October 31 through November 3, 2023. Thereafter, the parties filed post-hearing briefs. Sartorius Br. (EDIS Doc. ID 808445); Gator Bio Br. (EDIS Doc. ID 808435); Staff Br. (EDIS Doc. ID 808968); Sartorius Reply (EDIS Doc. ID 809407); Gator Bio Reply (EDIS Doc. ID 809408); and Staff Reply (EDIS Doc. ID 809754).

B. The Private Parties

1. Complainant

Sartorius is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 565 Johnson Avenue, Bohemia, New York, 11716. Amended Complaint, ¶ 24. Sartorius was incorporated on December 2, 2019. *Id*. Sartorius is a subsidiary of Sartorius AG, the parent company of the Sartorius Group headquartered in Göttingen, Germany. *Id.*, ¶ 25.

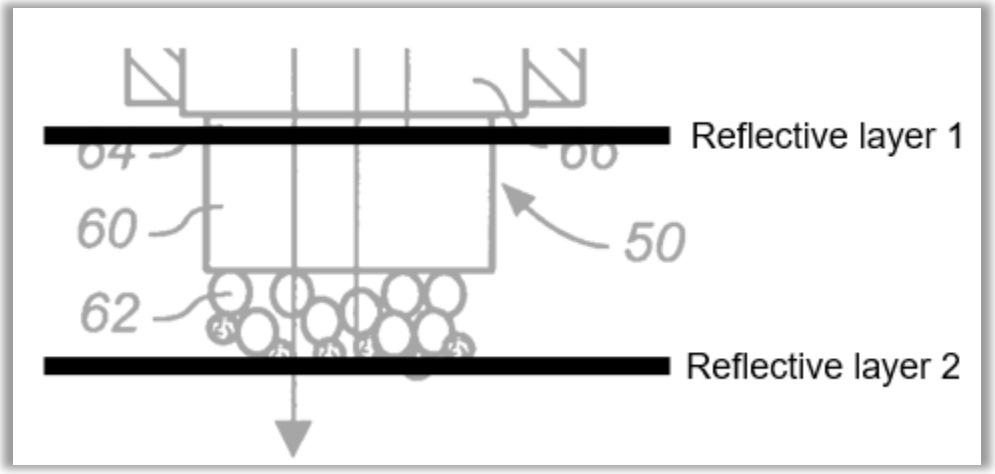
2. Respondent

Gator Bio is a corporation organized and existing under the laws of the State of California, with its principal place of business at 2455 Faber Place, Palo Alto, California, 94303. Amended Complaint, ¶ 27; Gator Bio Answer, ¶ 27 (EDIS Doc. ID 787660).

C. Overview of the Technology

Bio-layer interferometry is a technique that detects biomolecular interactions using the optical phenomenon known as Fabry-Perot interference. Tr. (Sailor) at 1089:15–22; and Tr. (Bailey) at 583:5–6. Such interference uses "two parallel partially transparent, partially reflective surfaces," namely reflective layer 1 (proximal) and reflective layer 2 (distal) on a probe, as shown below:

[redacted]



JX-0001 ('547 patent) at Fig. 4 (annotated); Tr. (Sailor) at 1090:8–12; and Tr. (Bailey) at 583:8–9.

The reflected beams constructively and destructively interfere with one another, resulting in an interference pattern that is indicative of the optical thickness of the film. Tr. (Schaafsma) at 877:5–878:17. Interference occurs when light is directed down a probe and reflects back from the reflective layers. Tr. (Bailey) 583:8–12. Specifically, light directed down the probe will bounce off reflective layer 1, forming a first reflected beam of light. Light that penetrates reflective layer 1 will reach reflective layer 2 creating a second beam of reflected light. Tr. (Sailor) 1090:12–15.

The first and second reflected beams combine and interfere with each other. Tr. (Sailor) at 1090:17–23. Depending on the refractive index and thickness of the layer that separates the two reflective surfaces, the beams will interfere either constructively (Tr. (Sailor) at 1090:17–24; and Tr. (Bailey) at 585:10–13) or destructively (Tr. (Sailor) 1091:7–11; and Tr. (Bailey) 585:14–19), resulting in an increased or decreased amplitude of the light waves.

By using bio-layer interferometry to monitor for wavelength shifts in the interference spectrum, biomolecular interactions can be detected across the visible light spectrum. Tr. (Sailor) at 1091:11–14; and Tr. (Bailey) 585:22–586:1 and 9–12. The binding of analyte to the film

increases or decreases the optical thickness of the film, resulting in a phase shift, which can be measured using a detector (e.g., spectrometer). Tr. (Schaafsma) at 877:5–878:17.

D. The Asserted Patent

The ’887 patent issued on November 4, 2008, based on U.S. Patent Application No. 11/326,689 filed on January 6, 2006. JX-0002 (’887 patent) at cover. The ’887 patent claims priority to U.S. Provisional Patent Application No. 60/645,153, filed on January 19, 2005, and U.S. Provisional Patent Application No. 60/642,454 filed on January 7, 2005.[1] *Id*.

The ’887 patent relates to methods for measuring enzyme activity using bio-layer interferometry. The specification explains that enzyme assays of the prior art “typically require labeling the substrate in such a way that the enzyme acting on the substrate produces a detectable change in signal.” *See* ’887 patent at 1:34–36. Labeled enzyme substrates, however, are often not commercially available and add to the time, expense, and inconvenience of enzyme activity measurements. *See id.* at 1:36–44. The invention of the ’887 patent “can be carried out using unlabeled substrates” and allows for “simple, fiber based, real-time enzyme activity assays, capable of providing specific activity measurements, [and] suitable for low-volume samples.” *See id.* at 1:48–54.

The ’887 patent’s invention relies on the sensor’s ability to detect sub-nanometer changes in the thickness of its optical layer detection surface. *See id.* at 4:31–33. The optical element includes a layer of analyte binding molecules. *See id.* at 4:20–22. When an enzyme substrate (i.e., analyte) binds to the layer of analyte binding molecules, the thickness of that layer changes and can be detected by the sensor. *See id.* at 4:33–36. The activity of an enzyme can thus be measured

[1] The ’887 patent is subject to the pre-AIA version of 35 U.S.C. because it has an effective filing date before September 16, 2012. *See* America Invents Act, Pub. L. No. 112-29, 125 Stat. 284.

[redacted]

by reacting the enzyme with the enzyme substrate in the presence of the sensor, with the reaction affecting the thickness of the optical layer.

Figure 4 of the ’547 patent (which is incorporated by reference in the ’887 patent) shows an example of a bio-layer interferometry probe.

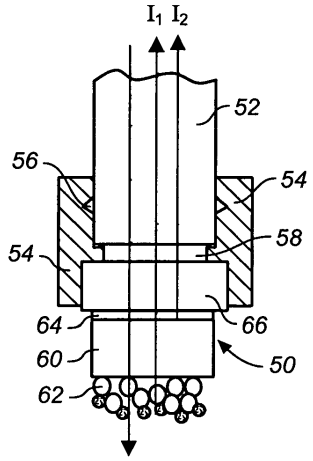
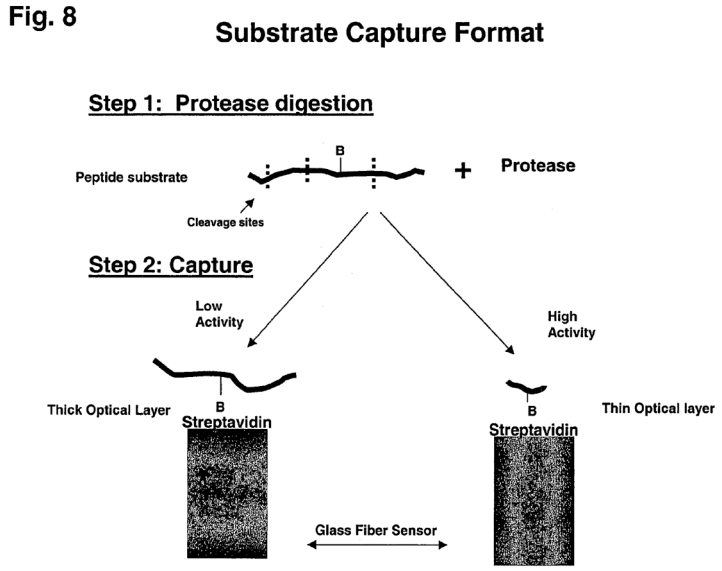


FIG. _4

’547 patent at Figure 4. The specification of the ’547 patent explains that the optical assembly of Figure 4 includes a first optical element 60 having first and second reflective layers 62, 64, *e.g.*, for assaying enzyme activity. *Id*. at 9:38–42; ’887 patent at 1:62–2:15. The optical assembly of Figure 4 can further include a second optical element 66, *e.g.*, for measuring enzyme concentration or amount. ’547 patent at 9:42–43; and ’887 patent at 2:20–30. In operation, “[t]he lower surface of the assembly is then exposed to a sample of analyte, under conditions that favor binding of sample analyte to the analyte-binding molecules forming reflective layer 62.” ’547 patent at 9:52–56. “As analyte molecules bind to this layer, the thickness of the layer increases, increasing the distance ‘d’ between reflective surfaces 62 and 64.” *Id.* at 9:56–59. “This produces a shift in the extrema of the interference wave produced by reflection from the two layers, . . . [which] is used to determine the change in thickness at the lower (distal-most) reflecting layer.” *Id.* at 9:59–64.

[redacted]

Figure 8 of the ’887 patent illustrates the use of a sensor to measure enzyme activity. In particular, the patent discloses in Example 3 (Figure 8) that trypsin (enzyme) activity measurements are made by using the substrate capture format and cytochrome C as a substrate. *Id*. at 7:24–25.



’887 patent, Figure 8. The specification of the ’887 patent shows an assay of protease activity using the substrate capture format, i.e., using a sensor including a layer of analyte binding molecules (e.g., streptavidin) such that the analyte binding molecules bind to the enzyme substrate (e.g., biotinylated cytochrome C). *Id*. at 7:49–55 (Example 3); and Figure 8. In Example 3, the biotin in the biotinylated cytochrome C (the “enzyme substrate” or “analyte”) binds to streptavidin, which is the molecule in the layer of analyte binding molecules that binds to the biotinylated cytochrome C. *Id*. at 7:59–63, Figure 8.[2]

[2] During prosecution, the applicant explained that in Example 3, the “sensor is coated with streptavidin and exposed to the biotinylated cytochrome C solution.” JX-0006.225 (referring to paragraphs 55–56 of the specification (JX-0006.016–017, which address Example 3)). The applicant further stated that, “[i]n other words, the layer of analyte binding molecules (e.g.,

[redacted]

The assay of Example 3 consists of adding a trypsin (enzyme) sample to a biotinylated cytochrome C solution. *See* '887 patent at 7:50–53. "After a digestion time period, a streptavidin coated sensor is placed in the enzyme/substrate mixture for substrate capture." *Id.* at 7:53–55. The specification explains that the "BLI sensor can assess the change in substrate size by a measuring the optical layer thickness upon binding the biotinylated peptide" as "protease activity produces smaller peptides with a thinner optical layer." *Id.* at 7:59–63; and Fig. 8.

Sartorius alleges infringement of claim 8, 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 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~~ analyte binding molecules,[3] 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.

'887 patent at 10:48–67.

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streptavidin) on the optical element is exposed to the enzyme substrate (e.g., biotinylated cytochrome C), '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.'" *Id*.

[3] The Commission determined that the "correct construction of 'the layer of *enzyme* binding molecules' requires substituting 'analyte' for 'enzyme' in this limitation." Comm'n Op. at 19 (Aug. 24, 2023) (EDIS Doc. ID 803150). That change is reflected in the claim as reproduced above and as discussed below.

E. Products at Issue

1. Accused Products

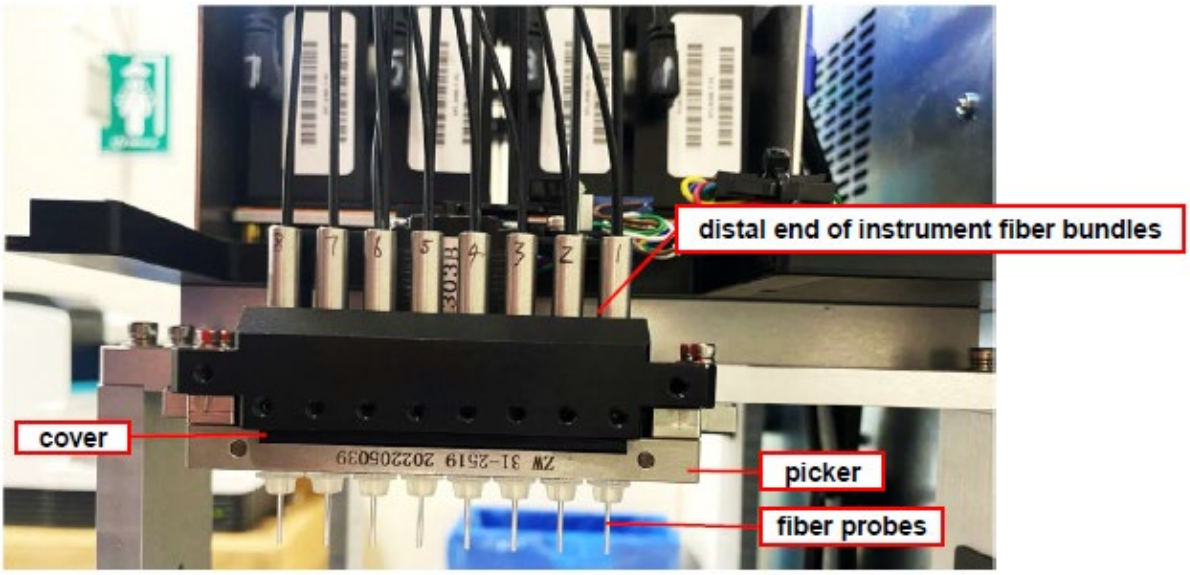
The accused products are bio-layer interferometers, biosensors, and kits containing biosensors and reagents manufactured by Gator Bio, imported by Gator Bio, and sold by Gator Bio. 87 Fed. Reg. 73330; *see also* Amended Complaint, ¶ 74; and Gator Bio Answer, ¶ 74. An exemplary accused Gator Bio bio-layer interferometer is shown on the left below, what has been called Gator Bio's first redesign fiber bundle is shown in the middle below, and what has been called Gator Bio's second redesign fiber bundle is shown on the right below. The fiber bundle is attached to the interferometer.



Tr. (Bailey) at 588:3–18; and CDX-0001C.12–13. An exemplary probe, used with the bio-layer interferometer including a fiber bundle is shown below:

CDX-0001C.14. The probe is a micro glass rod with its distal end coated with an optical layer and surface chemistry. Tr. (Bailey) at 589:16–20.

Gator Bio's bio-layer interferometer, also referred to as the instrument, operates with a fiber bundle and a number of probes to perform bio-layer interferometry, as shown below:



RDX-0002.3. The above photograph shows the inside of a Gator Bio interferometer. The fiber bundles are the black cables, which transmit light from a light source and then reflect it back to a spectrometer. The optical probes are shown at the bottom and are aligned with the optical fibers. Tr. (Tan) at 297:16–298:24; *see also* Tr. (Bailey) at 593:20–21 (CDX-0001C.19 shows the Gator Prime instrument with the top removed; and at 599:6–12 (CDX-0001C.25 "details where the fiber is in the instrument." "The optical fiber is what directs light from the light source." "It travels down the fiber where it then interfaces with the probes.").

a) Accused Instruments

The accused Gator Bio instruments are its GatorPrime, GatorPlus, and Gator Pro instruments. Sartorius Br. at 4. The GatorPrime and GatorPlus are 8-channel/8-spectrometer

[redacted]

instruments. CX-0102; and Tr. (Zuk) at 294:4–295:9. The Gator Pro is a 32-channel/32-spectrometer instrument. CX-0102; and Tr. (Zuk) at 295:11–296:4.

General Specifications

	Gator® Prime	Gator® Plus	Gator® Pro
Detection Technology		Next-gen Biolayer Interferometry	
Simultaneous Reads	8	8	8, 16, 24, and 32
Spectrometers	8	8	32
Acquisition Rate		2, 5, and 10 Hz	
Temperature Control		Ambient plus 4°C to 40°C	
Dimension (HxWxD) and Weight	47 x 31 x 67 cm, 35 kg	68 x 44 x 73 cm, 55 kg	84 x 114 x 77 cm, 220 kg
Automation Compatible	No	No	Yes

CX-0102.1.

The parties have stipulated that the GatorPrime instrument is representative of the accused instruments. Stipulation on Importation, Sale, and Inventory, ¶ 3 (Oct. 27, 2023) (EDIS Doc. ID 807186). Gator Bio's instruments are used in combination with Gator Bio's probes and kits, which are also called consumables. Sartorius Br. at 4.

b) Accused Probes/Kits

Gator Bio provides a large number of probes/kits that can be used with its instruments:

[redacted]

Gator Bio Probe Sales 2022

Product Name	Quantity	Sold Amount	Total Cost	Net Profit	Net Profit Percentage
AAV9	[redacted]				
AAVX					
Amine-Reactive Probes					
Aminopropylsilane (APS) Probes					
Anti-His Probes					
Anti-Human Fab Probes					
Anti-Human IgG Fc (HFC) Probes					
Anti-Human IgG Fc Gen II (HFCII) Probes					
Anti-Mouse IgG Fc (MFC) Probes					
APS Probes					
Flex.SA Kit					
Flex.SA Probes					
HFC Probes					
High Sensitivity AAV9 Kit					
High Sensitivity AAV9 Probes					
High Sensitivity AAVX Kit					
MFC probes					
Ni NTA Probes					
Ni-NTA kit					
Protein A Probes					
Protein G Probes					
Protein L Probes					
SA probes					
SMAP Probes					
Total					
Discount for probes					
Total adjusted for discount					

CX-0373C; Tr. (Schwartz) at 805:19–806:5; and *see also* CX-0102.2.

Sartorius has represented that "in addition to the accused instruments (i.e., the Gator Prime, Gator Plus, and Gator Pro), it accuses the following probes and kits of infringement: Gator Bio's HS-AAV kit, HS-AAV9 kit, AAV Ratio kit, and AAVX probe." Sartorius Statement Regarding the Scope of the Remedial Order (EDIS Doc. ID 805379). Sartorius does not accuse "non-HRP probes and kits," which are probes or kits that do not use the enzyme horseradish peroxidase (HRP). *See id*. and Order No. 32 at 15–17. In addition to Sartorius's statement on the scope of the accused probes/kits, the parties have stipulated that Sartorius "accuses only the following probes

and kits of infringement of [the '887 patent]: Gator Bio's HS-AAV kit, HS-AAV9 kit, AAV Ratio kit, and AAVX probe." Stipulation on Importation, Sale, and Inventory, ¶ 4.

Gator Bio and the Staff dispute that the AAVX probe can be used with HRP and thus dispute whether the AAVX probe should be identified as an accused probe. Gator Bio Reply at 34–36; and Staff Br. at 40–41. That issue is addressed in section VII.A.

2. Domestic Industry Products

Like the accused products, Sartorius's domestic industry products are bio-layer interferometers and probes/kits. Sartorius Br. at 1; CX-0190C.13 and 15 (showing Sartorius interferometers); CX-0026 (identifying Sartorius probes/kits); and Tr. (Kang) at 130:3–131:12 and 137:15–139:19.

a) Domestic Industry Instruments

Sartorius identifies the following Octet instruments as its domestic industry instruments: HTX (RH96), RED384 (RH16), RED96e, RED96, QKe, and BLItz (N1) (shown on CX-0190C.13), and the Octet R2, R4, and R8 (shown on CX-0190C.15). Tr. (Bailey) at 629:6–9.

CX-0190C.13.

[redacted]

CX-0190C.15.

b) Domestic Industry Probes/Kits

Sartorius identifies the following as its domestic industry probes/kits: Anti-AAVX (AAVX), Anti-CHO HCP (HCP) Kit, Anti-hIgG Fc Capture (AHC2), Mannose Screening (GlyM) Kit, Octet Amine Reactive 2nd Generation (AR2G), Octet Aminopropylsilane (APS), Octet Anti-Glutathione-S-Transferase (GST), Octet Anti-HIS (HIS2), Octet Anti-Human Fab-CH1 2nd Generation (FAB2G), Octet Anti-Human Fc Capture (AHC), Octet Anti-Human IgG Quantitation (AHQ), Octet Anti-Mouse Fc Capture (AMC), Octet Anti-murine IgG Quantitation (AMQ), Octet Anti-Penta-HIS (HIS1K), Octet High Precision Streptavidin (SAX), Octet High Precision Streptavidin 2.0 (SAX2), Octet Ni-NTA (NTA), Octet Protein A (ProA), Octet Protein G (ProG), Octet Protein L (ProL), Octet Super Streptavidin (SSA), Residual Protein A (RPA) Kit, Sialic Acid Screening (GlyS) Kit, Streptavidin (SA), AR2G Kit (AMC2). Sartorius Br. at 3, *citing* CX-0026.3–4; and Tr. (Kang) at 137:15–138:20 and 139:11–16.

II. JURISDICTION

A. Statutory Jurisdiction

Congress has directed that "[t]he Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative." 19 U.S.C. § 1337(b)(1).

Section 337(a)(1)(A) declares unlawful, *inter alia*, "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent . . .." 19 U.S.C. § 1337(a)(1)(B). Under the statute, the Commission has authority to investigate Sartorius's allegations of patent infringement with respect to Gator Bio articles imported into the United States.

B. Personal Jurisdiction

By filing a complaint and participating in this investigation, Sartorius consented to the personal jurisdiction of the Commission. *See Certain Toner Cartridges, Components Thereof, and Systems Containing Sam*e, Inv. No. 337-TA-1174, Order No. 40 (Initial Determination) at 34–35 (Jul. 23, 2020) (EDIS Doc. ID 716848), *unreviewed by*, Comm'n Notice (Sept. 8, 2020) (EDIS Doc. ID 719096). Gator Bio appeared and participated in this investigation, thus submitting itself to the personal jurisdiction of the Commission.

I conclude that the Commission has personal jurisdiction over Sartorius and Gator Bio. *See, e.g., Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, Initial Determination at 9 (Aug. 1, 2019) (EDIS Doc. ID 685112), *unreviewed in pertinent part by*, Comm'n Notice (Sept. 30, 2019) (EDIS Doc. ID 689653).

C. *In Rem* Jurisdiction

The Commission has *in rem* jurisdiction over accused products that have been imported into the United States. *See, e.g., Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976, 985–86 (C.C.P.A. 1981) (noting that the Commission has jurisdiction over imported goods). The importation requirement for a respondent can be demonstrated by proving that the respondent

imported, sold for importation, or sold after importation each product accused of infringing an enforceable patent.

The record evidence addressed in section IV demonstrates that Gator Bio's accused instruments have been imported into the United States. I therefore conclude that the Commission has *in rem* jurisdiction over the accused instruments. As also addressed in section IV, the record evidence demonstrates that Gator Bio's accused probes/kits have not been imported into the United States. I therefore conclude that the Commission does not have *in rem* jurisdiction over the accused probes/kits.

III. STANDING

The record evidence demonstrates that Sartorius, as assignee of the asserted patents, had standing to bring its complaint. *See* JX-0002 ('887 patent); CX-0001 (assignment from inventors to FortéBio, Inc.); CX-0003 (assignment from FortéBio, Inc. to Pall FortéBio Corp.); CX-0004 (assignment from Pall FortéBio Corp. to Pall FortéBio LLC); CX-0005 (assignment from Pall FortéBio LLC to Molecular Devices, LLC); and CX-0006 (assignment from Molecular Devices, LLC to Sartorius). This is not disputed by either Gator Bio or the Staff. *See generally* Gator Bio Br. and Staff Br. Accordingly, I find that Sartorius had standing to bring its complaint in this investigation.

IV. IMPORTATION

To prove a violation of section 337 by a respondent, the complainant must show that the respondent engaged in "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee" of products accused of infringement. 19 U.S.C. §§ 1337(a)(1)(A)-(B).

[redacted]

Gator Bio has stipulated that its accused instruments have been imported into the United States and does not dispute that the importation requirement of section 337 has been satisfied for those products. Stipulation on Importation, Sale, and Inventory, ¶ 2. I therefore find that the importation requirement of section 337 has been satisfied with respect to Gator Bio's accused instruments.

Though it agrees that its accused instruments are imported, Gator Bio contends that its accused instruments are not "articles that infringe" under section 337(a)(1)(B)(i) because its imported instruments must be used with one of its domestic probes to practice method claim 8. Gator Bio Reply at 3–4. That issue is addressed in section VII.C.

Sartorius contends that Gator Bio's accused probes/kits are imported because Gator Bio imports from China the optical fiber that is used to make the probes. Sartorius Br. at 5, *citing* Tr. (Zuk) 440:13–18; and CX-0643C (Zuk Dep.) at 117:12–118:14. Gator Bio and the Staff dispute importation of Gator Bio's accused probes/kits. Gator Bio Reply at 3–4; and Staff Br. at 10–11. In testimony Sartorius elicited immediately before the testimony it cites, Mr. Zuk, the chief technology officer of Gator Bio, Tr. (Tan) at 285:20–24; and Tr. (Zuk) at 381:11–13, testified that Gator Bio makes all its probes/kits in California. Tr. (Zuk) at 440:3–12. In addition, at deposition, Mr. Zuk testified:

> Q. And does Gator Bio make all of their biosensors in Palo Alto?
>
> A. Yes.
>
> Q. Who makes the biosensors at Gator Bio?
>
> . . .
>
> A. We have a manufacturing team that makes them for sale. And then, for R&D, the R&D chemists prepare the biosensors for their research.

CX-0643C (Zuk Dep.) at 117:9–17. Sartorius's economic expert, Dr. Schwartz, testified that he understood that Gator Bio probes/kits are not imported but are manufactured in the United States. Tr. (Schwartz) at 815:9–12. Likewise, Gator Bio's economic expert, Dr. Vander Veen, testified that Gator Bio's probes/kits are manufactured in the United States. Tr. (Vander Veen) at 546:10–21. The evidence demonstrates that Gator Bio manufactures its probes/kits in the United States. I find that Sartorius has not shown that Gator Bio's accused probes/kits are imported.

V. LEVEL OF ORDINARY SKILL IN THE ART

Sartorius contends that a person of ordinary skill in the art would "[h]ave at least an equivalent of a [master's] degree in physics or optics or a related field such as chemistry, and provides knowledge of optics, sensors or biomolecular interactions and approximately three to five years of experience in sensing and sensor technology or related field, and a working knowledge regarding the physical, chemical, or biological properties of those systems." Sartorius Br. at 5, *citing* Tr. (Sailor) at 1092:2–8.

Gator Bio asserts that a person of ordinary skill in the art would have an equivalent of a master's degree in physics, optics, biology, chemistry, chemical engineering, biomedical engineering, or a related discipline, and one to two years of applying optical biosensors. Gator Bio Br. at 34, *citing* Tr. (Forrest) 1022:15–1023:1; *see also* Tr. (Schaafsma) at 873:2–19.

Dr. Sailor, Sartorius's expert, testified that his opinions would not change depending on which level of ordinary skill was adopted. Tr. (Sailor) at 1092:23–25. Dr. Forrest, Gator Bio's expert, testified that his opinions would not change depending on which level of ordinary skill was adopted. Tr. (Forrest) at 1022:22–24. The Staff contends that Sartorius's proposed definition of a person having ordinary skill should be adopted. Staff Br. at 28.

[redacted]

There is no material dispute between the parties as to the appropriate level of skill in the art as no party contends that the different proposals would lead to different outcomes. To the extent I must determine the appropriate level of skill in the art, I adopt the definition proposed by Sartorius and the Staff. *See* Tr. (Forrest) at 1022:17–21; and Tr. (Sailor) at 1092:2–8. I find that one of ordinary skill in the art at the time of the inventions described in the '887 patent would have at least an equivalent of a master's degree in physics or optics or a related field such as chemistry, and provides knowledge of optics, sensors or biomolecular interactions and approximately three to five years of experience in sensing and sensor technology or related field, and a working knowledge regarding the physical, chemical, or biological properties of those systems.

VI. CLAIM CONSTRUCTION

A. Legal Standard

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, weight may be attached to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

The terms of a claim are generally given their ordinary and customary meaning which is the meaning that the term would have to one of skill in the art at the time of the invention. *Id.* at 1312–13. The ordinary meaning of a claim term is its meaning to one of skill in the art after reading the entire patent. *Id.* at 1321. The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[redacted]

A court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is intrinsic evidence, is "the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id*. "[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

In some situations, a "court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). Extrinsic evidence is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. While expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art," such testimony is "generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Phillips*, 415 F.3d at 1318–19. Further, while extrinsic evidence may be useful, it is less reliable than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id*. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on extrinsic evidence is

improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999), *citing Vitronics*, 90 F.3d at 1583.

B. Previously-Addressed Constructions

The parties agreed on the following constructions:

Claim Term	Agreed Construction
optical thickness	the product of the refractive index and the physical index
enzyme	a protein that catalyzes biochemical reactions
enzyme substrate	a reactant in a biochemical reaction catalyzed by an enzyme
enzyme activity	catalytic action of an enzyme on a substrate

Joint Chart of Agreed and Disputed Claim Terms for Construction (EDIS Doc. ID 792996).

Following briefing and a hearing, I issued several orders addressing claim construction issues. Relevant to the '887 patent, I considered whether there was an error in claim 8 that could be corrected and considered whether the preamble is limiting. Order No. 16; and Order No. 22. As to the first issue, the Commission found that the intrinsic record supports Sartorius's argument that the term "enzyme" in "the layer of *enzyme* binding molecules" was a minor clerical error, that the correction of that claim phrase to "the layer of *analyte* binding molecules" is not subject to reasonable debate based on consideration of the claim language and the specification, and that the prosecution history does not suggest a different interpretation. Comm'n Op. at 16–25 (Aug. 23, 2023). As to the second issue, I concluded that the preamble is not limiting but noted that I would reconsider that issue if raised by the parties because they had not addressed a newly-disputed preamble term. Order No. 16 at 24–25.

[redacted]

C. Disputed Claim Terms

The parties identify and spend considerable space addressing several disputed claim construction issues. Sartorius Br. at 6–10; Sartorius Reply at 6–15; Gator Bio Br. at 34–42; Gator Bio Reply at 4–23; Staff Br. at 28–33; and Staff Reply at 2–5. They are addressed below.

1. Air Gap

The parties did not address the meaning of the term "air gap" in their claim construction briefs or at the claim construction hearing. Sartorius argues that Gator Bio and the Staff waived their ability to assert constructions of "air gap" because they were not disclosed earlier. Sartorius Br. at 9 and Sartorius Reply at 13. The Staff notes that its proposed construction was included in its pre-hearing brief. Staff Reply at 2, n.1, *citing* Staff Pre-Hearing Br. at 41. Gator Bio argued in its pre-hearing brief that an "'air gap,' in optical parlance and particularly in the context of optical fiber systems, denotes a designed separation between two non-contacting elements." Gator Bio Pre-Hearing Br. at 103; *see also id*. at 329–30 (arguing that because the optical fibers of certain of its accused products and probes are in physical contact, those products do not include the claimed air gap). Based on their pre-hearing briefs, I conclude that neither the Staff nor Gator Bio waived their proposed constructions.

In addition, the fact that the construction of "air gap" was not addressed earlier does not mean it should not be addressed now. *See* Sartorius Reply at 12 (stating that "[b]ecause this issue was not raised at the claim-construction stage, it is waived"). The Commission has recognized that although parties may fail to identify a claim construction dispute during the claim construction phase of an investigation, when arguments presented at the evidentiary hearing and in post-hearing briefing "reveal[] that there [i]s indeed a material dispute over the meaning" of a claim term, Federal Circuit caselaw "require[s] resolution of the parties' claim construction dispute." *Certain*

[redacted]

Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof, Inv. No. 337-TA-1167, Comm'n Op. at 23 (Dec. 20, 2021) (EDIS Doc. ID 758899), *citing O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it"). The parties have presented a dispute over the meaning of "air gap" in claim 8, which will be addressed here.

The proposed constructions are:

Claim Term	Sartorius's Construction	Gator Bio's Construction	Staff's Construction
Air gap	plain and ordinary meaning—a gap filled with air	controlled spacing between surfaces that avoids undesired interference fringes	a designed separation between two non-contacting elements

Sartorius Br. at 9; Gator Bio Br. at 40–41; and Staff Br. at 31.

The essential dispute between the parties is whether the claimed air gap is an intentional design feature in the claim. The intrinsic evidence supports that it is.

a) The Claim Language Supports that the Claimed Air Gap Is a Designed Separation

Turning first to the claim language, claim 8 recites "a mechanical coupling that engages the first optical element with a fiber and provides an air gap." '887 patent, claim 8. According to the claim language, not only is the claimed air gap intentionally present, it is also provided by the mechanical coupling and is therefore a designed feature of the claimed structure. The claim further recites that the air gap is provided "between the first optical element and the fiber." The claim language itself thus instructs what provides the air gap (the mechanical coupling) and where it is

(between the first optical element and the fiber). This language supports that the air gap is a designed separation, as proposed by the Staff.

Gator Bio proposes that the claimed air gap is a controlled spacing that avoids undesired interference fringes. As to the first portion of Gator Bio's proposed construction—controlled spacing—Gator Bio appears to equate a designed separation with a controlled spacing, stating in its pre-hearing brief that an "'air gap,' in optical parlance and particularly in the context of optical fiber systems, denotes a designed separation between two non-contacting elements," Gator Bio Pre-hearing Br. at 103, and arguing at the hearing that "an air gap is a controlled or defined spacing that is provided for by a mechanical coupling," Tr. at 29:11–13, and that "an air gap is a defined or controlled spacing between an optical fiber . . . and an optical element," Tr. at 38:5–15. Because Gator Bio has not identified any difference between a designed separation and a controlled spacing and because "designed separation" captures that the air gap is an intentional design feature in the claim, I adopt this portion of the Staff's proposed construction.

b) The Specification Supports that the Claimed Air Gap Is a Designed Separation

The specification supports that the claimed air gap is a designed separation. First, the '887 patent specification itself only uses the term "air gap" in the claims. '887 patent, claims 1, 7, 8, and 18. The '887 patent specification, however, incorporates by reference application serial number 10/981,901, which issued as previously-asserted U.S. Patent No. 7,394,547. '887 patent at 4:1–10; *see also* JX-0001 ('547 patent).

Figure 4 of the '547 patent illustrates an optical assembly 50 that is removably carried on the distal end of an optical fiber 52. '547 patent at 9:22–24.

[redacted]

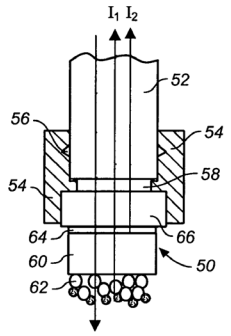


FIG. _4

'547 patent at Figure 4. The optical assembly 50 includes two optical elements, a first optical element 60 and a second optical element 66. *Id*. at 9:38–46. In operation, the optical assembly 50 is placed over the distal end of fiber 52 and snapped in place. *Id*. at 9:52–53.

Gripping arms 54 are designed to slide over the end of the fiber 52 and grip it "by engagement of an annular rim or detente 56 on the fiber with complementary shaped recesses formed in the arms." *Id*. at 9:24–28. This attachment positions the optical assembly 50 on the fiber 52 to "provide an air gap 58 between the distal end of the fiber and the confronting (upper) face of the assembly." *Id*. at 9:28–31. The air gap 58 in Figure 4 is shown between the distal end of fiber 52 and the second optical element 66. The '547 patent explains that an air gap may be "less than 100nm or greater than 2μm" and that "[w]ith an air gap of greater than about 100nm, but less that [sic, than] 2μm, internal reflection from the upper surface of the optical assembly can contribute significantly to undesirable fringes that can adversely impact the detection accuracy." *Id*. at 9:31–36.

The first optical element 60 has a first reflective layer 62 and a second reflective layer 64. *Id*. at 9:39–41. Layer 64 is sandwiched between first optical element 60 and second optical element 66. *Id*. at 9:48–51. In operation, the lower surface of the assembly is exposed to a sample of analyte, under conditions that favor binding of sample analyte to the analyte-binding molecules forming

[redacted]

reflective layer 62. *Id*. at 9:52–56. "As analyte molecules bind to this layer, the thickness of the layer increases, increasing the distance 'd' between reflective surfaces 62 and 64." *Id.* at 9:56–59. "This produces a shift in the extrema of the interference wave produced by reflection from the two layers, . . . [which] is used to determine the change in thickness at the lower (distal-most) reflecting layer." *Id.* at 9:59–64.

The '547 patent also includes Figure 5, which illustrates an optical assembly and fiber bundle in "an embodiment of the invention designed for detecting one or more of a plurality of analytes." *Id*. at 10:1–3.

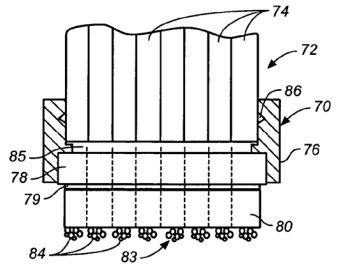


FIG. _5

'547 patent at Figure 5. A fiber bundle 72 is composed of an array of fibers 74. The optical assembly, indicated generally at 70, is composed of the basic optical elements described with respect to Figure 4, but in an array format. *Id*. at 10:4–9. "The assembly is carried on the fiber bundle 72 by engagement between a pair of flexible support arm[s], such as arm 76 and an annular rim or detente 86 on the bundle." *Id*. at 10:24–26. "With the assembly placed on the fiber bundle, the lower distal ends of the fibers are spaced from the confronting surface of optical element 78 by an air gap 85 whose spacing is preferably less than 100nm or greater than 2μm." '547 patent at 10:27–30.

The specification supports that the claimed air gap is a designed separation in the claimed structure. Both Figures 4 and 5 of the '547 patent show an air gap as a design feature between an

optical element and the optical fiber, and the specification supports that in describing those embodiments. I therefore conclude that the specification supports that the claimed air gap is a designed separation.

As to the second portion of Gator Bio's proposed construction—avoids undesired interference fringes—Gator Bio contends that the air gap "has a specific function that is called out in the specification for the patent." Gator Bio Br. at 41–42, *citing* Tr. (Schaafsma) at 904:8–25 (testifying that "undesirable fringes" "can adversely impact the detection accuracy"). Sartorius maintains that this portion of Gator Bio's construction is improper because it improperly incorporates a functional limitation. Sartorius Br. at 9. I agree with Sartorius that this portion of Gator Bio's proposed construction is unnecessary. While Gator Bio is correct that the '547 patent specification discloses that an air gap outside of a particular range "can contribute significantly to undesirable fringes that can adversely impact the detection accuracy," JX-0001 ('547 patent) at 9:35–37, there is nothing in the claim language that requires this functional feature. *Transmatic v. Gulton*, 52 F.3d 1268, 1278 (Fed. Cir. 1995) ("the district court erred by importing unnecessary functional limitations into the claim").

As to the second portion of the Staff's proposed construction—between two non-contacting elements—the Staff contends that "the term itself plainly indicates there is *no contact* between the optical element and the fiber because there is an 'air gap' between them." Staff Br. at 31–32 (emphasis in original). The Staff also argues that provision of the air gap by the claimed mechanical coupling "indicat[es] that the mechanical coupling ensures that there is no contact between the optical element and the fiber." *Id*. at 32. While I agree that the claim language requires an air gap that is provided by the mechanical coupling, that language of itself does not necessarily mandate that there can be no contact between those two components.

[redacted]

In addition, while the ’547 patent specification only shows embodiments in which there is no contact between the optical element and the fiber when an air gap is provided, the specification nowhere discloses or intimates that any and all contact is barred. Moreover, Figures 4 and 5 of the ’547 patent show a component that maintains a space between the optical element and fiber, arms 54 in Figure 4 and arm 76 in Figure 5, the patent does not suggest that is the only way to maintain an air gap between those elements.

The Staff also points to expert testimony to support its position. Staff Br. at 33. Dr. Schaafsma (Gator Bio’s expert) testified that “there’s a definite distinction between physical contact and an air gap in the industry and common knowledge at the time” of the invention of the ’887 patent. Tr. (Schaafsma) at 907:12–14. Dr. Sailor agreed that “one reason why you would want to provide an air gap between two optical fibers, Doctor, is to prevent two rotating fiber ends from grinding and scratching against each other.” Tr. (Sailor) at 1150:22–1151:1. This testimony, however, does not address whether any and all contact is precluded between the optical element and the fiber with the provision of an air gap.

Sartorius argues that the Staff’s proposed construction is incorrect because the word “gap” and the words “air gap” have been construed in other unrelated contexts to not preclude contact. Sartorius Reply at 14, *citing Wilson Sporting Goods Co. v. Hillerich & Bradsby Co*., 442 F.3d 1322 (Fed. Cir. 2006) (assessing the claim term “gap” in the context of a baseball bat); and *Innovative Display Techs. LLC v. Acer Inc.*, No. 2:13-cv-522, 2014 WL 4230037 (E.D. Tex. Aug. 26, 2014) (assessing the claim term “air gap” in the context of display screens). I agree with the Staff that “the technology and structures at issue in those cases (baseball bats and display screens) and their claim language are so far afield from the ’887 patent that they cannot provide real guidance to the interpretation of ‘air gap’ in the context of optical fiber interfaces.” Staff Reply

at 3. Thus, while I conclude that the claim language and specification do not mandate that all contact is precluded, as the Staff advocates, that conclusion is based on the claim language and specification here and does not depend (in any way) on how similar terms were construed in different patents directed to different technologies.

In addition, albeit different, both Gator Bio and the Staff seek to add a negative limitation to the claim through their proposed constructions. Gator Bio seeks to add that the air gap "avoids undesired interference fringes" while the Staff seeks to add that all contact (presumably between the optical element and optical fiber) is precluded. In both instances, the proposed "negative limitation finds no anchor in the explicit claim language" and there is no "express disclaimer or independent lexicography in the written description that would justify adding [the proposed] negative limitation." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1322–23 (Fed. Cir. 2003).

As noted, the specification does not mandate that all contact is precluded via the air gap. In addition, the specification states that "[w]ith an air gap of greater than about 100nm, but less that [sic, than] 2 μm, internal reflection from the upper surface of the optical assembly can contribute significantly to undesirable fringes that can adversely impact the detection accuracy." '547 patent at 9:33–37. I agree with Sartorius that this portion of the '547 patent specification does not mandate an air gap of a certain size and does not mandate avoidance of undesirable interference fringes. Sartorius Br. at 10. As a result, the negative limitations advocated by Gator Bio and the Staff are not adopted.

c) The Prosecution History Does Not Change that the Claimed Air Gap Is a Designed Separation

The prosecution history does not change that the claimed air gap is a designed separation. The originally-filed claims of the application that issued as the '887 patent did not recite an air

gap. *See* JX-0006 ('887 patent prosecution history) at 22–24. After the Examiner rejected the claims over the prior art, *id*. at 168–170, applicant amended the claims, including application claim 7, which issued as '887 patent claim 8:

> 7. (Currently Amended) 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 ~~positioned so that interference between a reflected beam from the proximal reflecting surface and a reflected beam from the distal reflecting surface varies as an enzyme substrate or portion thereof binds to the layer of binding molecules, and wherein the reflected beams are coupled into the fiber~~;
>
> 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.

Id. at 221. Applicant amended the claim to recite "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." *Id*. Applicant stated that application claim 7 was amended to recite the mechanical coupling and that support for the amendment was in non-provisional application number 10/981,901 (the '547 patent). *Id*. at 224. The remaining claim amendments were said to "correct inadvertent and/or typographical errors." *Id*.

[redacted]

Applicant specifically distinguished the prior art (Cunningham) based on the amended claim language, arguing that Cunningham did not "refer at all to an optical element coupled to a light source via a mechanical coupling that engages the first optical element with an optical fiber." *Id*. at 225. Applicant stated that Cunningham also "does not disclose the coupling providing an air gap between the first optical element and the fiber." *Id*. With respect to a secondary reference (Garini), applicant stated, among other things, that Garini does not disclose "the mechanical coupling that engages the optical element with the fiber." *Id*. at 228. Applicant also argued that Garini does not disclose "the air gap provided between the optical element and the fiber." *Id*. After those claim amendments and arguments, the claims were allowed. *Id*. at 441.

The claim amendments made by applicant to introduce the claimed air gap and applicant's arguments distinguishing the prior art on this basis, support that the claimed air gap is a designed separation between the optical element and the fiber.

Based on the parties' briefs and the arguments and testimony at the hearing, I conclude that the "air gap" in claim 8 of the '887 patent is a designed separation.

2. Claim 8 Preamble

The preamble of claim 8 recites "[a] method for assaying enzyme activity." '887 patent, claim 8. The parties dispute whether the preamble of claim 8 is limiting. Sartorius contends that the preamble is not limiting. Sartorius Br. at 6. Gator Bio and the Staff contend that it is. Gator Bio Br. at 34–35; and Staff Br. at 30–31. I considered this issue in Order No. 16. At that time, the parties agreed on the construction of the term "enzyme activity" as "catalytic action of an enzyme on a substrate," but did not address the meaning of the word "assaying." Order No. 16 at 21–25. Based on the parties' briefing and arguments at the claim construction hearing, I concluded that the preamble was not limiting. *Id*.

I specifically noted, however, that I had asked the parties to address the meaning of "assaying" in the preamble, after which the parties submitted proposed constructions. Supplement to Joint Chart of Agreed and Disputed Terms for Construction at 1–2 (EDIS Doc. ID 796151). I stated in Order No. 16 that "[w]hether the word 'assaying' is relevant to any argument that the preamble is limiting was not presented in the parties' briefing" and that "[t]o the extent such an argument is properly raised later, I [would] consider it at that time." *Id*.

In their supplemental joint chart, the parties proposed constructions of "assaying":

Claim Term	Sartorius's Construction	Gator Bio's Construction	Staff's Construction
Assaying '887 patent, claim 1	No construction needed because "assaying" is not a claim limitation. In the event that the ALJ finds "assaying" to be a claim limitation, "assaying" should be given its plain and ordinary meaning (i.e., "detecting, measuring, or monitoring").	Measuring.	Measuring.

Supplement to Joint Chart at 1–2.

Because a dispute remains between the parties as to whether the preamble is limiting based on their different proposed constructions of "assaying," I will reconsider the issue. I first consider the construction of "assaying" and then based on that construction consider whether the preamble is limiting.

[redacted]

a) Assaying

The preamble of claim 8 recites "assaying enzyme activity." The parties previously agreed that "enzyme activity" means "catalytic action of an enzyme on a substrate."

The claim language does not directly define the term "assaying." In reciting "detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity," however, the claim itself gives an indication of what "assaying enzyme activity" is. That is, by this claim term, what is assessed is enzyme activity.

The specification supports that "assaying enzyme activity" means measuring enzyme activity. The title of the '887 patent is "Enzyme Activity Measurements Using Bio-Layer Interferometry." '887 patent at title. The field of the invention states that the "invention relates to interferometry-based methods and compositions useful for measuring enzyme activity." *Id*. at 1:20–22. The background of the invention section of the specification states that "[o]ften in the course of development and manufacture of enzyme products it is necessary to measure the activity of the enzyme." *Id*. at 1:26–28. The specification also states that "[t]he invention is useful for measuring enzyme activity in any context for which such activity measurements are useful including, e.g., for discovery, modification, optimization, production, etc. of enzymes or enzyme inhibitors," and that the "invention may be practiced using any type of enzyme such as, e.g., hydrolases, glycosylases, esterases, and transferases, or inhibitors of such enzymes." *Id*. at 3:27–33. The specification further states that "[t]he invention is broadly applicable to enzyme activity measurements, including by way of example but not limitation, measurements of hydrolases (including proteases), glycosylases, esterases, transferases (including nucleotide transferases and phosphotransferases)." *Id*. at 4:44–49. The examples are consistently described as enzyme activity measurements. *Id*. at 5:40–63 (describing Example 2 as hydrolase activity measurements), 6:5–29

(describing subtilisin activity measurements), 7:19–8:13 (describing Example 3 as trypsin activity measurements), 8:32–52 (describing Example 4 as esterase activity measurements), and 8:54–9:43 (describing Example 5 as transferase activity measurements).

Sartorius contends that assaying means "detecting, measuring, or monitoring," but does not clearly articulate what, if any, differences there are between its suggested alternatives. Sartorius Br. at 6–9; and Supplement to Joint Chart at 1–2. As to detecting, Sartorius contends that the patent "repeatedly discloses detecting enzyme activity," first pointing out that the claim recites *detecting* a change in optical thickness . . . wherein the change is indicative of enzyme activity. Sartorius Br. at 7. While it is true that the claim recites that the change in optical thickness is detected, the claim does not recite detecting enzyme activity. Sartorius also points to figures 9 through 13 and col. 2, lines 55 through 67 as disclosing detecting the activity of enzymes. Sartorius Br. at 7. While Sartorius points to the brief description of the figures in making this argument, the more detailed discussion in the specification supports that enzyme activity is measured. '887 patent at 8:67–9:1 (describing figure 9 as "measuring DNA polymerase I activity") and 9:14–16 (describing figure 10 as an "approach to measur[ing] activity of nucleotide transferases").

Sartorius also argues that the specification shows that "assaying" includes "monitoring," in disclosing that "[i]n the development and manufacture of enzyme or enzyme inhibitor based products for therapeutic or industrial applications, it is critical to monitor the activity of the enzyme throughout the process." Sartorius Br. at 8, *quoting* '887 patent at 1:30–35. I agree with Gator Bio that Sartorius fails to explain how enzyme activity can be monitored without being measured and that monitoring enzyme activity suggests taking measurements over time. Gator Bio Reply at 22. In addition, the specification's use of the word "monitor" in that instance does not change its repeated focus on assaying enzyme activity as measuring. Through its repeated and consistent

focus on measuring enzyme activity, I conclude that the specification supports that "assaying" means measuring.

No party contends that the prosecution history is relevant to determining what "assaying" means in the preamble. Sartorius Br. at 6–9; Gator Bio Br. at 34–35; Staff Br. at 29–31; Sartorius Reply at 6–9; Sartorius Reply at 22–23; and Staff Reply.

The parties also point to expert testimony from the hearing regarding the meaning of "assaying" in support of their positions. Sartorius Br. at 7; and Gator Bio Br. at 35. Both point to testimony from Dr. Forrest, who testified that assaying refers to "taking some type of measurement of that particular thing" and that assaying enzyme activity could include simply detecting if the enzyme has any activity at all. Tr. (Forrest) at 1013:5–10 and 1067:3–6. Neither that testimony nor the other testimony referenced by the parties changes that the specification clearly and consistently discloses measuring enzyme activity.

Based on the evidence, I conclude that "assaying" in claim 8 of the '887 patent means measuring.

b) Whether the Preamble Is Limiting

In view of the construction of "assaying," I next consider whether the preamble is limiting. As noted, I previously determined it was not, based on the parties' briefing and arguments that did not address the meaning of assaying. I previously found that the preamble does not recite "the *raison d'etre* of the claimed method itself" because the body of the claim itself is complete in reciting that a change in optical thickness is detected, which is indicative of enzyme activity. Order No. 16 at 22, *quoting Eli Lilly and Co. v. Teva Pharms., Int'l GmbH*, 8 F.4th 1331, 1341 (Fed. Cir. 2021).

[redacted]

Specifically, the body of claim 8 recites "detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity." '887 patent, claim 8. The body of the claim thus recites that the detected optical thickness must relate to, that is, be indicative of enzyme activity. As a result, the body of the claim focuses on enzyme activity itself—that is what is tied to the detecting step.

I was not asked to, and did not, construe the detecting step of claim 8. Based on the language of the claim, tying enzyme activity to the claimed detecting, and the specification, which focuses on enzyme activity, I conclude that because the detecting step of claim 8 must be indicative of measuring enzyme activity, the detecting step requires that the detected change in optical thickness is a measure of enzyme activity. I reject Sartorius's argument that "indicative of enzyme activity" means only that enzyme activity causes a change in optical thickness. Sartorius Br. at 7. That is not what the claim requires. Instead, the claim requires that the detected change in thickness is indicative of or indicates enzyme activity. That is different from enzyme activity merely causing a change in thickness that is then detected. And the specification supports that enzyme activity itself is the focus.

Because "indicative of enzyme activity" in the detecting step recites a measure of enzyme activity and the parties had not addressed the relevance of "assaying" in the preamble, I previously concluded that the preamble was not limiting. Based on the parties' arguments on assaying, I conclude that the preamble is limiting. While I conclude that the detecting step requires that indicative of enzyme activity means a measure of enzyme activity, "assaying enzyme activity" in the preamble makes that crystal clear. This, as explained above, is supported by the specification, which repeatedly and consistently defines the invention as measuring enzyme activity.

[redacted]

3. Mechanical Coupling

Gator Bio contends that Sartorius's statements in an IPR directed to previously-asserted U.S. Patent No. 8,305,585 (IPR2023-0015) "foreclose any reading of the term 'a mechanical coupling that engages the first optical element with a fiber' that would cover an arrangement in which an optical fiber runs into a mechanical coupling and optical fiber runs out of it." Gator Bio Br. at 36.[4] Gator Bio contends that Sartorius's statements in the '585 patent IPR mandate this construction based on any of: (1) prosecution disclaimer; (2) claim construction; and (3) judicial estoppel. Gator Bio Reply at 4–16[5]; *see also* Gator Bio Br. at 36–40. Though not raised as a claim construction issue, in considering both infringement and technical domestic industry, the Staff agrees with Gator Bio that prosecution disclaimer applies. Staff Br. at 34–38 and 46–47.

The thrust of Gator Bio's argument is one of prosecution disclaimer, which I consider first, followed by Gator Bio's arguments on claim construction and judicial estoppel. Before that, however, as instructed by the Federal Circuit, I first consider the meaning of "mechanical coupling" "in the context of the patent and prosecution history and then turn to the question of whether [Sartorius] surrendered claim scope by clear disclaimer or redefinition." *K-fee Sys. GmbH v. Nespresso USA, Inc.*, 89 F.4th 915, 920 (Fed. Cir. 2023).

[4] Gator Bio states that it "refers throughout to the claim element breakdowns in RX-0221, RX-0222, and RX-0223." Gator Bio Reply at 5, n.2. These exhibits were not identified on the parties' Final Joint Exhibit List. (EDIS Doc. ID 808423).

[5] It does not appear that Gator Bio addressed its judicial estoppel argument in its initial post-hearing brief. *See* Gator Bio Br. at 36–40. Under Ground Rule 14.1, "[a]ny issue for which a party has the burden of proof that is not addressed in detail in the initial post-hearing initial brief shall be deemed abandoned or withdrawn." Order No. 10, Ground Rule 14.1 (EDIS Doc. ID 792151). Despite having abandoned this argument, I address Gator Bio's judicial estoppel argument below.

a) The Claim Language

Claim 8 recites that the mechanical coupling engages the first optical element with a fiber and provides an air gap between the optical element and the fiber. ’887 patent, claim 8. Based on this claim language, the mechanical coupling is a mechanical component that performs the functions of engaging the optical element with a fiber and that provides an air gap between the optical element and the fiber. No party urges a different construction based on the claim language itself. Gator Bio Br. at 36–40; Gator Bio Reply at 4–16; and Sartorius Reply at 9–12.

b) The Specification

The ’887 patent specification does not use the term “mechanical coupling.” Instead, the ’887 specification incorporates by reference application serial number 10/981,901, which issued as the previously-asserted ’547 patent. ’887 patent at 4:1–10; *see also* ’547 patent. The previously-asserted ’585 patent issued from a series of continuation applications from application serial number 10/981,901. JX-0004 (’585 patent) at cover.

The ’585 patent uses the term “mechanical coupling” only in the claims. *Id*. at claims 13, 18, and 19.[6] As for the specification, the ’585 patent includes Figure 2, which shows “an optical assembly 26 constructed in accordance with one embodiment of the invention, and an adjoining portion of the distal end region of an optical fiber 32 to which the optical assembly is fixedly attached.” ’585 patent at 7:14–17.

[6] Because the parties address the term “mechanical coupling” with respect to the ’585 patent IPR proceedings, citations to the ’585 patent are used here. That disclosure is the same as the disclosure of the ’547 patent, addressed previously.

[redacted]

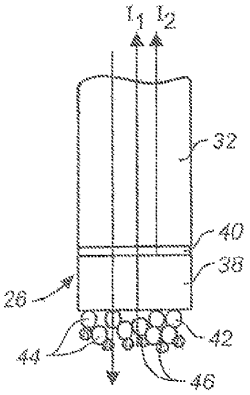


FIG. 2

The assembly 26 includes a transparent optical element 38 having first and second reflecting surfaces 42, 40 formed on its lower (distal) and upper (proximal) end faces, respectively. *Id.* at 7:18–20.

In addition to the embodiment in Figure 2, in which the optical assembly is fixedly attached to fiber 32, the '585 patent includes Figure 4, which shows an optical assembly 50 that is removably carried on the distal end of an optical fiber 52. *Id.* at 9:27–29.

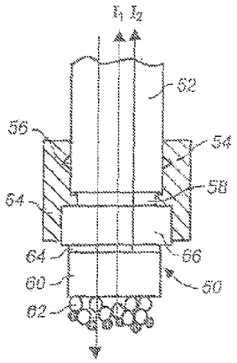


FIG. 4

The assembly includes a plurality of flexible gripping arms, such as arms 54, that are designed to slide over the end of the fiber and grip the fiber by engagement of an annular rim or detente 56 on the fiber with complementary-shaped recesses formed in the arms, as shown. This

[redacted]

attachment serves to position the optical assembly on the fiber to provide an air gap 58 between the distal end of the fiber and the confronting (upper) face of the assembly. *Id.* at 9:33–36.

The ’585 patent also includes Figure 5, which illustrates an optical assembly and fiber bundle in “an embodiment of the invention designed for detecting one or more of a plurality of analytes.” *Id.* at 10:5–7.

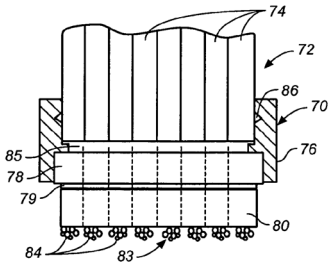


FIG. _5

’585 patent at Figure 5. A fiber bundle 72 is composed of an array of fibers 74. The optical assembly, indicated generally at 70, is composed of the basic optical elements described with respect to Figure 4, but in an array format. *Id*. at 10:10–14.

The ’585 patent thus discloses an embodiment in which the optical element is fixedly attached to the fiber (Figure 2) and embodiments in which the optical element is removably attached to the fiber (Figures 4 and 5). The parties do not assert that disclosure incorporated by reference into the ’887 patent limits how “mechanical coupling” should be construed in claim 8 of the ’887 patent. Gator Bio Br. at 36–40; Gator Bio Reply at 4–16; Sartorius Reply at 9–12. I conclude, based on the claim language and specification, that the claimed “mechanical coupling” is a component that engages the optical element with a fiber and provides an air gap between them. Importantly, claim 8 of the ’887 patent does not recite that the optical element is removably attached to the fiber via the mechanical coupling or otherwise. *See* ’887 patent, claim 8.

[redacted]

c) Prosecution of the ’887 Patent

As noted in the discussion of “air gap,” the applicant amended the claim that issued as patent claim 8 to include the “mechanical coupling” and distinguished the prior art on that basis. In doing so, the applicant specifically distinguished the prior art (Cunningham) based on the amended claim language, arguing that Cunningham did not “refer at all to an optical element coupled to a light source via a mechanical coupling that engages the first optical element with an optical fiber.” JX-0006 (’887 file history) at 225. The applicant also stated that Cunningham “does not disclose the coupling providing an air gap between the first optical element and the fiber.” *Id*. With respect to a secondary reference (Garini), the applicant stated, among other things, that Garini does not disclose “the air gap provided between the optical element and the fiber.” *Id*. at 228. The applicant did not state that the newly-claimed “mechanical coupling” rendered the optical element removable from the fiber. The prosecution history, therefore, does not change the construction of “mechanical coupling” in claim 8 as a component that engages the optical element with a fiber and provides an air gap between them.

d) The ’585 Patent IPR

As an initial matter, the parties dispute whether the record of the ’585 patent IPR should be considered in construing the “mechanical coupling” in claim 8 of the ’887 patent. Sartorius contends that “[a]s a matter of law, arguments made before the PTAB regarding an unrelated patent are irrelevant to this Investigation.” Sartorius Br. at 19. Gator Bio disagrees, noting that “the ’887 patent incorporates by reference the ’547 patent family (including the ’585 patent) for the specific purpose of describing the apparatus used in the claimed method.” Gator Bio Reply at 13. The Staff applies what it contends is the interpretation Sartorius argued “in the related IPR” when addressing

domestic industry and thus presumably believes that the ’585 patent IPR record can (and should) be considered. Staff Br. at 46.

The Federal Circuit recently reiterated that “[i]n the absence of an incorporation into the intrinsic evidence, this court’s precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not.” *Malvern Panalytical Inc. v. TA Instruments-Waters LLC*, 85 F.4th 1365, 1375 (Fed. Cir. 2023), *quoting Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004). The exception articulated in *Malvern* applies here; the subject matter of the ’585 patent was incorporated by reference into the specification of the ’887 patent. As a result, the “related [’585] patent [and] its prosecution history [are] available to construe the claims of [the ’887] patent.” *Malvern*, 85 F.4th at 1375.

(1) ’585 Patent IPR Proceedings

(a) ’585 Patent IPR Petition

Gator Bio filed the ’585 patent IPR petition, asking the PTAB to invalidate claims 1–19 of the ’585 patent. RX-0205. Claim 1 is the only independent claim and recites, “an optical element removably attached to the tip of the optical fiber and configured for receiving a beam of light from the optical fiber.” ’585 patent, claim 1. In asserting invalidity, Gator Bio relied on prior art to Yang (RX-0021), stating, among other things that Yang’s “probe includes an optical-fiber portion (shown in Fig. 1b) that is separate from the Y-shaped fiber, and the two fibers are connected via a ‘standard SMA905 connector,’ a common screw-type coupling with male and female components that removably engage one another.” RX-0205.0035; see also *id*. at 0044–0046, relying on Yang for disclosing “an optical element removably attached to the tip of the optical fiber and configured for receiving a beam of light from the optical fiber.” Gator Bio also relied on prior art to Sun (RX-

[redacted]

0023), stating that its "probe includes an 'optical fiber' portion (shown in Figure 1) that is separate from the Y-shaped optical fiber (shown in Figure 3), and these two fiber structures are connected by a 'standard SMA connector,' which again is a common screw-type mechanical coupling with male and female components that removably engage one another." *Id*. at 0061; *see also id*. at 0070–0073, relying on Sun for disclosing "an optical element removably attached to the tip of the optical fiber and configured for receiving a beam of light from the optical fiber."

(b) Arguments in the '585 Patent IPR

Sartorius's arguments in the '585 patent IPR centered on whether the prior art disclosed "an optical element removably attached to the tip of the optical fiber," as recited in claim 1. RX-0016.0050–0061 (Patent Owner Preliminary Response); *see also* '585 patent, claim 1. Sartorius stated: "All of the challenged claims recite 'an optical element removably attached to the tip of the optical fiber' . . . This claim element is not disclosed in any of the cited references." *Id*. at 0050.

Sartorius distinguished Figures 4 and 5 of the '585 patent, which it contended "depict and describe [a] removable optical element," from Figure 2, in which "the optical assembly is fixedly attached." *Id*. at 0050 and 0057. Sartorius also stated that "all of the cited references include standard cable connectors positioned mid-way down the length of the optical cable" and argued that "[w]hile such cable connectors allow the machine to be disassembled, they are not analogous to the claimed arrangement, requiring a removable optical element at the *tip* of the optical fiber." *Id*. at 0053 (emphasis in original).

As to Yang, Sartorius argued that Gator Bio had "not shown that the removability is located at the connection point between the fiber optical cable and the optical element, which the claims and specification specify is at the 'tip' of the optical fiber." *Id*. at 0055. Sartorius further argued that Gator Bio's "depiction of Yang with respect to [the removably attached optical element] does

not even attempt to demonstrate removability" and that a "Y-shaped optical fiber with an intermediate break down its length has five ends, but only one 'tip' to which the optical element may be attached." *Id*. at 0057. Sartorius compared Gator Bio's depiction of Yang's disclosure to that of its Figure 2, which it characterized as showing a fixedly attached optical element and stated was an unclaimed embodiment. *Id*.

Sartorius made similar arguments with respect to the primary reference Sun, contending that "Sun and Yang disclose nearly identical systems comprising a 'Y' shaped optical cable with a 'standard SMA connector'" and that "[f]or the same reasons, Sun does not disclose 'an optical element removably attached to the tip of the optical fiber.'" *Id*. at 0058. As it did with Yang, Sartorius argued that Gator Bio's depiction of Sun was like its Figure 2, which it again contended was an unclaimed embodiment. *Id*. at 0061.

In response, Gator Bio argued that its prior art combinations "teach 'an optical element removably attached to the tip of the optical fiber.'" RX-0018.0011–0013 (Petitioner's Preliminary Reply). And in its sur-reply, Sartorius reiterated its arguments that the prior art does not teach that element of '585 patent claim 1. RX-0019.0008–0010 (Patent Owner's Preliminary Sur-Reply).

(c) PTAB's Denial of Institution

The PTAB denied institution of the '585 patent IPR. RX-0213. In doing so, it recognized that the only dispute on the substance of the prior art was whether the "removable attachment limitation" was disclosed by Yang or Sun. *Id*. at 0016.[7] In particular, the PTAB concluded that Sartorius "advance[d] significant information that details how and why the disclosures in Yang

[7] The PTAB characterized the claim limitation "an optical element removably attached to the tip of the optical fiber and configured for receiving a beam of light from the optical fiber" in claim 1 of the '585 patent as "the removable attachment limitation." *Id*. at 0005–0006.

and Sun, upon which [Gator Bio] relies to make out the removable attachment limitation of the challenged claims, correspond to the unclaimed embodiment of Figure 2" in the '585 patent. *Id*. at 0021.

(2) Impact of the '585 Patent IPR on Construction of "Mechanical Coupling" in Claim 8 of the '887 Patent

(a) There Is No Prosecution Disclaimer Based on the '585 Patent IPR

Against this backdrop, I consider whether, based on its arguments in the '585 patent IPR, Sartorius "disclaimed or otherwise surrendered claim scope that comes within the claim language." *K-fee System*, 89 F.4th at 923. I conclude that there is no prosecution disclaimer from the '585 patent IPR that impacts the interpretation of "mechanical coupling" in '887 patent claim 8.

The primary focus of Sartorius's arguments in the '585 patent IPR was whether the prior art disclosed the claim element "an optical element removably attached to the tip of the optical fiber." RX-0016.0050–0061; and RX-0019.0008–0010. It is the reason institution of the IPR was denied. RX-0213.0021. That limitation is not part of claim 8 of the '887 patent. Instead, claim 8 recites "providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber." '887 patent, claim 8. There is nothing in that claim language or any other language of claim 8 that requires or suggests removability of the optical element through the mechanical coupling or otherwise. Nothing in the prosecution history of the '887 patent suggests otherwise.

Gator Bio contends that the '887 patent "uses the same claim language to set forth 'a mechanical coupling that engages [an] optical element with [an] optical fiber,'" comparing '887 patent claim 8 with '585 patent claims 13 and 18. Gator Bio Reply at 13. Gator Bio includes a

chart highlighting and comparing the language of claims 1, 13, and 18 of the ’585 patent with the language of claim 8 of the ’887 patent:

Patent	Claim Element	Claim Language
’887	[8A]	“an optical element coupled to a light source via **a mechanical coupling that engages the first optical element with a fiber**”
’585	[13]	“The assembly of claim 1, wherein said optical assembly is adapted for coupling to said light source through **a mechanical coupling that engages said optical element with said fiber**”
’585	[18]	“The assembly of claim 15, wherein said optical assembly is adapted for coupling to said light source through **a mechanical coupling that engages said second optical element with said fiber”**
’585	[1B]	“**an optical element removably attached to the tip of the optical fiber** and configured for receiving a beam of light from the optical fiber”

Gator Bio Reply Br. at 7. Gator Bio contends that the “main dispute in the IPR focused on the language of claims 1, 13, and 18 of the ’585 patent, which corresponds to the language of element [8A] of the ’887 patent.” *Id*. This is wrong. The main dispute, indeed, the only dispute, was the removable attachment limitation of ’585 patent claim 1. And the language of claim 8 of the ’887 patent does not “correspond” to the language of claims 1, 13, and 18 of the ’585 patent, as Gator Bio asserts.

Gator Bio’s argument completely ignores the removable attachment limitation of claim 1 of the ’585 patent, which was the focus of the ’585 patent IPR. While it is true that dependent claims 13 and 18 of the ’585 patent include language very similar to that of claim 8 of the ’887 patent, each of those dependent claims is modified by claim 1, which requires “an optical element removably attached to the tip of the optical fiber.” As a result, the mechanical coupling in claims 13 and 18 of the ’585 patent is subject to the removability requirement of claim 1, from which they both depend. In contrast, there is no removability requirement in claim 8 of the ’887 patent. This

[redacted]

fundamental difference in claim language refutes Gator Bio's argument that Sartorius's statements in the '585 patent IPR are applicable to '887 patent claim 8.

Gator Bio contends that "Sartorius clearly and unmistakably represented that an arrangement where the 'optical element' is merely a continuation of the 'optical fiber' corresponds to an 'unclaimed' embodiment shown in Figure 2." Gator Bio Reply at 8 (emphasis removed). Gator Bio asserts that "Sartorius differentiated this arrangement [Figure 2] from the claimed embodiment shown in Figure 4, where the optical element is removably attached or mechanically coupled to the optical fiber." *Id*., *citing* RX-0016.0051–61; *see also id*. stating that "according to Sartorius, the optical element in this arrangement [Figure 2] is not 'removably attached' or 'mechanically coupled' at the SMA connection but instead is 'adhered directly' to the tip of this one long optical fiber (i.e., the distal end of the optical-fiber probe)," *citing* RX-0016.0056–57 and 60–62. Gator Bio thus contends that in the '585 patent IPR Sartorius asserted that both the "removably attached" feature of '585 patent claim 1 and the "mechanical coupling" feature of claims 13 and 18 of the '585 patent were shown in Figure 4 but not in Figure 2 and provides its own annotated versions of Figures 2 and 4, showing what it contends Sartorius disclaimed:

***Unclaimed* Embodiment**

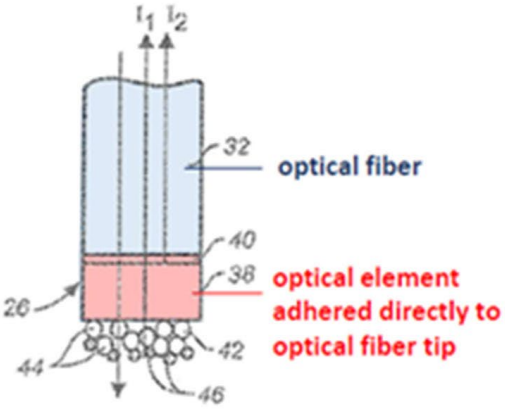


FIG. 2

***Claimed* Embodiment**

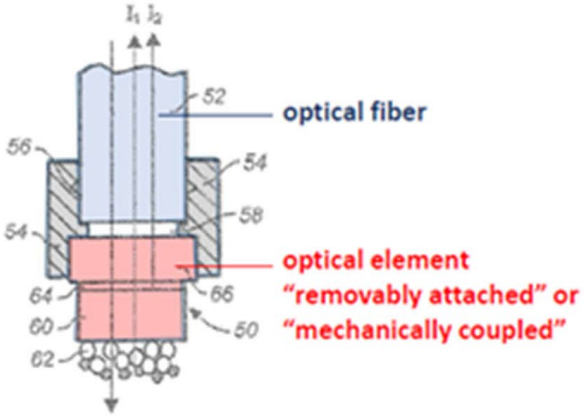


FIG. 4

[redacted]

Gator Bio Reply at 8.

In its arguments here, Gator Bio suggest that Sartorius equated removable attachment with mechanical coupling. Gator Bio Reply at 8 (arguing that "Sartorius differentiated this arrangement [Figure 2] from the claimed embodiment shown in Figure 4, where the optical element is removably attached or mechanically coupled to the optical fiber," *citing* RX-0016.0051–61). This is not true. Instead, as recognized by the PTAB itself, Sartorius's arguments focused on the "removably attached" requirement of claim 1. In arguing that claim element, Sartorius contended that the removability feature was not shown in the prior art or in its Figure 2. RX-0016.0050 ("All of the challenged claims recite 'an optical element removably attached to the tip of the optical fiber' . . . This claim element is not disclosed in any of the cited references"); 0052 ("The removability of the optical element allows for ready replacement with a fresh optical element"); 0053 ("The optical element, unlike the optical fiber, is removably attached to the distal end of the optical fiber"); 0054 (one of skill "reading Yang would have understood that the optical element is not removably attached to the tip of the optical fiber"); 0055 ("Petitioner has not shown that the removability [in Yang] is located at the connection point between the fiber optical cable and the optical element, which the claims and specification specify is at the 'tip' of the optical fiber"); 0057 ("This permanence [of the interference film in Yang] is similar to the first *unclaimed* embodiment in the '585 patent, depicted in Figure 2 . . . in which 'the optical assembly is fixedly attached'"); 0058 ("Sun does not incorporate a removable optical element attached to the distal end, or tip, of the optical fiber"); 0059 ("Sun also discloses that 'the *fiber optic probe end portion* is covered by a siliconization film,' referring to the optical element on the tip. . . These alleged optical elements on the 'end' or tip of the optical fiber in Sun are not removable"); 0059–60 ("the removable SMA connector in Sun is not located at the tip of the fiber optic cable, but rather part-

[redacted]

way down its length"); 0060 ("Even if the 'optical element' [of Sun] could be composed of optical fiber, the removability in Sun remains in the wrong location within the apparatus"); 0061 ("the siliconization film adhered directly to the tip of the optical fiber [in Sun is] similar to the first *unclaimed* embodiment depicted in Figure 2 of the '585 patent"); and RX-0019.0008–0010. Contrary to Gator Bio's argument, Sartorius did not argue the "mechanically coupled" feature of dependent claims 13 and 18 and instead focused on the removable attachment feature of claim 1.

In its only reference to claims 13 and 18, Sartorius stated:

> Because claims 1, 13, and 18 all unambiguously require a coupling between an optical fiber and an optical element, Petitioner is forced to contend that the portion of optical fiber running out the distal end of the SMA connector is, in fact, no longer optical fiber, but is instead the claimed "optical element" to which the optical fiber is coupled. This makes little sense; applicants understood the difference between the various optical components in their assembly, and the unique terms that identified them.

RX-0016.0056.

Gator Bio contends that by the above statement, Sartorius "made no distinction between claim 1" (which references a removable attachment) and "claims 13 and 18" (which reference a mechanical coupling), but instead treated those claims in an identical fashion. Gator Bio Reply at 15. Gator Bio reads far too much into this statement. First, claim 1 of the '585 patent does not "unambiguously require a coupling between an optical fiber and an optical element." Claim 1 recites an optical assembly comprising a number of components including an optical fiber having a tip and in which an optical element is "removably attached to the tip of the optical fiber." '585 patent, claim 1. Claim 13 recites that the optical assembly is adapted for coupling to a light source through "a mechanical coupling that engages said optical element with said fiber." *Id*. at claim 13. Claim 18 recites that "said optical assembly is adapted for coupling to said light source through a mechanical coupling that engages said second optical element with said fiber." *Id*. at claim 18. By

their own language, these claims recite different things: claim 1 recites an optical element removably attached to the tip of the optical fiber and claims 13 and 18 recite a mechanical coupling that engages said optical element or said second optical element with the optical fiber. Sartorius's arguments did not equate "removably attached" with the "mechanical coupling" and the claim language shows they are different.

In addition, Gator Bio repeatedly argues that through its statements in the '585 patent IPR, Sartorius established a "fiber-in-fiber-out rule" or "fiber-in-fiber-out arrangement" that it disclaimed. Gator Bio Br. at 36, 37, 39, 40, and 62; and Gator Bio Reply at 5, 9, 10, 11, 12, 14, 15, 16, 24, 26, 27, 54, 55, and 56. The Staff agrees. Staff Br. at 34–38 and 46–47. The crux of Gator Bio's argument is that because Sartorius distinguished the configurations of Yang and Sun (which it contends show a fiber-in-fiber-out arrangement) in the '585 patent IPR, that configuration cannot be covered by claim 8 of the '887 patent. *See* Gator Bio Br. at 37–38; and Gator Bio Reply at 8–13 and 54–55. Again, however, Sartorius's arguments in the '585 patent IPR focused on whether the prior art disclosed "an optical element removably attached to the tip of the optical fiber." They did not establish an overarching "rule" that a different claim of a different patent (claim 8 of the '887 patent), without that limitation, cannot cover a "fiber-in-fiber-out" arrangement.[8] Further, Sartorius did not argue that when fiber goes into and out of a connection, there is not "a mechanical coupling that engages said optical element with said fiber," as recited in '585 patent claim 13, or that there is not "a mechanical coupling that engages said second optical element with said fiber," as recited in '585 patent claim 18.

[8] That is not to say that the claim necessarily covers such a configuration; what the claim covers is considered elsewhere.

Gator Bio also highlights and bolds statements in the ’585 patent IPR arguing and finding that Figure 2 illustrates an unclaimed embodiment. Gator Bio Reply at 8, 9, and 12. Sartorius’s statements and the PTAB’s finding that Figure 2 shows an unclaimed embodiment, however, are irrelevant to ’887 patent claim 8, which does not contain the same limitation as claim 1 of the ’585 patent. Stated another way, while Sartorius may have disclaimed the Figure 2 embodiment from the ’585 patent claims because it shows an optical element that is not removably attached to the tip of the optical fiber, there is no such disclaimer from claim 8 of the ’887 patent, which does not recite a removable optical element.

There is simply no basis to attribute the arguments made in the’585 patent IPR to claim 8 of the ’887 patent and there is no basis to establish a “fiber-in-fiber-out rule” attributable to claim 8 of the ’887 patent based on the arguments Sartorius made in the ’585 patent IPR. The reason is simple: the claims are different, and Sartorius argued and the PTAB accepted that an element in ’585 patent claim 1, not present in ’887 patent claim 8, distinguished the prior art.

I therefore conclude that there is no prosecution disclaimer attributable to claim 8 of the ’887 patent based on the arguments in the ’585 patent IPR.

(b) There is No Claim Construction Applicable to the Claimed “Mechanical Coupling” in ’887 Patent Claim 8 Based on the ’585 Patent IPR

Gator Bio contends that I may “hold Sartorius to its IPR statements short of finding a prosecution disclaimer by applying general principles of claim construction.” Gator Bio Reply at 13. It is unclear what “general principle of claim construction” would suggest using arguments about a term that does not appear in claim 8 of the ’887 patent—an optical element is “removably attached to the tip of the optical fiber” in claim 1 of the ’585 patent—to construe that claim.

The cases Gator Bio relies on do not support that proposition. *See id*. In *Sequoia Technology, LLC v. Dell, Inc.*, the Federal Circuit reiterated that "statements made by a patent owner during an IPR proceeding, whether before or after an institution decision, can be considered for claim construction" and then considered the effect of IPR arguments on the same claim language. 66 F.4th 1317, 1327 (Fed. Cir. 2023). That is not the situation here, where the claim language addressed in the '585 patent IPR is different from the language of claim 8 of the '887 patent. In *Sandbox Logistics LLC v. Proppant Express Investments LLC*, the Federal Circuit affirmed the application of prosecution disclaimer during original prosecution with respect to the same claim element. 813 Fed. App'x 548, 556 (Fed. Cir. 2020). Again, that is not the situation here.

Gator Bio also relies on *DNA Genotek Inc. v. Spectrum Solutions LLC*, 2022 WL 17331255, No. 3:21-cv-00516 at *21 (S.D. Cal. Nov. 29, 2022) for the proposition that even when patents are unrelated, a patentee's IPR statements can be "highly persuasive extrinsic evidence," warranting a narrow construction. Gator Bio Reply at 12. There, the patentee in an IPR on a different patent stated, in distinguishing the asserted patent as prior art, that "the invention disclosed in [the asserted patent] was limited" in a certain way. *Id*. When the distinguished patent was asserted, the district court found the patentee's statements "highly relevant for claim construction purposes" and in combination with disclaimers in the specification of the asserted patent itself, used the IPR statements to construe the claims. *Id*. at *22. Nothing similar happened here. Sartorius did not take a position on the scope of claim 8 of the '887 patent in the '585 patent IPR. Instead, Sartorius took a position on different claims—those of the '585 patent—with a limitation wholly absent from '887 patent claim 8. Those statements are not relevant to the construction of "mechanical coupling" in '887 patent claim 8. In addition, while Sartorius stated that Figure 2 was an unclaimed

embodiment, that statement was made in the context of the '585 patent and the claimed removable attachment feature. There is no basis to port that statement over to the '887 patent claims, which do not include that feature.

For these reasons and the reasons explained above with respect to prosecution disclaimer, I conclude that the '585 patent IPR does not impact the construction of "mechanical coupling" in claim 8 of the '887 patent.

(c) There Is No Judicial Estoppel Based on the '585 Patent IPR

Gator Bio also contends that I "may hold Sartorius to its IPR statements by applying judicial estoppel." Gator Bio Reply at 12, *citing Alcohol Monitoring Sys., Inc. v. ActSoft, Inc.*, No. 07-cv-02261, 2011 WL 5075619 at *4 (D. Colo. Oct. 25, 2011). The factors considered in determining whether judicial estoppel applies are not met here. The first is that "a party's position must be clearly inconsistent with an earlier position taken." *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1380 (Fed. Cir. 2014); *see also New Hampshire v. Maine*, 532 U.S. 742 (2001). None of the statements Sartorius made during the '585 patent IPR purport to define "an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber," as recited in claim 8. Instead, they refer to "an optical element removably attached to the tip of the optical fiber and configured for receiving a beam of light from the optical fiber" of claim 1 of the '585 patent. As a result, Sartorius cannot be making an inconsistent argument that could trigger judicial estoppel.

VII. INFRINGEMENT

The complainant in a section 337 investigation bears the burden of proving infringement by a preponderance of the evidence. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331,

[redacted]

1349 (Fed. Cir. 2010). A finding of infringement requires "sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999).

By statute, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). Infringement of a method claim occurs when a party performs all steps of the claimed process. *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1333 (Fed. Cir. 2008); *see also Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014) (internal citations omitted). Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008).

"[A] violation of Section 337 may arise from an act of induced infringement." *Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1351 (Fed. Cir. 2015). Section 271(b) of the Patent Act states: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To prevail on a claim of induced infringement, in addition to inducement by the defendant, the patentee must also show that the asserted patent was directly infringed. *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002). "Section 271(b) covers active inducement of infringement, which typically includes acts that intentionally cause, urge, encourage, or aid another to directly infringe a patent." *Arris Group v. British Telecomms. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011). Liability for inducement requires proof that the party had "knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

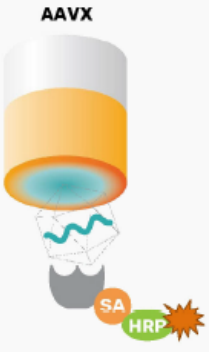
[redacted]

A. Because Gator Bio's AAVX Probe Cannot Be Used With HRP, It Is Not an Accused Probe

Sartorius does not accuse "non-HRP probes and kits," which are probes/kits that do not use horseradish peroxidase (HRP), Sartorius Statement Regarding the Scope of the Remedial Order, and the parties have stipulated that Sartorius "accuses only the following probes and kits of infringement of [the '887 patent]: Gator Bio's HS-AAV kit, HS-AAV9 kit, AAV Ratio kit, and AAVX probe." Stipulation on Importation, Sale, and Inventory, ¶ 4. Gator Bio and the Staff dispute that Gator Bio's AAVX probe can be used with HRP and thus dispute whether it should be identified as an accused probe. Gator Bio Reply at 34–36; and Staff Br. at 34, 40–41.

Sartorius contends that Gator Bio's AAVX probe uses HRP, Sartorius Br. at 13, relying on a Gator Bio presentation, CX-0132C, depicting a probe as "AAVX" and showing it binding a complex that includes HRP:

CRUDE SAMPLE TITER USING HIGH SENSITIVITY AAV KIT



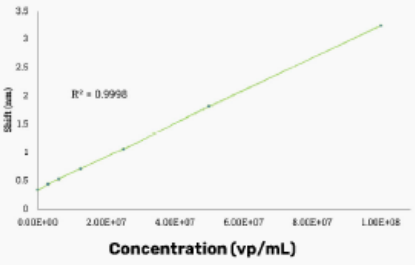


Figure 2. Standard curve for AAV5 generated using HS AAV probe.

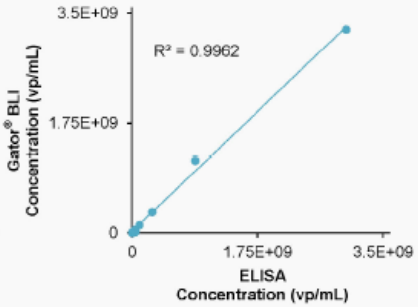


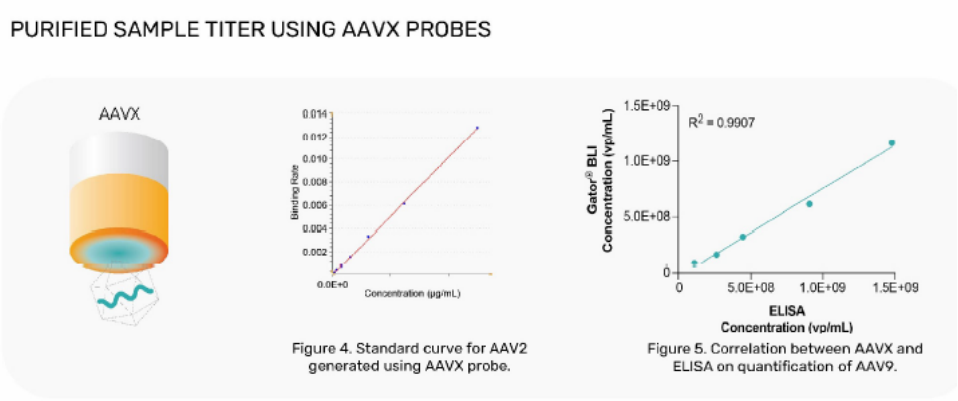
Figure 3. Correlation between HS AAV9 and ELISA on quantification of AAV9.

Titer	5.33E+07 of *AAV5*	1.00E+09 of *AAV8*
Matrix Interference	% Recovery	
HEK293T Lysate* (~100 mg/mL of intracellular proteins from 1E+08 cells/mL of HEK293T cell suspended in PBS, 1:10 dilution in buffer)	80.18%	115%
Cell Lysis Buffer (IX PBS, 100mM NaCl, 0.001% Pluronic)	96.31%	119%
Spent Media (DMEM media, 10% FBS, 2mM L-Glutamine)	84.08%	110%

Table 1. HS AAV Kit performance in different matrices.

CX-0132C.

Gator Bio contends that the labeling of the probe as AAVX in this portion of CX-0132C is a typographical error and contends that there are multiple reasons demonstrating that this is so. Gator Bio Reply at 34–36. As for the document itself, Gator Bio notes that while the probe is indeed labeled "AAVX," the section of the document is titled "Crude Sample Titer Using High Sensitivity AAV Kit" and that other portions of that section refer to an "HS AAV" probe or kit (not an AAVX probe). In addition, the section Sartorius relies on is directly above another section discussing the use of a stand-alone AAVX probe, which is shown binding AAV capsids without HRP:

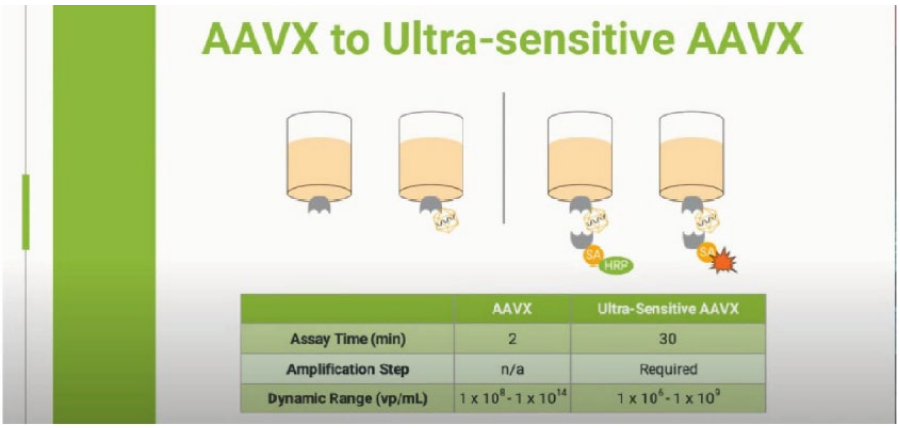


CX-0132C. In context, it is apparent that the section Sartorius relies on is about the HS-AAV probe/kit and not the standalone AAVX probe. I agree with Gator Bio that what Sartorius relies on is a typographical error.

Without addressing the substance of the document, Sartorius contends that Mr. Zuk's testimony, that it was a typographical error to label a probe used with HRP as AAVX, "lacks credibility, given [he] was shown these documents [sic, this document] at his deposition and yet failed to fix this error between then and his testimony at the hearing." Sartorius Br. at 30, *citing* Tr. (Zuk) at 477:23–478:8. Review of the entirety of the document itself, however, confirms that

there is a mistake in it, which Sartorius studiously avoids addressing. Further, on this point, I find Mr. Zuk's testimony credible as it confirms what is clear from reviewing the document itself.

Gator Bio presented additional persuasive evidence that in practice, its AAVX probe is not used with HRP, further confirming that the AAVX designation in CX-0132C is wrong. Mr. Zuk explained that Gator Bio's AAVX probes do not use HRP and are incompatible with HS-AAV assays using HRP. Tr. (Zuk) at 400:11–13 and 403:12–17. Gator Bio product literature for its HS-AAV kit (which the parties agree uses HRP) specifically states that it is "Not compatible with Gator® AAVX probe." RX-0218. In addition, Gator Bio played a portion of a presentation given by Mr. Zuk in May 2022, CPX-019, in which he compared Gator Bio's AAVX probe with a product it was developing, namely an ultra-sensitive AAVX probe, as show in the screen grab below:



	AAVX	Ultra-Sensitive AAVX
Assay Time (min)	2	30
Amplification Step	n/a	Required
Dynamic Range (vp/mL)	1×10^{8} - 1×10^{14}	1×10^{6} - 1×10^{9}

CX-0265.1; CPX-0019 at 10:32–12:19; and Tr. (Zuk) at 450:7–19. The left side in the above screen grab shows an AAVX probe as only binding an AAV capsid, and identifies the "amplification step" as "n/a." The right side shows an ultrasensitive probe, which uses HRP. *Id*. In addition, Sartorius's expert, Dr. Bailey, testified that Gator Bio's AAVX probes are not sold with HRP, are incompatible with the HS-AAV kit, and that he had no evidence of anyone using a standalone

AAVX probe with HRP. Tr. (Bailey) 687:13–688:5. This evidence is not addressed or disputed by Sartorius.

The evidence supports that Gator Bio's AAVX probe is not and cannot be used with HRP. As a result, because Sartorius only asserts infringement with respect to Gator Bio's probes that use HRP, the evidence supports that Gator Bio's AAVX probe is not an accused probe.

B. Use of the GatorPrime Instrument With Gator Bio's HRP Probes/Kits Does Not Infringe Claim 8

I consider next whether use of the GatorPrime instrument, which the parties have agreed is representative of the accused instruments, with any of Gator Bio's HRP probes/kits practices claim 8. Stipulation on Importation, Sale, and Inventory, ¶ 3. As detailed below, the record demonstrates that such use does not infringe claim 8. For ease of reference, claim 8 is reproduced below with corresponding claim element designations, which unless otherwise indicated, I use below:

'887 Patent: Breakdown of Claim 8

Element	Claim Language
[8Pre]	A method for assaying enzyme activity, comprising:
[8A]	providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber and
[8B]	provides an air gap between the first optical element and the fiber,
[8C]	the optical element including (a) a proximal reflecting surface and a distal reflecting surface
[8D]	separated by at least 50 nm, and
[8E]	(b) a layer of analyte binding molecules;
[8F]	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,
[8G]	the reflected beams coupled into the fiber; and
[8H]	detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity.

RDX-0006C.18.

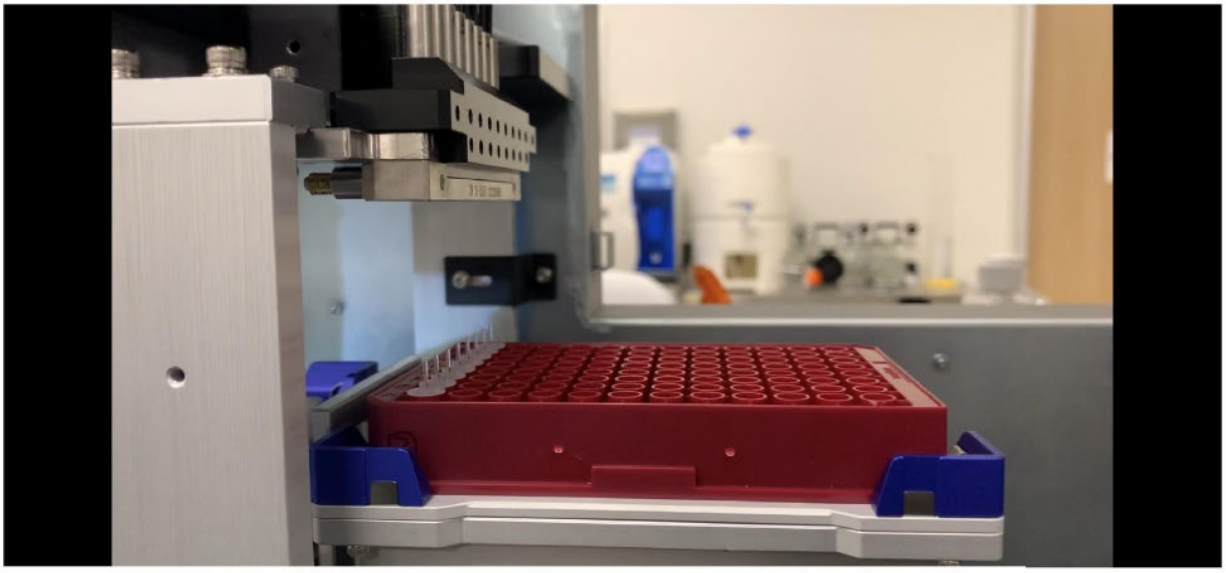
1. Element [8pre]

Claim 8 recites "a method for assaying enzyme activity." Because the analysis of element [8pre] is related to the analysis of element [8H], I address the preamble with element [8H].

2. Element [8A]

Claim 8 recites "providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber." '887 patent, claim 8. Sartorius contends that the GatorPrime when used with an optical element (probe) meets this claim element. Sartorius Br. at 14–21.

The evidence shows that the GatorPrime has a light source. Tr. (Bailey) at 593:20–594:2; and CX-0285C.22. The evidence also shows that Gator Bio's probes are an optical element comprised of optical fiber with an optical layer with two reflective surfaces, [redacted]. Tr. (Zuk) at 440:3–442:4; and CX-0642C (Tan Dep.) at 118:5–119:4. Those probes are used with the GatorPrime instrument, as shown below:

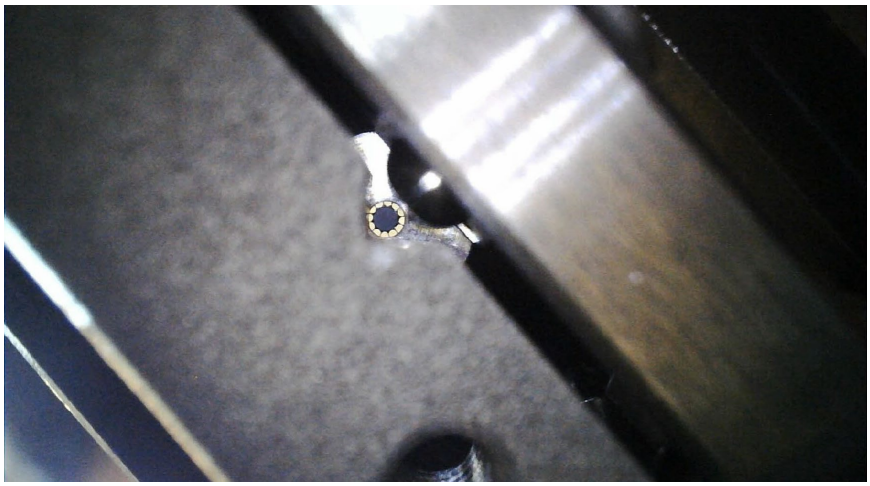


RX-0001.

The above photo shows the inside of a GatorPrime instrument. Tr. (Tan) at 299:17–20. Dr. Tan, the founder of Gator Bio, testified about the interaction between the GatorPrime instrument when loaded with probes. He testified that the probes are placed in a 96-well plate (in red above), which is on a motorized stage, and which in operation moves the plate up so the probes are in what is called the "picker position." *Id*. at 299:21–300:4. The picker has V-grooves, each having a [redacted] the probe into position so that it is in contact with the fiber. *Id*. at 300:5–9. Mr. Tan testified that the probe and fiber "are in physical contact" and that the stage is [redacted] "to make sure all the probes will contact and push against the bottom of these ferrules" (i.e., the bottom of the fiber bundle). *Id*. at 300:9–24.

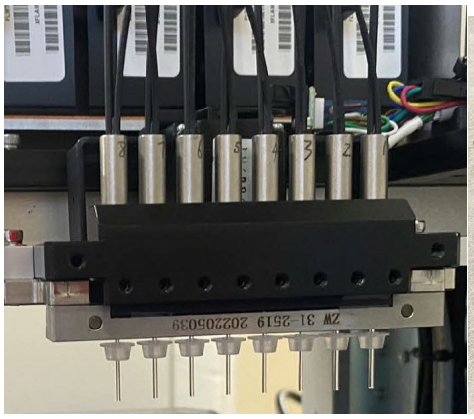
Dr. Bailey also testified that the optical fiber engages the V-groove in the instrument, as shown below:

[redacted]



Tr. (Bailey) at 596:8–15; and CX-0285C.71.

The photo below on the left shows in black what Gator Bio refers to as its picker. The optical fibers (connected to a light source) come down into the picker and the probes come up into the picker. CX-0285C.24; and Tr. (Bailey) at 666:7–667:2. The photo below on the right shows the internal components of the picker. CX-0285C.73; and Tr. (Bailey) at 667:2–9.



Dr. Bailey testified that when a probe is lifted into its vertical position, a [redacted], horizontally engaging the probe and locking it into the V-groove, creating spatial alignment between the probe and fiber to ensure an efficient path for optical transmission of light from the lamp in the instrument. Tr. (Bailey) at 598:2–19.

The evidence thus shows that Gator Bio's optical element (probe) is coupled to a light source via a mechanical coupling that engages the optical element with a fiber in the instrument.

Gator Bio disputes that there is a mechanical coupling that engages its probe with a fiber of the GatorPrime instrument. Gator Bio Reply at 24–27. So does the Staff. Staff Br. at 34–38. Gator Bio and the Staff's arguments center on their position that Gator Bio's probes are like the prior art probes that Sartorius distinguished in the '585 patent IPR and that the "fiber-in-fiber-out rule" supposedly established in that IPR precludes Sartorius from asserting that this claim element is met. As discussed above, I reject Gator Bio and the Staff's arguments based on the '585 patent IPR because the '585 patent claims were distinguished from the prior art on a basis that does not apply to claim 8 of the '887 patent. There is no estoppel or claim construction from the '585 patent IPR that is applicable to claim 8. There is, therefore, nothing from the'585 patent IPR that precludes or limits Sartorius's assertion that the GatorPrime instrument used with a Gator Bio accused probe/kit meets this claim element.

Neither Gator Bio nor the Staff raise any other arguments disputing this claim element. The evidence supports that the use of the GatorPrime instrument with Gator Bio's HRP probes/kits meets element [8A].

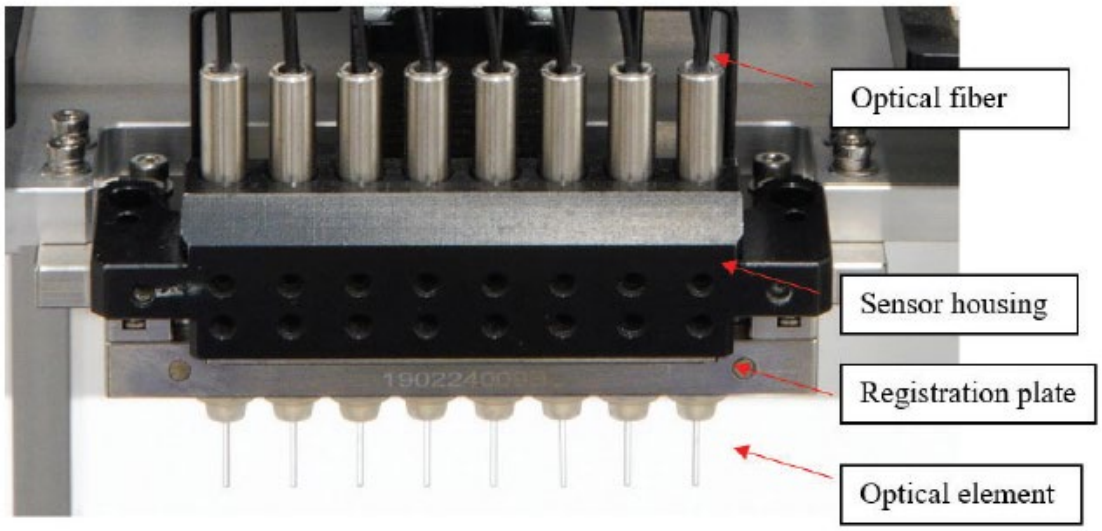
3. Element [8B]

Claim 8 recites that the mechanical coupling "provides an air gap between the first optical element and the fiber." '887 patent, claim 8. There are two versions of Gator Bio's fiber bundle relevant to this issue, which Sartorius respectively calls the first redesign and the second redesign. Sartorius contends both of Gator Bio's first and second redesign meet this claim element. Sartorius Br. at 21–30. Gator Bio disputes that both its first redesign and second redesign have a mechanical

coupling that provides an air gap between its optical element and the fiber. Gator Bio Reply at 27–34. The Staff agrees with Gator Bio. Staff Br. at 33–39.

As detailed above, I have construed "air gap" to mean a "designed separation." *See* section VI.C.1. As explained in more detail below, I conclude that when a probe is used with the GatorPrime instrument with the first redesign fiber bundle, there is an air gap between the optical element and the fiber, while when a probe is used with the GatorPrime instrument with the second redesign fiber bundle, there is not.

Sartorius initially identified a registration plate in the GatorPrime instrument and asserted that "the GatorPrime's optical fiber and first optical element are separated by the registration plate," as shown below:



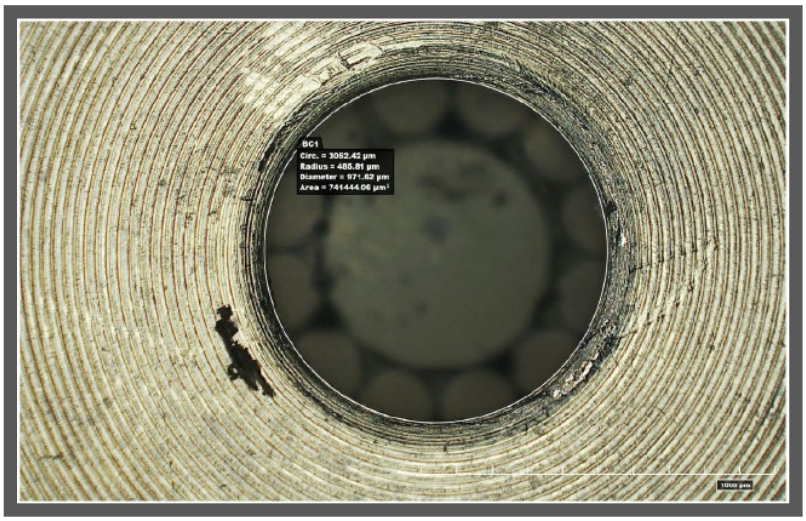
Complaint Ex. 052, '887 patent claim chart at 2.

Following a motion by Gator Bio, the Commission entered a Consent Order directed to Gator Bio instruments including a registration plate. Sartorius now accuses Gator Bio instruments without a registration plate. According to Sartorius, those instruments include a fiber bundle, which it calls the first redesign, with a recess in the fiber bundle that creates an air gap between

the fiber and the optical element (probe) when the probe is attached to the instrument. Tr. (Tan) at 305:1–5. In response, Gator Bio contends that in around February 2023 it implemented an updated fiber bundle, referred to as the second redesign, which eliminated any such recess. Gator Bio Br. at 18, *citing* Tr. (Tan) at 305:10–307:15. Each is considered below.

a) Gator Bio's First Redesign

In Gator Bio's first redesign, the fiber is surrounded by a metal cladding, also called a metal casing, as shown below:



CX-0284C.18.

Optical microscopy showed that the average diameter of the casing is 980±6 µm (micrometers). Tr. (Bailey) at 603:25–605:19. Dr. Bailey testified that the consistency in this measurement across a number of fibers supports that the diameter of the metal casing is an intentional design feature and not a manufacturing defect. *Id.* at 605:20–22. Dr. Bailey also performed micrometer caliper measurements on Gator Bio's APS and AR probes, finding an average diameter of them to be 999±2 µm and 1000±3 µm, respectively. Tr. (Bailey) at 605:24–606:16. The charts below show Dr. Bailey's measurements:

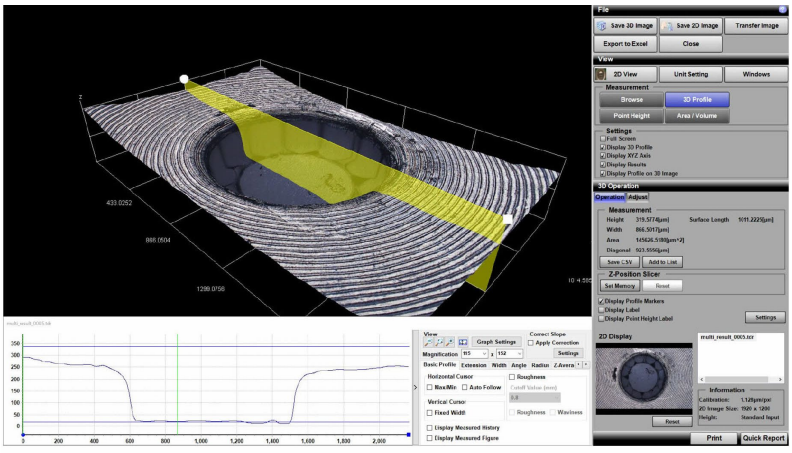
[redacted]

Opening of Metal Casing (optical microscopy)	
Replicate	Diameter (µm)
1	972
2	973
3	980
4	989
5	987
6	978
7	985
8	976
Average	**980**
SD	**6**

Diameter of Probes (caliper) (µm)		
Replicate	APS Probe	AR Probe
1	999	995
2	998	1001
3	999	1000
4	999	1005
5	995	999
6	998	1000
7	1000	1001
8	1000	998
9	997	1002
10	1000	1002
Average	**999**	**1000**
SD	**2**	**3**

CX-0286C.3 and CX-0286C.2. Based on Dr. Bailey's measurements, Gator Bio's probes cannot fit within the opening in the metal casing. Tr. (Bailey) at 606:18–24 and 608:16–20 (testifying that the optical element (probe) cannot fit within the metal casing and must rest on top of it).

Dr. Bailey performed profilometry measurements on Gator Bio's first redesign fiber bundle, revealing a depression at its tip with an average depth of 204±9 µm. Tr. (Bailey) at 606:25–608:23. That is, the optical fiber is not flush with its metal casing. This depression is shown below on the left and Dr. Bailey's profilometry measurements are shown below on the right:



Depth of recess (micrometers) (via profilometry)
201
199
198
206
209
197
199
225
204
9

CX-0279C.20; and CX-0286C.03. The evidence thus supports that the first redesign fiber bundle is structured so that there is a depression in the fiber bundle, in that the optical fiber is inset relative to the metal casing. Tr. (Bailey) 603:25–604:8.

The evidence supports that because the probe cannot fit within the metal casing, and because there is a depression in the metal casing such that the optical fiber is inset within it, when the probe contacts the fiber bundle, there is an air gap with a depth of 204±9 μm between the optical element and the optical fiber. Tr. (Bailey) at 608:21–23.

Gator Bio argues that "[t]he alleged recess in the First Redesign . . . [is] neither designed nor controlled" and that any recess in its first redesign fiber bundle is an undesigned "manufacturing defect." Gator Bio Reply at 28, *citing* Tr. (Tan) 305:6–9 (Gator Bio has no specification identifying a recess) and 306:1–17 (the recess is "probably the manufacturing defect"). Dr. Tan's self-interested testimony and the lack of a design specification, however, are outweighed by Dr. Bailey's consistent measurements demonstrating that: (1) Gator Bio's probes do not fit within the metal casing; and (2) there is a spacing between the metal casing and the fiber. Collectively, these result in an air gap when the probe is put in contact with the fiber bundle.

Gator Bio next argues that Sartorius has not shown that in its first redesign, a mechanical coupling provides the air gap, as claimed. Gator Bio Reply at 33–34. Sartorius contends that the picker in the GatorPrime instrument is the mechanical coupling that provides the claimed air gap. Sartorius Br. at 21. Dr. Bailey testified that the probes would fall out of the instrument without being connected via the picker, and that there would then be no air gap between the fiber and the optical element. Tr. (Bailey) 598:11–19 ("The fact that the probes stay mechanically coupled or stay loaded and do not fall back down to gravity confirms that they are in fact mechanically coupled in the instrument").

Gator Bio first contends that Sartorius waived any argument that the picker in the GatorPrime instrument provides an air gap between the fiber and the probe. Gator Bio Reply at 33. Sartorius argued in its pre-hearing brief that there is an air gap between the Gator Bio probe and fiber and that the picker in the instrument puts the probe in place relative to the fiber. Sartorius Pre-Hearing Br. at 327, referencing 222–226. I therefore disagree that this issue was waived.

Gator Bio next contends that "[t]o be sure, the picker holds the fiber probes in position," but "the picker does not 'provide' any alleged recess," "which would exist independently of the picker." Gator Bio Reply at 33. While it is true that the depression in the metal casing such that the optical fiber is inset relative to the metal casing exists independently of the picker, the evidence, as detailed above, shows that it is the picker that aligns and maintains the fiber with the probe and thus provides the air gap between the fiber and probe, as claimed.

The evidence supports that the use of the GatorPrime instrument with the first redesign fiber bundle and with Gator Bio's HRP probes/kits meets element [8B].

b) Gator Bio's Second Redesign

Sartorius contends that Gator Bio's second redesign fiber bundle used in conjunction with a probe satisfies this claim element, which again, recites that the mechanical coupling "provides an air gap between the first optical element and the fiber." '887 patent, claim 8. Sartorius Br. at 24–30. Gator Bio contests that this limitation is met, Gator Bio Reply at 27–34, as does the Staff, Staff Br. at 38–39.

As recognized by Sartorius, Gator Bio's second redesign fiber bundle does not have a metal casing at its end, as does its first redesign. Sartorius Br. at 24, *citing* Tr. (Bailey) at 609:6–9. Nevertheless, Dr. Bailey performed profilometry measurements, which he opined show a recess (i.e., a depression) in the middle of the fiber, as shown below on the left:

[redacted]

CX-0282C.2 and CX-0286C.4.

Dr. Bailey measured the depth of this recess and determined that it had an average depth of 1.78±0.33 µm, as shown above on the right. As he did with respect to the first redesign, Dr. Bailey measured the diameter of the fiber of the second redesign and determined that the average diameter is 1146±2 µm. Tr. (Bailey) at 609:18–25; and CX-0286C.4. That diameter is greater than the average diameter of Gator Bio's representative probes, which, as noted previously, Dr. Bailey determined is 999±2 µm and 1000±3 µm, respectively. Tr. (Bailey) at 605:24–606:16; and CX-0286C.2. Dr. Bailey's measurements thus revealed that, unlike the first redesign, the diameter of the probe is smaller than the diameter of the recess in the optical fiber by about 146 µm. Gator Bio Reply at 29–30.

Gator Bio contends that in its second redesign, the probe and the optical fiber are in physical contact. *Id*. Dr. Tan testified that the probe and the fiber in the second redesign are in physical contact when the probe interfaces with the fiber. Tr. (Tan) at 307:9–15. Dr. Schaafsma testified that, based on Dr. Bailey's measurements, the probe and fiber are in physical contact. Tr.

[redacted]

(Schaafsma) at 910:17–912:10. Dr. Bailey agreed that given the larger diameter of the recess, the probe could fit within the recess in the fiber. Tr. (Bailey) at 672:10–14.

Sartorius argues that it is unlikely that the probe would actually be disposed within the recess because the diameter of the recess is only slightly larger than that of the probe, thus requiring near-perfect alignment. Sartorius Br. at 25, *citing* Tr. (Bailey) at 611:10–18. Sartorius, however, presented no evidence showing such misalignment in practice. And Dr. Tan testified that it is important to precisely place the fiber and probe and that Gator Bio does so through the V-groove of its picker. Tr. (Tan) at 374:16–375:7. Dr. Kang testified that one of the things Gator Bio customers care about is precision. Tr. (Kang) 170:2–5. Based on the record evidence, I agree that in Gator Bio's second redesign, the fiber and the probe are in physical contact when the probe is loaded into the instrument.

Sartorius nevertheless contends that Dr. Bailey measured "an air gap in the Second Redesign based on surface roughness." Sartorius Br. at 24. In particular, Sartorius contends that "[e]ven if perfectly aligned within the recess, there would still be spaces between the surface of the fiber and the probe in which air could reside—signifying an air gap." Sartorius Br. at 25.

Dr. Bailey's optical microscopy measurements demonstrated an average roughness of the optical fiber of 145±28.2 nm (nanometers), as shown below:

[redacted]

Roughness of fiber bundle within recess (nanometers)

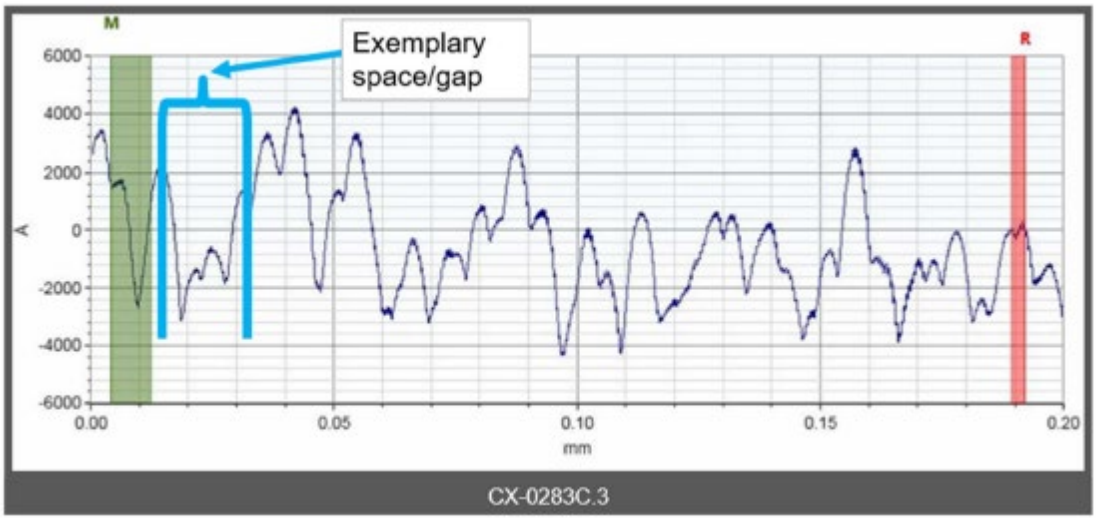
(via profilometry)

Ra	Rq	Rt
144.1	177.0	855.0
129.9	157.1	722.4
100.5	135.2	769.9
151.1	195.6	1115.3
127.1	157.2	777.9
178.2	266.9	1560.2
140.3	179.1	1033.9
188.5	229.2	1097.4
145.0	**187.2**	**991.5**
28.2	**42.9**	**277.1**

Key:
Ra: Average surface roughness
Rq: Root-mean-squared surface roughness
Rt: Maximum difference in height within sample

CX-0286.4. As a point of comparison, because 1 micrometer equals 1000 nanometers, using the same scale Sartorius used when detailing its measurements of the first redesign, while the first redesign has an air gap averaging 204±9 µm, Sartorius contends that the second redesign has an air gap created by surface roughness averaging .145±.0282 µm, more than fourteen hundred times smaller.

Dr. Bailey showed what he opined was an air gap with a profilometer trace:



[redacted]

Sartorius Br. at 27; and CX-0283C.3. Overlaid on Dr. Bailey's measurements, Sartorius identifies with a blue bracket what it contends is an exemplary air gap in Gator Bio's second redesign caused by surface roughness. CX-0283C.3.

In essence, Sartorius argues that because some air may come between the probe and the fiber due to surface roughness of the fiber, the claimed air gap element is met. I disagree. As discussed above, the claimed air gap is a designed separation between the fiber and the probe. Sartorius presented no evidence that a spacing that may result in air between the second redesign fiber bundle and the probe because of surface roughness of the fiber is a designed separation. And although the parties addressed the construction of "air gap" in their post-hearing briefs, Sartorius makes no cogent argument that Gator Bio's second redesign includes an air gap as that term was construed by either Gator Bio or the Staff. Sartorius Br. at 21–30. And while I did not completely adopt either of the constructions advanced by Gator Bio or the Staff, Gator Bio argued that the claimed air gap is a "controlled spacing," which it equated with a designed separation, and the Staff argued that it was a "designed separation." Gator Bio Br. at 40–42; and Staff Br. at 31–33. Sartorius does not argue or present any evidence that a space for air created by surface roughness is either a controlled spacing or a designed separation. And the evidence demonstrates it is not. As Gator Bio demonstrated at the hearing, surface roughness is present on virtually all materials. Tr. (Schaafsma) at 915:17–25. Such unavoidable and undesigned imperfections cannot be the claimed air gap.

Sartorius argues that "there would still be spaces between the surface of the fiber and the probe in which air could reside—signifying an air gap." Sartorius Br. at 25, *citing* Tr. (Bailey) 614:18–615:5. However, Dr. Bailey provided no explanation of how any such space caused by surface roughness is a controlled or designed separation.

[redacted]

Sartorius argues that Gator Bio could have eliminated the surface roughness to avoid infringement. Sartorius Br. at 29, *citing* RX-0041 (Qian) at 1. This, however, is irrelevant because the claimed air gap is an affirmative element of the claim that Sartorius must show is present, not something that Gator Bio must prove it designed out of its products by eliminating all surface roughness. Nonetheless, in support of its argument, Sartorius cites Qian, a reference addressing the immobilization of antibodies on ultraflat polystyrene surfaces. Sartorius Br. at 29; and RX-0041 (Qian) at 1. Sartorius does not address any potential differences between polystyrene and the optical fiber used in the second redesign and thus does not demonstrate how Qian is relevant to this issue.

Sartorius further cites the testimony of Dr. Sailor:

> So if you look at the specification, you know, a POSA would be able to make and use the invention recited in Claim 8 without undue experimentation. A POSA would understand that surface roughness can contribute to an air gap. That you could control surface roughness with polishing techniques. At that time you could do fling polishing [sic] or laser polishing to get surfaces, you know, atomically flat.

Sartorius Br. at 30; and Tr. (Sailor) at 1121:17–24.

Again, this testimony is irrelevant because it does not support (and in fact refutes) that an air space caused by surface roughness is a designed separation. In addition, Dr. Sailor's testimony was contradicted by Dr. Schaafsma, who testified:

> Q. Based on your experience, Doctor, working with optical systems, did people skilled in the art look at nanoscale surface roughness of fiber end faces to determine whether there was an air gap?
>
> A. I have never heard of such a thing before.
>
> Q. In your opinion, is looking to nanoscale surface roughness consistent with how a person of ordinary skill in the art would have understood and applied the air gap limitation in Claim 8 of the '887 Patent?

[redacted]

A. It is absolutely not. There is no way to control nanoscale surface roughness, so it could not possibly be a designed element in a system like this.

. . .

A. It couldn't be designed out, either.

. . .

Q. Can you tell us whether the nanoscale surface roughness that Dr. Bailey claims to have measured and says is an air gap is consistent with what the specification says is an air gap?

A. Yeah, I can. The specification describes a structure that has numeric values associated with it, it is a controlled feature of the design, and it has a particular function. There's an optical function that's ascribed to it.

As I've said, I think a POSA would understand this, and would understand the purpose of it and how to design it.

I think that they would not consider that nanoscale surface roughness qualifies under this description, nor is it described anywhere in the patent, this nanoscale surface roughness.

Tr. (Schaafsma) at 907:22–914:1. Based on the testimony at the hearing, I find Dr. Schaafsma's opinion more credible regarding whether one of ordinary skill of the art would have considered spaces containing air caused by the surface roughness as the claimed air gap. Dr. Sailor does not explain why one of ordinary skill in the art would take surface roughness into account to determine whether there is an air gap. And Sartorius has not demonstrated such an understanding among those of ordinary skill in the art. Moreover, the evidence supports that if nanoscale surface roughness caused the claimed air gap, then: (1) it could not be controlled; (2) vibration, temperature, and humidity, among other conditions, could cause the claimed air gap to appear and disappear; and (3) it may be impossible to avoid. Tr. (Schaafsma) at 915:17–917:15. As a designed separation, the claimed air gap cannot be so transitory and inconsistent.

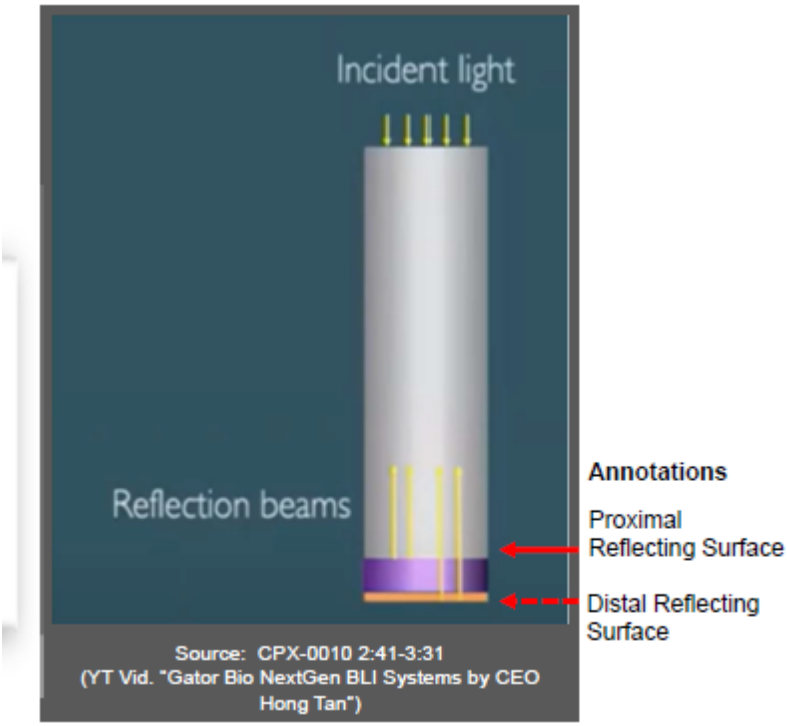
Finally, Sartorius argues that Gator Bio could have filled the air spaces created by surface roughness with an index-matching liquid to avoid having the claimed air gap. *See* Sartorius Br. at 30. As an initial matter, Sartorius failed to raise this argument in its pre-hearing brief and thus waived it. *See* Sartorius Pre-Hearing Br. at 327. Even if it was not waived, Sartorius's argument fails for the same reason its other arguments fail. A designed separation is not created by the lack of an index-matching liquid addressing surface roughness.

The evidence supports that the use of the GatorPrime instrument with the second redesign fiber bundle and with Gator Bio's HRP probes/kits does not meet element [8B].

4. Element [8C] and Element [8D]

Claim 8 recites "the optical element including (a) a proximal reflecting surface and a distal reflecting surface separated by at least 50 nm." '887 patent, claim 8. Sartorius contends that this claim element is met. Sartorius Br. at 18–19. Neither Gator Bio nor the Staff dispute that this limitation is met. *See* Gator Bio Reply at 23–48; and Staff Br. at 33–41. Dr. Bailey testified that in the Gator Bio probes, the proximal reflecting surface is defined by a refractive index contrast between the fiber-optic component of the optical element and the optical layer and that the distal reflecting surface is created at the interface between the surface chemistry at the tip of the optical element and the sample into which the optical element is dipped. Tr. (Bailey) at 615:22–616:6. This is illustrated below:

[redacted]



CDX-0001C.41; CPX-0010 at 2:41–3:31.

Depending on the probe, the proximal and distal reflecting surfaces are separated by either: [redacted]-0134C.2; CX-0135C.2; Tr. (Bailey) at 616:19–617:13; Tr. (Zuk) at 441:15–442:1; and CX-0642C (Tan Dep.) at 118:19–119:4. Because these separations are greater than 50nm, the evidence supports that the use of the GatorPrime instrument with Gator Bio's HRP probes/kits meets element [8C] and element [8D].

5. Element [8E]

Claim 8 recites that the optical element includes "(b) a layer of analyte binding molecules." '887 patent, claim 8. Sartorius contends that this limitation is met. Sartorius Br. at 19. Neither Gator Bio nor the Staff dispute that this limitation is met. *See* Gator Bio Reply at 23–48; and Staff Br. at 33–41.

Dr. Bailey testified that Gator Bio's HRP probes include a layer of surface chemistry that includes "a layer of analyte binding molecules," which varies based on the probe. Tr. (Bailey) 618:4–25. In particular, Gator Bio's HS-AAV kit and HS-AAV9 kit use a CaptureSelect anti-AAVX antibody, while Gator Bio's AAV Ratio kit uses "an immobilized DNA binding protein," as an analyte binding molecule. Tr. (Zuk) at 417:11–18 and 420:10–21. The evidence thus supports that the use of the GatorPrime instrument with Gator Bio's HRP probes/kits meets element [8E].

6. Element [8F]

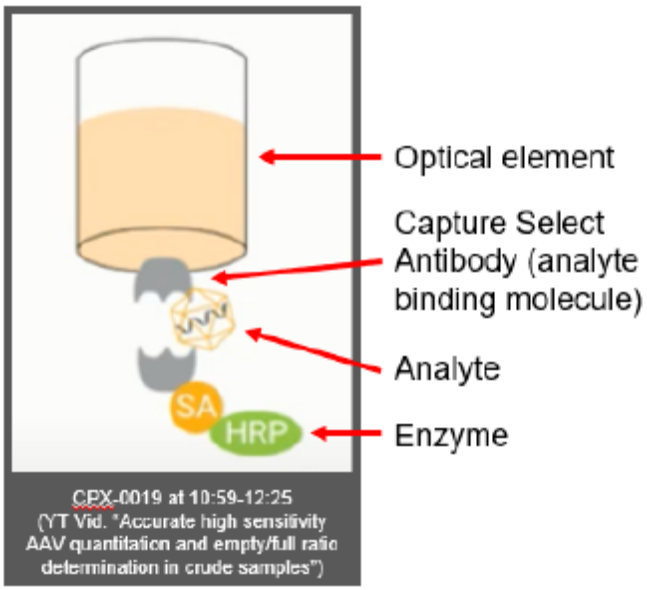
Claim 8 recites "exposing the optical element to an enzyme substrate reacted or reacting with an enzyme, whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules, and wherein interference between a reflected beam from the proximal reflecting surface and a reflected beam from the distal reflecting surface varies as the enzyme substrate or portion thereof binds to the layer of analyte binding molecules." '887 patent, claim 8; and Comm'n Op. at 19 (Aug. 24, 2023). Because the parties address portions of this claim element separately, I do as well.

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

The first portion of element [8F] recites, "exposing the optical element to an enzyme substrate reacted or reacting with an enzyme." Sartorius contends this limitation is met. Sartorius Br. at 30–36. Gator Bio disputes that this element is met. Gator Bio Reply at 38–41. The Staff does not specifically address this portion of element [8F]. Staff Br. at 33–41.

As noted with respect to element [8E], the evidence shows that Gator Bio's HRP probes/kits are coated with a layer of analyte binding molecules, such as a CaptureSelect anti-AAVX

antibodies.[9] Tr. (Bailey) at 617:24–618:25 and 620:17–19; and Tr. (Forrest) at 1067:22–1068:7. As shown below, the probe with a layer of CaptureSelect anti-AAVX antibodies (shown in grey) is dipped into a sample that may contain an AAV capsid (identified as the analyte). If present, the AAV capsid binds to the CaptureSelect antibodies. Tr. (Bailey) at 617:24–618:25 and 620:17–19; CPX-0019 at 10:59–12:25; and Tr. (Forrest) at 1067:22–1068:11 (the probe "is first exposed to a sample to capture free AAV capsids").



Sartorius Br. at 31; and CPX-0019 at 10:59–12:25 (annotations added).

Additional detection reagents are then exposed to the tip of the probe. Tr. (Bailey) at 620:17–24. This includes a second detection antibody, streptavidin, (identified as SA, above) linked to the enzyme HRP, such that the streptavidin binds to the AAV capsid. *Id*. at 620:25–621:1

[9] As noted with respect to element [8E], Gator Bio's HS-AAV kit and HS-AAV9 kit use a CaptureSelect anti-AAVX antibody, while Gator Bio's AAV Ratio kit uses "an immobilized DNA binding protein," as an analyte binding molecule. Tr. (Zuk) at 417:11–18 and 420:10–21. Because the parties' arguments focus on CaptureSelect, and do not include separate arguments with respect to the immobilized DNA binding protein used in Gator Bio's AAV Ratio kit, I have assumed that they operate the same.

[redacted]

and 622:4–15; *see also id.* at 682:15–20; and Tr. (Forrest) at 1068:15–24. Once this complex is formed, the probe is exposed to a "substrate solution" containing chloronaphthol, Tr. (Forrest) 1068:25–1069:5, "and the enzyme activity is monitored," Tr. (Zuk) at 450:20–22; *see also* Tr. (Bailey) at 624:16–625:1. When the probe is dipped into the chloronaphthol substrate, the HRP will react with the chloronaphthol. Tr. (Forrest) 1067:7–1069:13 ("when exposed to the chloro-naphthol, the HRP bound to the probe oxidizes hydrogen peroxide and chloro-naphthol, which causes the chloro-naphthol to precipitate out of the solution"); *see also* Tr. (Bailey) at 621:15–623:10; and Tr. (Zuk) at 450:20–451:3.

Gator Bio's dispute about this portion of element [8F] relates to the location of the enzyme (HRP) when the probe is exposed to the chloronaphthol. In its HRP probes, the HRP enzyme is already on the probe when it is exposed to the chloronaphthol substrate. According to Gator Bio, claim 8 requires that the enzyme is already reacting with the enzyme substrate before the enzyme substrate is exposed to the probe. Because the HRP is not already reacting or has not already reacted with the chloronaphthol substrate when the probe is exposed to the substrate, Gator Bio contends that it does not practice the step of "exposing the optical element at an enzyme substrate *reacted or reacting with an enzyme*." Gator Bio Reply at 39. Sartorius, in contrast, contends that claim 8 does not preclude the enzyme from already being on the probe when it is exposed to the substrate such that the enzyme does not need to already be reacting with the substrate when the substrate is exposed to the probe. Sartorius Br. at 34–35.

By reciting that the exposing step is, with respect to an enzyme substrate, reacted or reacting with an enzyme, claim 8 allows for a situation in which the enzyme has already reacted with the substrate before probe exposure (the enzyme is not on the probe when exposed to the substrate) and allows for a situation in which the enzyme reacts with the probe upon exposure (the

enzyme is on the probe when exposed to the substrate). Because in Gator Bio's HRP probes/kits, the HRP enzyme reacts with the enzyme substrate when it is exposed to the probe, the evidence supports that this claim element is met. Tr. (Forrest) at 1067:7–1069:13.

Gator Bio argues that the prosecution history of the '887 patent forecloses this conclusion, contending that the applicant distinguished prior art in which a substrate was immobilized on a probe before the probe was exposed to an enzyme. Gator Bio Reply at 39–40. In particular, the applicant argued:

> Cunningham also fails to disclose "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" of claim 7. The Examiner cited paragraph 272 of Cunningham as disclosing a protease inhibitor assay where the substrate is cleaved and the resulting product is determined. However paragraph 272 discloses at most binding of a 4-amino acid peptide substrate (NHS-GDED-pNA) to the biosensor (paragraph 274) and exposing the biosensor to the Caspase-3 solution (paragraph 275). There is no exposure of the biosensor to the substrate reacted/reacting with an enzyme where the substrate binds to analyte binding molecules on the biosensor surface.

JX-0006 at 226.

In the above paragraph, the applicant argued that Cunningham does not disclose the claimed method because in Cunningham, the enzyme substrate is already bound to the probe, after which it is exposed to a solution containing enzyme. In Gator Bio's HRP probes, the enzyme is already attached to the probe after which the probe is exposed to the enzyme substrate. Gator Bio argues that this is a distinction without a difference. Gator Bio Reply at 40. But in Cunningham, there is no action of exposing the optical element to a substrate "whereby the enzyme substrate or portion of the enzyme substrate binds to the layer of analyte binding molecules" because the substrate is already bound to the probe. I therefore conclude that the applicant's argument during prosecution does not foreclose Sartorius's argument.

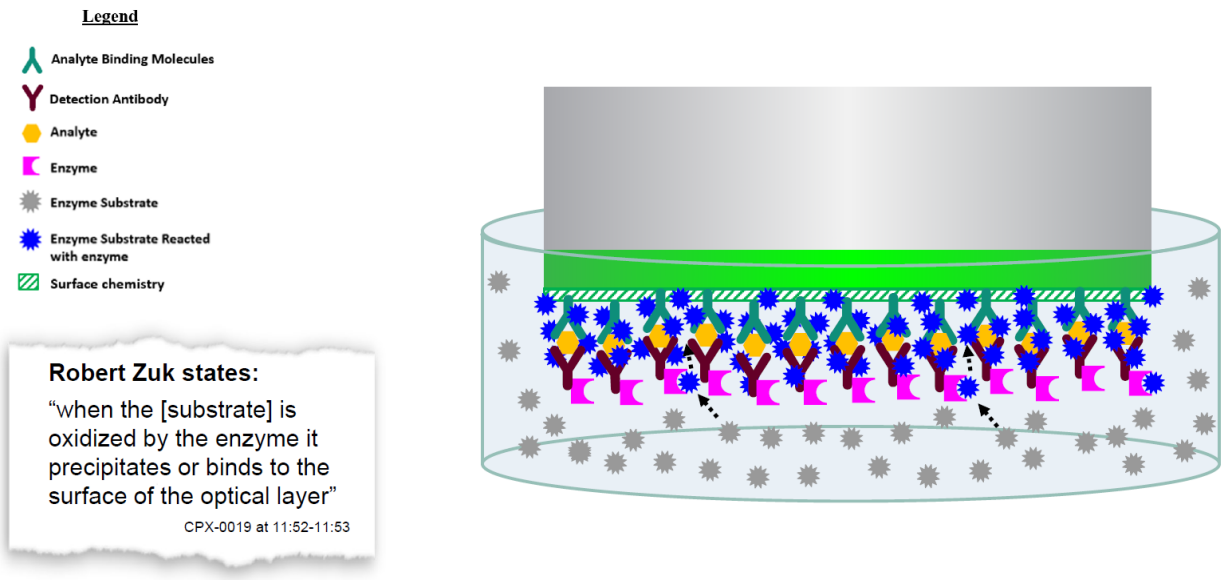
The evidence thus supports that the GatorPrime instrument used with Gator Bio's HRP probes/kits meet this portion of element [8F].

b) whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules

The next portion of element [8F] recites "whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules." '887 patent, claim 8. The question with respect to this portion of element [8F] is whether the substrate containing chloronaphthol (the enzyme substrate) or a portion of it binds to the layer of CaptureSelect (the analyte binding molecules).

Sartorius contends that this portion of element [8F] is met. Sartorius Br. at 31–34. Gator Bio contends that Sartorius provided insufficient evidence supporting that this portion of the claim is met and that the record evidence supports that it is not. Gator Bio Reply at 41–43. The Staff does not address this issue. Staff Br. at 33–41.

In testifying that this portion of the claim is met, Dr. Bailey used the demonstrative below:



CDX-0001C.53.

[redacted]

In the above demonstrative, the CaptureSelect antibodies are identified as the green upside-down Y's and the chloronaphthol is identified by the blue asterisks. Tr. (Zuk) at 450:14–18; Tr. (Bailey) at 618:21–25; and Tr. (Forrest) at 1029:11–14. Based on this demonstrative, Dr. Bailey testified that the chloronaphthol binds "indiscriminately" to any available surface, including the CaptureSelect antibodies. Tr. (Bailey) at 623:1–3. In particular, he testified:

> So this -- what this well [the cylinder in CDX-0001C.53] contains is an enzyme substrate. This substrate, then, is what is catalytically in this case oxidized, chemically oxidized by the enzyme. So it's catalytically oxidized. In the oxidation process the molecule goes from being soluble in water to being insoluble in water. So since it is no longer soluble in water, it indiscriminately precipitates onto any available surface. It will bind to whatever it encounters first. This could be the inorganic surface. It could be the surface chemistry. It could be the analyte binding molecules. It could be anything. It is indiscriminately. It is [insoluble]. It just crashes all over the place.

Tr. (Bailey) at 622:16–623:7.

Gator Bio contends that Dr. Bailey's testimony is not sufficient to establish that chloronaphthol (the enzyme substrate) binds to the layer of CaptureSelect (the analyte binding molecules). Gator Bio Reply at 41–43.

The Federal Circuit has stated that expert testimony does not provide substantial evidence of infringement when it is "conclusory, unsupported, contrary to the evidence in the case, or not directed to the claim limitation at issue." *Dominion Energy, Inc. v. Alstom Grid LLC*, 725 Fed. App'x 980, 986–87 (Fed. Cir. 2018); *see also Yoon JA Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006) and *Commscope Technologies, Inc. v. Dali Wireless Inc.*, 10 F.4th 1289, 1296–98 (Fed. Cir. 2021). Dr. Bailey's testimony suffers from each of the infirmities identified by the Federal Circuit in *Dominion Energy*.

Dr. Bailey's testimony was conclusory and unsupported. It was also equivocal. He testified that the chloronaphthol "will bind to whatever it encounters first," which "could be the inorganic

surface," "could be the surface chemistry," "could be the analyte binding molecules," "It could be anything." Tr. (Bailey) 622:16–623:10. That equivocal testimony, stating what could happen, is insufficient to establish that the chloronaphthol actually binds to the CaptureSelect antibodies.

Dr. Bailey's testimony is also not supported by any examination or testing of Gator Bio's HRP probes. *Id.* at 694:1–696:9 (Dr. Bailey did not analyze any of Gator Bio's HRP probes). Such testimony can be, and in this case is, insufficient to support a finding of infringement. *Yoon JA Kim*, 465 F.3d at 1329 (rejecting expert testimony on infringement where there was no analysis of whether additional ingredients would affect the claimed composition).

Dr. Bailey's testimony is also contrary to the evidence. Mr. Zuk testified, as did Dr. Bailey, that the chloronaphthol is hydrophobic. Tr. (Zuk) at 421:11–14; and Tr. (Bailey) at 622:24–623:1. Mr. Zuk also testified that the surface of the probe is hydrophobic and that hydrophobic molecules will bind to each other in an aqueous environment such that the chloronaphthol will bind to the surface of the probe. In contrast, any exposed residues of the CaptureSelect antibodies (the analyte binding molecules) are hydrophilic, such that the chloronaphthol will not bind to them. Tr. (Zuk) at 421:1–422:25 and 467:12–24.

Sartorius argues that Mr. Zuk's testimony should not be credited because there is insufficient evidence supporting a finding that he has personal knowledge regarding the hydrophobic or hydrophilic nature of enzyme substrates or analyte binding molecules. Sartorius Br. at 32–33, *citing* Fed. R. Evid. 602. Sartorius also notes that Mr. Zuk was not disclosed as an expert and did not submit an expert report. *Id*. at 33. First, Sartorius did not object to this testimony

at the hearing, so any such objection, whether based on alleged lack of personal knowledge or for failure to provide an expert report, is waived.[10]

On the merits, Sartorius's argument is seriously undercut by its own reliance on a presentation by Mr. Zuk explaining the operation of Gator Bio's probes. Sartorius Br. at 31 and 39. In addition, the evidence supports that Mr. Zuk was competent to testify on the nature of enzyme substrates and analyte binding molecules. Mr. Zuk was the vice president of development at FortéBio when it developed its bio-layer interferometry products, Tr. (Zuk) at 383:15–19, and is now the chief technology officer at Gator Bio, *id.* at 381:12–13. Mr. Zuk also established that he has personal knowledge of the chemistry at the tip of Gator Bio's probes. Tr. (Zuk) at 390:1–5. I therefore credit Mr. Zuk's testimony regarding the nature of enzyme substrates and analyte binding molecules as based on his personal knowledge.

Mr. Zuk's testimony is also supported by other record evidence. Dr. Forrest testified that he agreed with Mr. Zuk's testimony and that "based on biophysical principles," the enzyme substrate (chloronaphthol) "would be expected actually just to bind to certain portions of the biosensor." Tr. Forrest at 1029:8–25. Sartorius argues that Dr. Forrest conceded at his deposition that chloronaphthol binds to the analyte binding molecules. Sartorius Br. at 33. That, however, is not supported by the record. Instead, at his deposition, as recounted at the hearing, Dr. Forrest testified that a precipitant (the chloronaphthol) "does adsorb to the tip of the probe." Tr. (Forrest) at 1030:20–23. This is consistent with evidence cited in the demonstrative slide used by Dr. Bailey, quoting Mr. Zuk as stating that "when the [substrate] is oxidized by the enzyme, it precipitates or

[10] Sartorius objected to other testimony provided by Mr. Zuk, and I overruled that objection. Tr. (Zuk) at 473:1–13.

binds to the surface of the optical layer." CDX-0001C.53, *quoting* CPX-0019 at 11:52–53; *see also* Tr. (Zuk) at 450:23–25 (playing that portion of CPX-0019).

The evidence demonstrates that chloronaphthol will bind to the surface of the probe and not to the CaptureSelect antibodies. Sartorius attempts to equate the surface of the probe with the CaptureSelect antibodies. Sartorius Br. at 32–33 (arguing that the chloronaphthol binds "indiscriminately to the optical layer of the probe, which includes the analyte binding molecules"). The claim requires that the "the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules." Sartorius has not presented evidence that the specifically-recited binding occurs. And the record evidence, based on the biophysical properties of the involved materials, supports that it does not.

The Federal Circuit in *Commscope* rejected the same type of argument Sartorius advances here. There, the claim required "switching a controller off." 10 F.4th at 1292. In asserting infringement, the patent owner relied on expert testimony that "you turn the feedback off" and labeled the distinction as "hair-splitting" and "irrelevant in light of the purpose of the invention." *Id*. at 1296 and 1298. In rejecting this argument, the Federal Circuit noted that "reliance on the claim terms as construed by the district court is not 'hair-splitting.'" *Id.* at 1298.

Likewise, here, Sartorius equates the surface of the probe with the analyte binding molecules. Sartorius Br. at 33. Based on its own representation, CDX-0001C.53, these are not the same. In any event, Sartorius presented no evidence of what is actually claimed—that the enzyme substrate (or portion thereof) binds to the analyte binding molecules—instead relying on evidence that the enzyme substrate (or portion thereof) binds to the surface of the probe. *Id.* Consistent with the analysis in *Commscope*, Sartorius has failed to present substantial evidence that element [8F] is met.

The record evidence does not support that the GatorPrime instrument used with Gator Bio's HRP probes/kits meet this portion of element [8F].

c) 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 analyte binding molecules

The next portion of element [8F] recites "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 analyte binding molecules." Comm'n Op. at 19 (Aug. 24, 2023). As with the previous portion of the claim, this portion of the claim requires that the enzyme substrate or portion thereof binds to the layer of analyte binding molecules.[11] For the same reasons explained above, Sartorius has not presented persuasive evidence that Gator Bio's enzyme binds to the layer of analyte binding molecules. As a result, the record evidence does not support that the GatorPrime instrument used with Gator Bio's HRP probes/kits meet this portion of element [8F].

7. Element [8G]

Claim 8 next recites "the reflected beams coupled to the fiber." '887 patent, claim 8. Sartorius contends that this limitation is met. Sartorius Br. at 32. Neither Gator Bio nor the Staff dispute that this limitation is met. *See* Gator Bio Reply at 23–48; and Staff Br. at 33–41.

The evidence supports that reflected beams of light from the probe are coupled into the fiber of the GatorPrime instrument. Tr. (Tan) at 297:22–25, 338:22–339:12, and 390:6–9; Tr. (Bailey) at 585:21–586:12; and Tr. (Schaafsma) at 877:21–878:16 and 900:21–901:4.

[11] As explained above, "enzyme binding molecules" is construed as "analyte binding molecules." *See* section I.D.

The evidence supports that the GatorPrime used with Gator Bio's HRP probes/kits meet element [8G].

8. Element [8pre] and Element [8H]

The preamble of claim 8 recites a "method of assaying enzyme activity" and the last element of claim 8 recites "detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity." '887 patent, claim 8. Sartorius contends that these elements are met. Sartorius Br. at 13–14 and 37. Gator Bio disputes that these elements are met, as does the Staff. Gator Bio Reply at 36–38; and Staff Br. at 40.

Sartorius contends that when the GatorPrime instrument is used with its HRP probes, the HRP enzymatically catalyzes a reaction that oxidizes the chloronaphthol substrate, causing it to precipitate and bind to the surface of the probe. Sartorius Br. at 13, *citing* Tr. (Bailey) at 621:15–623:10; and Tr. (Forrest) at 1069:9–1070:6. This enzymatically-induced precipitation causes a change in the interference pattern associated with the probe. *Id*., *citing* Tr. (Tan) at 297:21–25 and 339:9–15; and Tr. (Bailey) at 625:25–627:29. Sartorius contends that if "the enzyme did not have any activity, this precipitation would not occur." *Id*. Sartorius further argues that "by detecting the change in the interference that results from the enzyme HRP catalyzing a reaction with its substrate, [Gator Bio] performs a method of assaying enzyme activity." *Id*. Sartorius makes similar arguments with respect to element [8H], contending that the "enzyme activity of HRP causes the substrate to bind to and increase the optical thickness of the optical layer." *Id*. at 37.

Gator Bio contends that when its HRP probes are used with its instruments, no information about the concentration or activity of the HRP enzyme is provided except that the enzyme must have some activity for the test to work. Gator Bio Reply at 37, *citing* Tr. (Forrest) at 1025:17–1027:2. The lack of a signal can mean that the item being tested for is not present (AAV capsids

or the ratio of empty-to-full AAV capsids). *Id*. Dr. Forrest testified that "I can't glean any information about how active or inactive that HRP label is as an enzyme based on this activity. Just how much viral capsid is present." *Id*., *quoting* Tr. (Forrest) at 1026:25–1027:2.

With respect to both element [8pre] and element [8H], the most Sartorius contends is that the enzyme causes the precipitation of chloronaphthol. That, however, is not what the claim requires. In reciting "assaying enzyme activity," the claim requires measuring enzyme activity. The enzyme activity that Sartorius relies on is simply a trigger—it causes the precipitation. The evidence persuasively demonstrates that what is measured when the GatorPrime is used with one of Gator Bio's HRP probes is altogether different and is the concentration of AAV capsids or the ratio of empty-to-full AAV capsids. Likewise, in reciting "detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity," the claim requires a measure of enzyme activity. The evidence persuasively demonstrates that the change in optical thickness is indicative of the concentration of AAV capsids or the ratio of empty-to-full AAV capsids and is not indicative of enzyme activity. Tr. (Forrest) at 1024:1–1027:2; Tr. (Zuk) at 387:25–389:7 and 404:5–405:19.

The evidence supports that the GatorPrime instrument used with Gator Bio's HRP probes/kits does not meet element [8pre] or element [8H].

C. Articles That Infringe

Gator Bio contends that its accused instruments are not "articles that infringe" under section 337(a)(1)(B)(i) because they cannot themselves "perform the recited steps of method claim 8 and have countless noninfringing uses; it is the non-imported U.S.-made probes that are alleged to be the claimed optical element and that are used to carry out any allegedly infringing methods." Gator Bio Reply at 3–4 (emphasis removed). Gator Bio devotes just two sentences of its post-

hearing reply brief to this argument. Neither Sartorius nor the Staff addresses this issue at all. Because the record on this issue is undeveloped and because I have found that the use of Gator Bio's GatorPrime instruments with one of its HRP probes does not practice claim 8, I do not address this issue. *See Certain Soft-Edged Trampolines and Components Thereof*, Inv. No. 337-TA-908, Comm'n Op. at 9 (May 1, 2015) (EDIS Doc. ID 556253) (declining to consider issue with undeveloped arguments).

I also note that in a footnote in its post-hearing reply brief, Gator Bio contends that although it should prevail on its argument "regardless of the Commission's current interpretation of *Suprema*, Gator Bio preserves an argument that the Commission misreads *Suprema* as disavowing either a nexus requirement or all consideration of the state of imported articles at the time of importation." Gator Bio Reply at 4, n.1. This argument was not presented in Gator Bio's 490-page pre-hearing brief and was therefore abandoned. *See* Gator Bio Pre-Hearing Br. (EDIS Doc. ID 798382); and Order No. 10 (Ground Rules) at § 11.2 (EDIS Doc. ID 792151). It was also not raised in Gator Bio's initial post-hearing brief. To the extent Gator Bio has the burden of demonstrating that either *Suprema* or the Commission's interpretation of *Suprema* is wrong, Gator Bio additionally abandoned this issue by not raising it in its initial post-hearing brief. Order No. 10 at § 14.1.

D. Induced Infringement

Sartorius contends that Gator Bio induces itself to infringe claim 8. Sartorius Br. at 38–39. Gator Bio disputes Sartorius's inducement claim, as does the Staff. Gator Bio Reply at 46–48; and Staff Br. at 41–42. To prevail on an induced infringement claim, the patentee must first establish that there has been direct infringement. *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd*, 501 F.3d

1307, 1316 (Fed. Cir. 2007). Because Sartorius has not demonstrated this threshold issue, its claim of induced infringement fails.

VIII. DOMESTIC INDUSTRY – TECHNICAL PRONG

Sartorius contends that it practices claim 8 of the '887 patent and that its Octet R8 is representative of its domestic industry instruments. Sartorius Br. at 39–58. The parties have stipulated that for certain purposes Sartorius's APS and AR probes are representative of its domestic industry probes. Stipulation on Importation, Sale, and Inventory, at p.2, ¶ 5.[12] I first address representativeness, followed by whether Sartorius has demonstrated a technical domestic industry.

A. Representative Products

1. Domestic Industry Instruments

Sartorius contends that the Octet R8 is representative of its Octet R Series line of products, including the Octet R2, Octet R4, Octet R8, Octet RED96, Octet RED96e, Octet RH96 (HTX), Octet RH16 (RED384), Octet QKe, and Octet N1 (BLItz) instruments. Sartorius Br. at 39–40, *citing* Tr. (Bailey) at 632:14–16. Those instruments are shown below:

[12] The parties' stipulation has two paragraphs numbered as 5. The portion of the stipulation referenced above refers to the paragraph 5 on page 2.

[redacted]

CX-0190C.13.

CX-0190C.15.

According to Sartorius, each of its domestic industry instruments performs the same functions and runs the same experiments using the same probes. Sartorius Br. at 40, *citing* Tr. (Kang) at 131:15–19; and Tr. (Bailey) at 629:20–630:1. Based on review of Gator Bio documents, visual inspection of the domestic industry instruments at Sartorius's Fremont and Ann Arbor facilities, including observation of basic assays, and conversations with various Sartorius

[redacted]

engineers, Dr. Bailey testified that the Octet R8 is representative. Tr. (Bailey) at 630:13–23 and 634:7–19.

According to Sartorius, the optical subassemblies of its domestic industry instruments, illustrated below (CX-0187C), have the same essential components—a light source, fiber optic bundles, spectrometers, optical couplings, and probes—that allow for all of its probes to engage each of its instruments in the same way. Sartorius Br. at 40–41.

CX-0187C.3.

Sartorius argues that any differences between its domestic industry instruments have no effect on how an optical fiber in the instrument engages with a probe. Sartorius Br. at 41. As Mr. Kang testified, though the length of the fiber bundles may vary for the different instruments, in substantive structure and operation, the fiber optic bundles for the different instruments are the

[redacted]

same. Tr. (Kang) at 137:9–14. Additionally, the evidence supports that though the RH96 and the N1 instruments have unique features (the RH96 uses a multiplexor allowing a single spectrometer to process data from up to six channels, (CX-0187C.11; and Tr. (Kang) at 136:21–24), and the N1 has one spectrometer and requires manual operation (CX-0187C.14; and Tr. (Kang) 137:2–8)), those features do not affect how the fiber in the instrument interacts with the probe and are, therefore, irrelevant to claim 8. Tr. (Bailey) at 629:15–630:1.

Gator Bio argues that Sartorius has not shown that the Octet R8 is representative of its other domestic industry instruments. Gator Bio Reply at 48–49. The Staff agrees based on the Sartorius fiber bundle that Dr. Bailey analyzed. Staff Br. at 44–45. As to that issue, Gator Bio argues that Dr. Bailey's analysis is unreliable because he examined only a single fiber bundle and because he relied on conversations with Mr. Kang and his team of engineers. Gator Bio Reply at 48–49, citing Tr. (Bailey) at 711:7–25. The evidence shows, however, that Dr. Bailey visually inspected all of Sartorius's different domestic industry instruments at its Fremont and Ann Arbor facilities and observed them performing basic assays. Tr. (Bailey) at 630:13–23 and 634:7–19.

The evidence also shows that Dr. Bailey relied on documents to assess the representativeness of the Octet R8. *Id.* at 632:4–23. Based on these documents, Dr. Bailey determined that all Sartorius domestic industry instruments have the same essential components with the same general framework, known as an optical subassembly—consisting of a light source, fiber optic bundles, spectrometers, and optical couplings. *Id.* at 630:25–631:7. Dr. Bailey also determined that the Octet R8 is representative by examining Sartorius's optical subassembly documentation (CX-0187C), which shows that the subassemblies for the Octet R2, R4, and R8 are similar except for the number of fiber-optic bundles and spectrometers, and thus the number of channels. Tr. (Bailey) at 632:7–13; and CX-0187C.3. Dr. Bailey also testified that based on

Sartorius's optical subassembly guide, he concluded that the R8 was not only representative of the R2 and R4, but of all of Sartorius's domestic industry instruments. Tr. (Bailey) at 632:14–16; and CX-0187C. Mr. Kang testified that the optical subassemblies in Sartorius's domestic industry instruments are essentially the same, allowing for all Sartorius probes to engage with each of them in the same way. CX-0187C; and Tr. (Kang) at 131:25–132:7 (discussing the optical subassemblies), 133:2–24 (discussing the R Series), 134:3–17 (discussing the Red96/Red96e), 134:20–136:2 (discussing the RH16), 136:13–20 (discussing the RH96), and 137:2–8 (discussing the N1). The evidence thus supports that the optical subassemblies across Sartorius's domestic industry instruments are essentially the same.

Gator Bio argues that Sartorius's documents indicate that its Anti-CHO (Chinese hamster ovary cells) HCP (host cell protein) detection kit can only be used with a subset of Sartorius's domestic industry instruments. Gator Bio Reply at 49, *citing* Tr. (Forrest) at 1037:15–1038:17; CX-0201.3 (identifying particular instruments); and CX-0202.3 (same). The application and technical notes explain, however, in a step-by-step way, how to set up an assay using a specific Sartorius domestic industry instrument having a particular number of channels. *See* CX-0201 at .4–.9 (providing step-by-step instructions for 8, 16, and 96-channel Octet® instruments); and CX-0202.9 ("Reagent quantities given below are for 8-channel assays on Octet® R8 BLI systems and the 8-channel read head on the Octet® RH16 BLI system (Figure 10). Reagent quantities in parenthesis are for the 16-channel read head on the Octet® RH16 BLI Systems"). In addition, the Octet Biosensor Selection Guide shows that Sartorius's Anti-CHO HCP detection kit application notes are not limited to instruments with 8, 16, or 96 channels because it provides the dynamic range for instruments with one channel (i.e., the Octet N1) and instruments with 32 or more

channels (i.e., the RH96). CX-0026.4. The evidence thus supports that Sartorius's Anti-CHO HCP detection kit can be used with all of Sartorius's domestic industry instruments.

The evidence supports that Sartorius's Octet R8 is representative of Sartorius's domestic industry instruments.

2. Domestic Industry Probes

Dr. Bailey identified a list of 25 different probes as Sartorius's domestic industry probes. Tr. (Bailey) at 630:6–12; and Tr. (Schaafsma) at 925:13–14.

Sartorius and Gator Bio filed a stipulation, stating in part:

> The parties stipulate that for purposes of determining infringement of the '887 patent in the present investigation, the Aminopropylsilane (APS) probes and Amine-Reactive (AR) probes shall be treated as representative of the Accused Probes with respect to the following limitations: "an optical element 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" and "the optical element including…a proximal reflecting surface and a distal reflecting surface separated by at least 50 nm." ('887 patent at claim 8.) For the avoidance of doubt, Gator Bio does not concede (and in fact disputes) that these limitations are present in the identified APS and AR probes or the four Accused Probes, only that the identified probes are representative of the Accused Probes for purposes of addressing these limitations.

Stipulation on Importation, Sale, and Inventory, at p.2, ¶ 5.

Thus, for certain purposes, the parties have agreed that the Sartorius APS and AR probes are representative. That, however, does not end the analysis because it only addresses the physical attributes of the probe, not those that relate to the reactions that occur when assaying enzyme activity.

Sartorius contends that all of its probes share the same base sensor components and only differ with respect to their surface chemistry at the distal end, which determines the target analyte. Sartorius Br. at 42. The evidence supports that all of Sartorius's probes are a [redacted]

[redacted]

with an [redacted] and either a layer of [redacted] or an [redacted] surface. Tr. (Kang) at 142:3–145:16; and Tr. (Barnabei) at 209:2–210:23.

In asserting technical domestic industry, Sartorius relies on its Anti-CHO HCP detection kit, which uses HRP. Sartorius Br. at 54, reproducing CX-0201.2 (showing Sartorius's "Anti-CHO HCP Biosensor" used with HRP) and 57, reproducing Figures 5 and 10 of CX-0201 (showing data from CHO-HCP assays). Gator Bio contends that Sartorius's Anti-CHO HCP detection kit is not representative because Sartorius has not shown that anyone has actually used any of its other probes/kits with HRP or any other enzyme. Gator Bio Reply at 50. Sartorius contends that its technical documents instruct users to use HRP with its other probes. Sartorius Br. at 55.

A complainant must provide evidence "of an actual article that practices the patent." *Microsoft Corp. v. Int'l Trade Comm'n*, 731 F.3d 1354, 1362 (Fed. Cir. 2013). In *Microsoft*, the Federal Circuit affirmed the Commission's finding that Microsoft had not demonstrated that it met the domestic industry requirement because it "simply failed to identify any actual phones with the required components performing as required." *Id*.

The asserted claim in *Microsoft* required "client applications on the mobile device that are configured to automatically register notification requests and receive notifications in response to a change in a state property of the mobile devices for which they have registered." *Id*. The evidence Microsoft's expert cited in support of his opinion that Windows Mobile phones practiced the "client applications" limitation was source code Microsoft provided to mobile-phone manufacturers. *Id.* Microsoft provided no evidence regarding the specific code "actually installed and run on a particular third-party mobile device" and "provided no evidence that 'Windows Mobile' phones always contain the entirety of Windows Mobile, rather than only portions." *Id*. On

that basis, the Federal Circuit affirmed "the Commission's finding of no proven domestic industry." *Id*.

Analogously here, claim 8 is directed to "assaying enzyme activity" and recites, among other things, "exposing the optical element to an enzyme substrate reacted or reacting with an enzyme." '887 patent claim 8. With respect to all but its Anti-CHO HCP detection kit, which indisputably comes with and is used with HRP, Sartorius relies on general instructions indicating that its other probes can be used with HRP, stating that those documents "instruct users to apply HRP in substantially the same way." Sartorius Br. at 55, relying on CX-0202 and CX-0502; *see also id*. at 53 (stating that Sartorius "further publishes technical documents, such as technical and application notes, that instruct individuals to use DI probes with HRP"). The only evidence Sartorius relies on are its instructions to users that other probes can be used with HRP. Sartorius presented no evidence that it provides HRP with any of its other probes. And as in *Microsoft*, Sartorius presented no evidence that anyone has used any of its other probes with HRP. As a result, consistent with *Microsoft*, the evidence supports that only Sartorius's Anti-CHO HCP detection kit is a domestic industry probe/kit.

B. Use of Sartorius's Octet R8 Instrument With Its Anti-CHO HCP Detection Kit Does Not Practice Claim 8

As detailed below, the record contains persuasive evidence that use of Sartorius's Octet R8 instrument with a probe of its Anti-CHO HCP detection kit does not practice claim 8 of the '887 patent.

1. Element [8pre]

Claim 8 recites "a method for assaying enzyme activity." Because the analysis of element [8pre] is related to the analysis of element [8H], I address the preamble with element [8H].

2. Element [8A]

Claim 8 recites "providing an optical element coupled to a light source via a mechanical coupling that engages the first optical element with a fiber." '887 patent, claim 8. Sartorius contends that this element is met in its Octet R8 product. Sartorius Br. at 43–46. Gator Bio and the Staff dispute that this element is met. Gator Bio Reply at 54–56; and Staff Br. at 46–47.

The evidence shows that the Octet R8 includes a light source, namely a lamp. Tr. (Bailey) at 634:23–635:4. The Octet R8 also includes a fiber bundle, which carries light from the lamp to the optical element. *Id.* at 635:6–15. Sartorius documents describing the Octet optical subassembly, and identifying the Octet R Series as exemplary, illustrate how the lamp carries light to the probes via a fiber. CX-0187C.3; and Tr. (Bailey) at 633:23–634:3. The optical element includes a plastic hub, which serves as a mechanical coupling that couples the optical element and the fiber. CX-0194C.14; Tr. (Bailey) at 634:7–11; and Tr. (Kang) at 132:8–10.

Gator Bio and the Staff argue that the Octet R8 when used with one of Sartorius's domestic industry probes does not meet this limitation for the same reasons that they contend that the Gator Bio instruments and probes do not infringe—because of statements Sartorius made in the '585 patent IPR. Gator Bio Reply at 54–56; and Staff Br. at 46–47. As explained above, however, Sartorius's statements in the '585 patent IPR did not disclaim any scope of claim 8 the '887 patent. Neither Gator Bio nor the Staff advance any other argument that this claim element is not met.

The evidence supports that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets element [8A].

[redacted]

3. Element [8B]

Claim 8 recites "provides an air gap between the first optical element and the fiber." '887 patent, claim 8. Sartorius contends that this element is met. Sartorius Br. at 51–53. Both Gator Bio and the Staff dispute that this element is met. Gator Bio Reply at 56–58; and Staff Br. at 47–48.

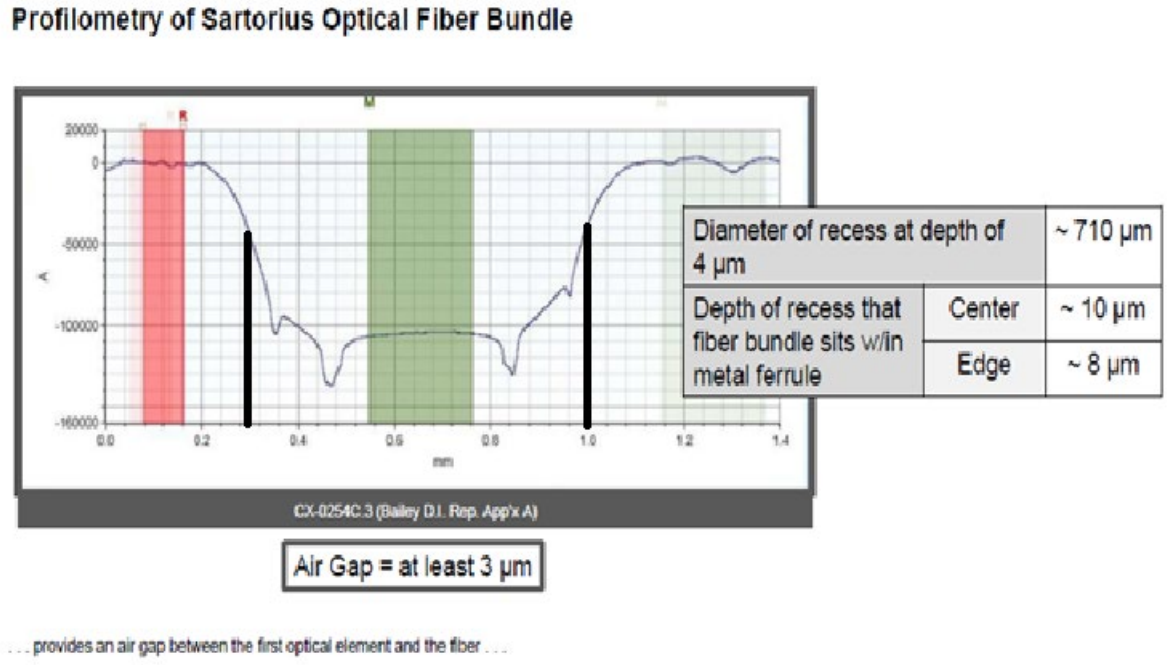
Dr. Bailey testified that a plastic hub coupling the fiber in the Octet R8 instrument to a probe provides the claimed air gap. CX-0194C.14; CX-0257C.9; and Tr. (Bailey) at 634:4–15. Using optical microscopy, Dr. Bailey measured a recess in the fiber with a diameter of about 660 µm. Tr. (Bailey) 639:7–15. Using a micrometer caliper, Dr. Bailey determined an average diameter of Sartorius's APS and AR2G probes as 711±2 µm and 710±2 µm, respectively. *Id.* at 639:21–641:5. Based on Dr. Bailey's measurements, Sartorius asserts that its probes will not fit completely within the recess in the fiber. Sartorius Br. at 51–53.

Using profilometry, Dr. Bailey determined that the depth of the recess in the fiber is about 10 µm in the center and 8µm at the edge. *Id.* at 641:9–17. At a diameter of roughly 710 µm, which is the average diameter of Sartorius's probes, the depth of the recess is roughly 4 µm. Because of the depth to which the probe can fit into the fiber, Dr. Bailey determined that when the probe and fiber are placed in contact, there is an air gap between the fiber and the probe of at least 3 µm. *Id.* at 641:18–23.

Gator Bio argues that Sartorius has failed to show that the fiber bundle analyzed by Dr. Bailey is representative, and that Dr. Bailey's testimony is unreliable because he only examined a single fiber bundle. Gator Bio Reply at 56, *citing* Tr. (Bailey) at 711:7–25. However, as Mr. Kang testified, "[t]he fiber bundle is the same" for the various Octet instruments, though its length may vary among different instruments. Tr. (Kang) at 137:9–14. In addition, Dr. Bailey observed N1, R2 and R4 instruments, in addition to the R8, and determined that each includes the same essential

components. Tr. (Bailey) at 629:10–630:1. Dr. Bailey further testified that Sartorius's probes work with all those instruments, and each he examined contained the same interfaces between the probes and the fiber bundles. *Id.* Gator Bio has not shown that Dr. Bailey's testimony is unreliable because he only took measurements of one fiber bundle. In addition, Gator Bio provided no evidence that Dr. Bailey's measurements were wrong.

Pointing to one of his demonstrative slides, CDX-0001C.78, Gator Bio argues that Dr. Bailey's conclusion that Sartorius's probes do not fit completely within the recess of the fiber bundle is unreliable because the recess and the probe have roughly the same diameter. Gator Bio Reply at 56. Dr. Bailey's demonstrative slide is reproduced below:



CDX-0001C.78 (annotated). The annotations on CDX-0001C.78 (the black vertical lines) show, based on Dr. Bailey's measurements, where the probe will sit with respect to the fiber and show that the probe will not completely fit within the recess. As to Gator Bio's argument, Dr. Bailey's

slide, based on his measurements, indicates that the diameter of the probe and the diameter of the recess are the same when the recess is at a depth of 3 μm. This is consistent with Dr. Bailey's testimony—the recess in the fiber is too small to completely accommodate the probe. Tr. (Bailey) at 641:3–23.

Gator Bio argues that the air gap between Sartorius's fiber and its probe is not a designed separation because there are no technical or manufacturing specifications referring to it. Gator Bio Reply at 57. This does not, however, negate Dr. Bailey's measurements, which Gator Bio did not substantively challenge.

Finally, Gator Bio argues that there is no mechanical coupling that provides the air gap, for reasons similar to those it advanced when arguing non-infringement of its first redesign. Gator Bio Reply at 57–58. The evidence shows that a plastic hub orients Sartorius's fiber relative to its probe and provides an air gap because it is what situates and holds in place the fiber relative to the probe. CX-0194C.14; CX-0257C.9; and Tr. (Bailey) 634:4–15. The recess itself is not the gap; instead, the plastic hub aligns and holds the optical element near the fiber and creates the air gap. Tr. (Bailey) at 638:10–639:6.

The evidence supports that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets element [8B].

4. Element [8C] and Element [8D]

Claim 8 recites "the optical element including (a) a proximal reflecting surface and a distal reflecting surface separated by at least 50 nm." Sartorius contends that its probes meet this element. Sartorius Br. at 46–49. Gator Bio and the Staff dispute the reliability of the evidence Sartorius relies on. Gator Bio Reply at 51–53; and Staff Br. at 43.

[redacted]

Gator Bio and the Staff contend that CX-0237C, a Sartorius presentation, is unreliable and should be given no weight. The portion Sartorius relies on is shown below:

CX-0237C.8.

Relying on the above image, Dr. Bailey testified that the [redacted] Tr. (Bailey) at 642:20–643:15. Sartorius also relies on this presentation as showing that its probes [redacted] CX-0237C.8; Tr. (Kang) at 144:17–22 and 144:23–145:4; and Tr. (Bailey) at 643:7–15.

Gator Bio contends that the evidence Sartorius relies on is unreliable because it is "a 13-year-old presentation" from Gator Bio's predecessor, which Mr. Kang described as "very old." Gator Bio Reply at 51. Gator Bio further contends that Sartorius's only basis for relying on CX-0237C is "Mr. Kang's *ipse dixit* say-so." *Id*. I considered Gator Bio's argument that CX-0237C should be excluded in ruling on the parties' motions in limine. *See* Order No. 33. There, I

[redacted]

determined not to exclude CX-0237C and noted Mr. Kang's deposition testimony that CX-0237C "is still valid." *Id*. at 7.

Gator Bio contends that Mr. Kang is not credible because he signed the declaration accompanying Sartorius's complaint, which included a claim chart for the '887 patent that added labels to screenshots of a Gator Bio video that did not use the words in the labels Sartorius added. Gator Bio Reply at 53. It is difficult to see how Mr. Kang's credibility is impugned by a claim chart including labels clearly not on the original source material and intended to make infringement allegations. *See* Complaint, Ex. 52.

Gator Bio also contends that CX-0237C is not reliable because its expert testified that "one would not look to documents like the 2010 presentation to draw a conclusion to any reasonable degree of scientific certainty about whether [Sartorius's probes] meet the claim language, but would instead look to controlled manufacturing documents of the sort Sartorius surely has but strategically chose not to present." Gator Bio Reply at 53, *citing* Tr. (Schaafsma) at 924:9–925:5. Sartorius responds that CX-0237C is: (1) a "proprietary document detailing the composition and manufacturing steps" of its probes; (2) the most comprehensive document it has; and (3) "still referenced by Sartorius." Sartorius Br. at 48. Sartorius also provided evidence that ten of its probes that are still manufactured and sold today were originally launched between 2005–2010, the same time period in which CX-0237C was created. Tr. (Barnabei) at 209:2–210:23; CX-0558. Mr. Kang testified that Sartorius's probes share the same components and form factor and only differ with respect to their surface chemistry. Tr. (Kang) at 128:7–15 and 139:20–140:3.

Gator Bio also questions the reliability of CX-0237C because of alleged discrepancies between some of Dr. Bailey's measurements and those identified in the presentation. Gator Bio Reply at 51–52. Dr. Bailey measured the diameter of the core of the optical fiber as 689.20 μm,

while CX-0237C states that the core diameter is 600 ± 10 µm. Tr. (Bailey) 705:24–709:17; CX-0255C.6; and CX-0237C.8. Dr. Bailey testified, however, that his optical measurements were less accurate than his caliper measurements because of the cladding on the fiber and the glue used in the hub caused the image to blur. Tr. (Bailey) at 707:6–13, 743:21–744:3, and 744:9–16. Dr. Bailey testified that his caliper measurements of 711±2 µm and 710±2 µm, respectively were entirely consistent with CX-0237C. *Id.* at 639:21–641:5; CX-0237C.8; and CX-0194C.14.

There is nothing mandating that technical specification be maintained in any specific type of documents, as Gator Bio contends. In addition, the fact that a document (or anything else for that matter) is old does not mean it is not reliable. Finally, while documents can and sometimes do contain mistakes (*see* discussion regarding the mistake Gator Bio contends exists in one of its documents), the evidence does not support that CX-0237C is not reliable.

Other than its arguments regarding the reliability CX-0237C, neither Gator Bio nor the Staff dispute this claim element. The evidence supports that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets element [8C] and element [8D].

5. Element [8E]

Claim 8 recites "(b) a layer of analyte binding molecules." '887 patent, claim 8. Sartorius contends that this element is met. Sartorius Br. at 53–54. Gator Bio and the Staff do not dispute that this element is met. *See* Gator Bio Reply at 48–63; and Staff Br. at 45–48.

The probe in Sartorius's Anti-CHO HCP detection kit includes a layer of analyte binding molecules that are "used to bind to an antigen of interest." Tr. (Bailey) 644:7–15 and 645:4–9. Sartorius's Anti-CHO HCP detection kit also includes the Cygnus antibody, an analyte binding molecule. Tr. (Bailey) at 644:7–15. As Dr. Bailey testified, the probe in Sartorius's Anti-CHO

HCP detection kit "is functionalize[d] with an analyte binding molecule, which is the Cygnus 3G anti-HCP antibody." Tr. (Bailey) 646:7–18 and 647:16–22.

The evidence supports that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets element [8E].

6. Element [8F]

Claim 8 recites "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 analyte binding molecules." '887 patent, claim 8; and Comm'n Op. at 19 (Aug. 24, 2023). Because the parties address portions of this claim element separately, I do as well.

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

The first portion of element [8F] recites "exposing the optical element to an enzyme substrate reacted or reacting with an enzyme." '887 patent, claim 8. Sartorius contends that this portion of element [8F] is met. Sartorius Br. at 53–55. Gator Bio contends it is not. Gator Bio Reply at 60. The Staff does not address this issue. Staff Br. at 45–48.

As noted with respect to element [8E], the evidence shows that the probe in Sartorius's Anti-CHO HCP detection kit is coated with an analyte binding molecule, namely, the Cygnus 3G anti-HCP antibody. Tr. (Bailey) at 646:7–18 and 647:16–22. In the document relied on by Sartorius with respect to this claim element, the probe with a layer of Cygnus 3G anti-HCP antibodies (shown as the upside-down Y's in teal) is exposed to a sequence of proteins, beginning from the

surface of the probe: (i) anti-HCP antibody: (ii) HCP; (iii) fluorescein tagged anti-HCP antibody; and (iv) HRP anti-tag (anti-fluorescein) antibody. Tr. (Forrest) at 1071:7–1072:19; *see also* Tr. (Bailey) at 645:10–13.

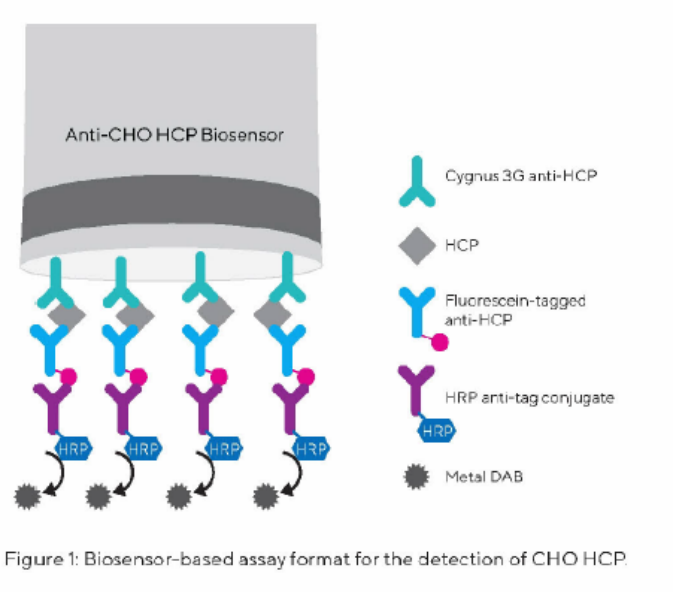


Figure 1: Biosensor-based assay format for the detection of CHO HCP

Sartorius Br. at 54; and CX-0201.2.

Once this sequence of proteins is formed on the tip of the probe, the probe is exposed to an enzyme substrate called metal DAB. Tr. (Bailey) at 645:15–23 and 648:5–11; and Tr. (Forrest) at 1072:10–13. Dr. Bailey testified that the metal DAB (enzyme substrate) is catalytically oxidized by the HRP (the enzyme), which was "bound specifically to the probe." Tr. (Bailey) at 648:5–11.

Like Gator Bio's HRP probes, with Sartorius's probe in its Anti-CHO HCP detection kit, the enzyme HRP is already attached to the probe when the probe is exposed to the metal DAB. CX-0201.2. The parties' dispute about this portion of element [8F] is the same as their dispute with respect to infringement, namely whether the enzyme (HRP) must already be reacting with the enzyme substrate (here, the metal DAB) when the probe is exposed to the enzyme substrate. Gator Bio Reply at 60. For the same reasons explained with respect to infringement of this portion of

element [8F], that is not required by the claim. The evidence shows that once the probe is exposed to the metal DAB, the HRP reacts with it. The exposing step is satisfied because the optical element continues to be exposed to the metal DAB reacting with the HRP.

The evidence supports that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets this portion of element [8F].

b) whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules

The next portion of element [8F] recites "whereby the enzyme substrate or a portion of the enzyme substrate binds to the layer of analyte binding molecules." '887 patent, claim 8. Sartorius contends that this claim element is met. Sartorius Br. at 54 and 56. Gator Bio disputes that this element is met. Gator Bio Reply at 61–63. The Staff does not address this portion of element [8F]. Staff Br. at 43–48.

Sartorius's failure of proof with respect to this portion of element [8F] is like its failure to provide evidence of infringement of this portion of element [8F]. Dr. Bailey testified:

> This is a metal/DAB for Sartorius's. And that is deposited all over the surface indiscriminately all over all the surface chemistry, all of the analyte binding molecules. Again, the product of the enzyme reaction is insoluble, so it will nonspecifically bind, that's still binding, bind to every available surface in this reaction. So that satisfies that limitation.

Tr. (Bailey) at 645:20–646:2. For the reasons explained above with respect to infringement of this portion of element [8F], Dr. Bailey's conclusory testimony does not support that the metal DAB or a portion of the metal DAB binds to the layer of Cygnus 3G anti-HCP antibodies and Dr. Bailey did no testing to support his assertion. In addition, the evidence supports that it does not. In its diagram illustrating the action when the Anti-CHO HCP detection kit probe is exposed to the metal DAB, the metal DAB is shown reacting with, and therefore at least momentarily binding to, the

HRP. It is not shown binding to anything else, including the Cygnus 3G anti-HCP antibodies, as shown below:

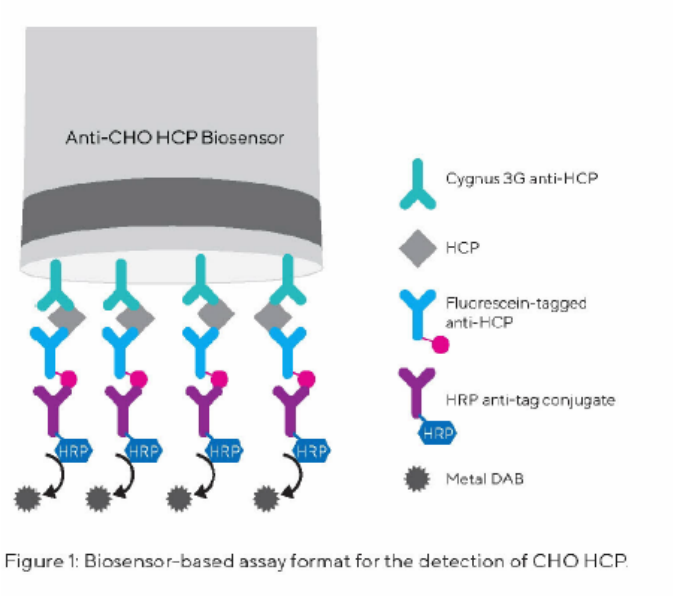


Figure 1: Biosensor-based assay format for the detection of CHO HCP

CX-0201.2. And Sartorius failed to provide substantial evidence that HRP will bind to the Cygnus 3G anti-HCP antibody. *See Dominion Energy,* 725 Fed. App'x at 986–87; *Yoon JA Kim*, 465 F.3d at 1320; and *Commscope*, 10 F.4th at 1296–98.

The evidence does not support that the use of Sartorius's Octet R8 instrument with the probe in its Anti-CHO HCP detection kit meets this portion of element [8F].

c) 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 analyte binding molecules

The next portion of element [8F] recites "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 analyte binding molecules." Comm'n Op. at 19 (Aug. 24, 2023). As with the previous portion of the claim, this portion of the claim requires that the enzyme substrate or portion thereof binds to the layer of analyte binding

molecules. For the same reasons explained above, Sartorius has not presented substantial evidence that its enzyme binds to the layer of analyte binding molecules. As a result, Sartorius has not demonstrated that use of its Octet R8 instrument with a probe of its Anti-CHO HCP detection kit meets this portion of element [8F].

7. Element [8G]

Claim 8 next recites "the reflected beams coupled into the fiber." '887 patent, claim 8. Sartorius contends that this limitation is met. Sartorius Br. at 54. Neither Gator Bio nor the Staff dispute that this limitation is met. *See* Gator Bio Reply at 48–63; and Staff Br. at 43–48.

The evidence supports that reflected beams of light from the probe of Sartorius's Anti-CHO HCP detection kit are coupled into the fiber of the Octet R8 instrument. Tr. (Bailey) at 585:21–586:12; and Tr. (Tan) at 297:22–25.

Sartorius has demonstrated that use of its Octet R8 instrument with a probe of its Anti-CHO HCP detection kit meets element [8G].

8. Element [8pre] and Element [8H]

The preamble of claim 8 recites a "method of assaying enzyme activity" and the last element of claim 8 recites "detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity." '887 patent, claim 8. Sartorius contends that these elements are met. Sartorius Br. at 42–43 and 56–58. Gator Bio disputes that these elements are met, as does the Staff. Gator Bio Reply at 59–60; and Staff Br. at 45–46.

The parties' arguments with respect to technical domestic industry as to element [8pre] and element [8H] are the same as those for these elements as to infringement. Gator Bio argues that the HRP used with the probe of its Anti-CHO detection kit causes the substrate to bind to the probe and increase its thickness. Sartorius Br. at 42–43 and 56–58. For the same reasons explained above

with respect to infringement, the evidence does not show that use the Sartorius Octet R8 instrument with the probe of its Anti-CHO HCP detection kit meets element [8pre] or element [8H].

IX. ASSIGNOR ESTOPPEL AND VALIDITY

Sartorius contends that assignor estoppel bars Gator Bio and the Staff[13] from asserting invalidity of claim 8, Sartorius Br. at 86–92, and asserts that if assignor estoppel does not apply, neither Gator Bio nor the Staff have demonstrated invalidity, Sartorius Reply at 18–42. Gator Bio asserts that assignor estoppel does not bar any of its invalidity arguments and asserts that claim 8 is invalid: (1) as obvious under 35 U.S.C. § 103; (2) under 35 U.S.C. § 112 as indefinite, not enabled, and for failure to comply with the written description requirement based on Sartorius's proposed construction of "air gap"; (3) under 35 U.S.C. § 101 for lack of utility and subject matter eligibility for the same reason; and (4) based on obviousness-type double patenting. Gator Bio Br. at 42–63; *see also* Gator Bio Reply at 70–71.

The Staff contends that assignor estoppel bars Gator Bio's invalidity defense under § 103 but does not bar Gator Bio's invalidity defenses under § 112 based on indefiniteness, lack of enablement, and lack of written description, does not bar Gator Bio's invalidity defense based on obviousness-type double patenting, and does not bar the Staff from asserting invalidity. Staff Br. at 55–61. The Staff does not take a position on whether assignor estoppel bars Gator Bio's invalidity defense under § 101. *See id*. The Staff also asserts that claim 8 is: (1) not invalid as obvious under § 103; (2) invalid under § 112 for indefiniteness, lack of written description, and

[13] While recognizing that the Commission has already held otherwise in this investigation, Sartorius also contends "for preservation purposes" that the "Staff may not assert invalidity where the sole respondent is barred by assignor estoppel." Sartorius Br. at 92.

lack of enablement based on Sartorius's proposed construction of "air gap;" (3) not invalid under § 101; and (4) not invalid for obviousness-type double patenting. Staff Br. at 48–55.

A. Legal Standard

Assignor estoppel is an equitable doctrine that "prevent[s] an assignor from warranting one thing and later alleging another" and "applies when an invalidity defense in an infringement suit conflicts with an explicit or implicit representation made in assigning patent rights." *Minerva Surgical, Inc. v. Hologic, Inc*., 141 S. Ct. 2298, 2311 (2021). Assignor estoppel prohibits one in privity with the assignor from challenging the validity of a patent when the assignee sues for infringement. *MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1379–80 (Fed. Cir. 2016).

Assignor estoppel is not without limits. The Supreme Court has "made clear that not every assignor defense in every case w[ill] fall within its scope." *Minerva*, 141 S. Ct. at 2309. Rather, assignor estoppel applies "only when its underlying principle of fair dealing comes into play," and it "go[es] only so far as, and not beyond, what [the assignor] represented in assigning the patent application." *Id.* at 2309–10. "[W]hen the assignor has made neither explicit nor implicit representations in conflict with an invalidity defense, then there is no unfairness in its assertion" and "so there is no ground for applying assignor estoppel." *Id.* at 2310.

Post-assignment developments can bear on the equities and demonstrate that principles of fair dealing do not warrant applying assignor estoppel. *Id*. One such development is a "change in patent claims," which "can remove the rationale for applying assignor estoppel." *Id.* Another is a change in the law such that an "inventor may claim that the patent is invalid in light of that change in law without contradicting [any] earlier representation." *Id.*

Assignor estoppel does not preclude a fact-finder from considering the state of the art and how it bears on the scope of the asserted patent claim. Otherwise, "a judge 'would be denied' the 'most satisfactory means' of 'reaching a just conclusion' about the patent's scope—a conclusion needed to resolve the infringement charge." *Id.* at 2306, *quoting Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co.*, 266 U.S. 342, 350–351 (1924).

B. Background Facts

Robert Zuk is the first-named inventor of the '887 patent. He joined FortéBio in 2004 and was the vice president of development, responsible for research and development of its probes, and worked on developing bio-layer interferometry devices, assays, and methods. Tr. (Zuk) at 383:15–19 and 437:21–24; and Tr. (Tan) at 333:12–13. Mr. Zuk left FortéBio in 2008 and co-founded Gator Bio in 2017 with Dr. Tan. Tr. (Zuk) at 383:23–384:11. He is Gator Bio's chief technology officer, responsible for research and development of its probes. Tr. (Zuk) at 381:11–17; and Tr. (Tan) at 285:20–24.

The '887 patent claims priority to provisional application no. 60/145,153, which was filed on January 19, 2005. '887 patent at cover. The provisional application[14] was titled "Enzyme Activity Measurements Using Bio-Layer Interferometry" and as filed, included claim 7, which recited:

[14] The parties did not provide provisional application no. 60/645,153 as an exhibit. It is available at: https://patentcenter.uspto.gov/applications/60645153/ifw/docs?application=.

[redacted]

7. A method for assaying enzyme activity, comprising:
providing an optical element coupled to a light source via a 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 positioned so that interference between a reflected beam from the proximal reflecting surface and a reflected beam from the distal reflecting surface varies as an enzyme substrate or portion thereof binds to the layer of analyte binding molecules, and wherein the reflected beams are coupled into the fiber;
exposing the optical element to a substrate reacted or reacting with an enzyme, whereby the substrate or a portion of the substrate binds to the layer of analyte binding molecules; and
detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity.

Mr. Zuk executed an assignment of provisional application no. 60/645,153 to FortéBio, Inc. on April 13, 2005, "[f]or good and valuable consideration, the receipt of which" was specifically acknowledged. CX-0001; and Complaint Ex. 23. Non-provisional application no. 11/326,689 was filed on January 6, 2006, and included the same claim 7 as the provisional application. JX-0006.23. Claim 7 of the '689 application was amended during prosecution as follows:

[redacted]

7. (Currently Amended) 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 ~~positioned so that interference between a reflected beam from the proximal reflecting surface and a reflected beam from the distal reflecting surface varies as an enzyme substrate or portion thereof binds to the layer of binding molecules, and wherein the reflected beams are coupled into the fiber~~;

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-0006.221. Following that amendment, application claim 7 issued as '887 patent claim 8. *Id*. at 441.

C. Gator Bio's Section 103 Invalidity Defense Is Estopped

Gator Bio argues that claim 8 is invalid as obvious under 35 U.S.C. § 103 based on a 2002 article of Sun (RX-0023) in view of a 2002 patent publication to Cunningham (RX-0074). Gator Bio Br. at 43–56; *see also id*. at 8–11. Gator Bio also relies on a 1995 publication to Yu (RX-0075). *Id*. at 11 and 54. Sartorius contends that assignor estoppel bars Gator Bio from asserting this invalidity defense. Sartorius Br. at 86–92. The Staff agrees. Staff Br. at 55–57.

Assignor estoppel "applies only when an inventor says one thing (explicitly or implicitly) in assigning a patent and the opposite in litigating against the patent's owner" but "absent that kind

[redacted]

of inconsistency, an invalidity defense raises no concern of fair dealing—so assignor estoppel has no place." *Minerva*, 141 S. Ct. at 2304, 2311. The doctrine must "stay attached to its equitable moorings." *Id*. at 2309.

Mr. Zuk at least implicitly represented that claim 7 of the '153 provisional application was valid when he assigned his rights in that application to FortéBio in April 2005 "[f]or good and valuable consideration, the receipt of which" was specifically acknowledged. CX-0001; and Complaint Ex. 23. *Minerva*, 141 S. Ct. at 2309; *see also id.* at 2310 ("[T]he original warranty need not be express; as we have explained, the assignment of specific patent claims carries with it an implied assurance."). Gator Bio now asserts that claim 8 (which issued from provisional application claim 7) is invalid.

As the Supreme Court explained in *Minerva*, if the assignor later raises an invalidity defense against the assigned patent, "the assignor disavows that implied warranty" and "breaches norms of equitable dealing." *Id.* at 2309 and 2310. The principle of fair dealing "demands consistency in representations about a patent's validity[.]" *Id.* at 2310. Contradiction in representations is what creates unfairness. *Id*. Such contradiction exists here because Mr. Zuk at least implicitly warranted the validity of provisional application claim when he assigned his rights to that application to FortéBio.

The examples of when an inventor's representation of validity may not contradict a later invalidity challenge identified in *Minerva* do not apply here. This was not an assignment of inchoate future rights. *Id*. at 2310. Nor has there been a change in the law that could have changed the obviousness arguments. *Id*. And Gator Bio does not contest that application claim 7 as assigned is materially broader than claim 8 as issued. *Id*.; *see* Sartorius Br. at 89–90 (arguing that assigned claims broader than claim 8); Gator Bio Br. at 61–63 (not addressing Sartorius's argument); Gator

[redacted]

Bio Reply at 70–71 (same); and Staff Br. at 56 (arguing that "Gator Bio has not challenged Sartorius' [sic] contention that the originally filed claims are broader than those that issued; therefore, Gator Bio tacitly concedes the point").

Gator Bio contends that "assignor estoppel does not bar Gator Bio's obviousness defense because it is "inextricably intertwined with the scope of the asserted claim and the wildly contradictory positions has taken both in this Investigation and in the related IPR of the '585 patent." Gator Bio Br. at 62. In particular, Gator Bio contends that Sartorius has taken inconsistent positions by arguing that: (1) the prior art in the '585 patent IPR corresponded to an unclaimed embodiment while asserting here that the same arrangement practices "nearly identical claim language;" (2) for purposes of infringement, nanoscale surface roughness meets the claimed "air gap" but arguing that the prior art does not disclose an "air gap;" and (3) methods using labeled reagents infringe while such methods are distinguished as prior art in the '887 patent. Gator Bio Br. at 62–63.

As to Gator Bio's first argument, as explained above, I disagree that Sartorius's arguments distinguishing the '585 patent claims, which contain a limitation wholly absent from claim 8 of the '887 patent, apply to claim 8 of the '887 patent. The language of claim 8 is not "nearly identical" to or even remotely close to the language of the '585 patent claims. Sartorius's arguments are, therefore, not "wildly contradictory," as Gator Bio contends.

As to Gator Bio's second argument, as also explained above, I have rejected Sartorius's proposed construction of "air gap" as essentially anyplace that air may be between the first optical element and the fiber. Nonetheless, considering the equities, I do not find Sartorius's argument that the prior art must explicitly teach the claimed air gap, Sartorius Br. at 23–26, as being made in bad faith or otherwise defeating the application of assignor estoppel. The same is true with

respect to Gator Bio's third argument. I do not find Sartorius's infringement arguments to be made in bad faith or to otherwise defeat the application of assignor estoppel.

Equity here supports that the assignor may not assert invalidity under § 103. In assigning the provisional application, Mr. Zuk at least implicitly warranted the validity of provisional application claim 7, which was identical to claim 7 of the non-provisional application, and which, following amendment, issued as claim 8. There is no question that application claim 7, which was subject to Mr. Zuk's implicit warrant of validity, was broader than claim 8 as issued.

Application of assignor estoppel to the alleged infringer, Gator Bio, requires that Gator Bio and the assignor, Mr. Zuk, be in privity. "Privity, like the doctrine of assignor estoppel itself, is determined upon a balance of the equities." *MAG Aerospace*, 816 F.3d at 1380, *quoting Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990). Whether the doctrine extends beyond the assignor to an alleged infringer "depend[s] on the equities dictated by the relationship between the inventor and [the alleged infringer] in light of the act of infringement." *Shamrock*, 903 F.2d at 793. "The closer that relationship, the more the equities will favor applying the doctrine to [the alleged infringer]." *Id.* In other words, what matters in deciding whether the assignor and the alleged infringer are in privity for purposes of assignor estoppel is how close their relationship is as it relates to the alleged infringement. Thus, the critical timing in determining privity is when the assignor and alleged infringer developed what is asserted to infringe. *See Intel Corp. v. Int'l Trade Comm'n*, 946 F.2d 821, 839 (Fed. Cir. 1991).

Gator Bio does not dispute that Mr. Zuk and Gator Bio are in privity. Gator Bio Br. at 61–63; and Gator Bio Reply at 70–71. Nor could it. There is no dispute that Mr. Zuk, the assignor, worked with Gator Bio on the development of its probes and assay methods. He has been and is currently Gator Bio's chief technology officer of Gator Bio and his chief responsibility is research

and development of Gator Bio's probes, Tr. (Zuk) at 381:11–17; and Tr. (Tan) at 285:20–24, like the title and role he had at FortéBio when he assigned the '153 provisional application. Tr. (Zuk) at 383:15–19 and 437:21–24. Based on the record evidence, I find that Mr. Zuk is in privity with Gator Bio such that the application of assignor estoppel extends to Gator Bio.

Based on the record evidence, and balancing the equities, I conclude that the doctrine of assignor estoppel precludes Gator Bio's obviousness defense under § 103.[15]

D. Gator Bio's Obviousness-Type Double Patenting Defense Is Estopped and Fails on the Merits

Gator Bio contends that claim 8 is invalid for obviousness-type double patenting based on claims 1 and 19 of the '547 patent in view of Cunningham. Gator Bio Br. at 56–60. Sartorius contends that this defense is estopped and that it fails on the merits. Sartorius Reply at 17 and 41–42. The Staff disagrees with Sartorius on estoppel, Staff Br. at 60, and contends that the defense fails on the merits, *id*. at 53–55.

"The prohibition against double patenting is a longstanding doctrine of patent law." *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014). It "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

The '547 patent, according to Gator Bio, expires in November 2024 while the '887 patent expires in July 2026. Gator Bio Br. at 57. By not filing a terminal disclaimer, disclaiming the term

[15] I agree with the Staff that Gator Bio may argue that Sartorius's arguments conflict with the state of the art and may argue narrower constructions based on the prior art. Staff Br. at 57; *see also Minerva*, 141 S. Ct. at 2306.

of the ’887 patent extending beyond that of the ’547 patent, Gator Bio contends that Sartorius is improperly extending the term of the ’887 patent. *Id*.

To assess obviousness-type double patenting, Gator Bio recognizes that the claims are construed and compared to determine whether “those differences render them patentably distinct.” *Id*. Notwithstanding that recognition, Gator Bio does not actually compare any language of claim 8 with language of claims 1 and 19 of the ’547 patent. Instead, Gator Bio provides a chart with just citations to the claim language. Gator Bio Br. at 58. The chart below compares the actual claim language based on Gator Bio’s citations:[16]

’887 patent claim 8	**’547 patent claims 1 and 19**
A method for assaying enzyme activity, comprising:[17]	Claim 1- An assembly for use in detecting an analyte in a sample based on interference, comprising:
[8A] - providing an optical element coupled to a light source via a mechanical coupling that engages the optical element with an optical fiber	15:12–15 (claim 1) - 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.
[8B] - provides an air gap between the first optical element and the fiber,	15:14–15 (claim 1) - an air gap between the first optical element and the fiber.
[8C] - the optical element including (a) a proximal reflecting surface and a distal reflecting surface	15:20–23 (claim 1); Fig. 4 - 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.
[8D] - separated by at least 50 nm, and	15:23–24 (claim 1) - said first and second reflecting surfaces separated by at least 50 nm.

[16] In citing claim elements ([8A], [8B], etc.) Gator Bio refers to RDX-0006C.0018 as identifying the claim language. Gator Bio Br. at 46, n.4.

[17] Gator Bio did not include the preamble language in its chart, Gator Bio Br. at 58, but contends that Cunningham teaches a method for assaying enzyme activity, as recited in the preamble of claim 8. Gator Bio Br. at 59.

[8E] - (b) a layer of analyte binding molecules;	15:24–26 (claim 1) - wherein said first reflecting surface comprises a layer of analyte binding molecules.
[8F] 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~~ analyte binding molecules,	15:26–29 (claim 1) - 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. 16:14–19 (claim 19) - A method for detecting analyte in a sample, comprising: providing the apparatus of claim 18 and a sample; exposing said first reflecting surface to said sample, and determining whether said exposure results in a change in optical thickness of said first reflecting surface.
[8G] the reflected beams coupled into the fiber; and	15:20–29 (claim 1) - 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.
[8H] detecting a change in optical thickness of the first reflecting surface, wherein the change is indicative of enzyme activity.	16:14–19 (claim 19) - A method for detecting analyte in a sample, comprising: providing the apparatus of claim 18 and a sample; exposing said first reflecting surface to said sample, and determining whether said exposure results in a change in optical thickness of said first reflecting surface.

See Gator Bio Br. at 58.

Comparing the actual claim language shows the significant differences between the ’887 and ’547 patent claims. This is seen primarily when comparing elements [8F] and [8H] of claim 8 with the portions of claims 1 and 19 the ’547 patent that Gator Bio cites. Nothing there corresponds

to "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" in element [8F] or that the change in optical thickness "is indicative of enzyme activity" in element [8H]. Instead, the '547 patent claims are directed to an assembly for detecting an analyte in a sample and recite components of that assembly. They are entirely silent with respect to enzyme activity. This is hardly surprising. The application that issued as the '547 patent was incorporated by reference into the '887 patent because of its disclosure of "assemblies and apparatus." '887 patent at 4:3–10; and '547 patent at cover. Only the later-filed '887 patent-related applications disclose methods of and examples for measuring enzyme activity.

Gator Bio recognizes that the '547 patent claims are silent with respect to enzyme activity, contending instead that one of ordinary skill in the art "would have been motivated to use the BLI sensor apparatus claimed by the '547 Patent to measure enzyme activity, as taught by Cunningham." Gator Bio Br. at 58. In doing so, Gator Bio argues that the motivation to combine it identified in arguing invalidity under § 103 applies to its obviousness-type double patenting defense. Gator Bio Br. at 58. In essence, therefore, Gator Bio makes the same arguments in asserting obviousness-type double patent that it makes in its obviousness defense under § 103. *See* Gator Bio Br. at 43–56. For the same reasons Gator Bio's § 103 defense is estopped, therefore, so is its obviousness-type double patenting defense.

Even if assignor estoppel does not apply, I find that claim 8 of the '887 patent is patentably distinct from claims 1 and 19 of the '547 patent. Claim 8 of the '887 patent recites "assaying enzyme activity," "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 "detecting a change in optical thickness of the first reflecting

surface, wherein the change is indicative of enzyme activity." Nothing relating to enzyme activity is recited or even remotely suggested in the '547 patent claims. Gator Bio's obviousness-type double patenting defense is therefore rejected.

E. Gator Bio and the Staff's Other Invalidity Defenses Are Moot

Gator Bio contends that claim 8 of the '887 patent is invalid for: (1) indefiniteness; (2) lack of written description; (3) lack of enablement; (4) lack of utility; and (5) lack of subject matter eligibility all based on Sartorius's proposed construction of "air gap." Gator Bio Br. at 42–43; *see also id*. at 61. The Staff agrees that under Sartorius's proposed construction, claim 8 is invalid for indefiniteness, lack of written description, and lack of enablement. Staff Br. at 51–52. The Staff disagrees that under Sartorius's proposed construction, claim 8 is invalid under 35 U.S.C. § 101. *Id*. at 53. These arguments are moot because I have not adopted Sartorius's proposed construction of "air gap."[18]

X. DOMESTIC INDUSTRY – ECONOMIC PRONG

Section 337(a)(3) identifies the following criteria for determining the existence of a domestic industry:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned --
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

[18] I specifically disagree that the Staff is precluded from contesting validity, as urged by Sartorius. Sartorius Br. at 92. The Commission has already stated that assignor estoppel does not bar the Staff from contesting validity. Comm'n Op. at 29 (Aug. 24, 2023).

19 U.S.C. §1337(a)(3).

Because the statutory criteria are listed in the disjunctive, satisfaction of any one of them is sufficient to meet the economic prong of the domestic industry requirement. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 26 (Feb. 17, 2011) (EDIS Doc. ID 444708); *InterDigital Communications, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1303, n.4 (Fed. Cir. 2013). Sartorius contends that it has substantial investment in plant and equipment under section 337(a)(3)(A) and in labor and capital under section 337(a)(3)(B). Sartorius Br. at 59–74. The Staff agrees. Staff Br. at 61–75. Gator Bio disagrees. Gator Bio Reply at 63–70.

As an initial matter, Gator Bio notes that Sartorius previously asserted that it also had an economic domestic industry under section 337(a)(3)(C), alleging [redacted] in qualifying expenditures. Gator Bio Reply at 63. Gator Bio suggests that because that expenditure is larger than those Sartorius identifies under sections 337(a)(3)(A) and 337(a)(3)(B), its expenditures under those latter sections are not significant. *Id*. Gator Bio cites no decisions supporting such an argument. I will therefore consider the evidence and arguments presented under sections 337(a)(3)(A) and 337(a)(3)(B) and not the argument Sartorius abandoned.

A. Sartorius's Business

Sartorius was founded in late 2019 to acquire assets from Danaher, including the Octet line of products,[19] comprising both instruments and probes. Tr. (Lessler) at 68:22–70:24. Sartorius's personnel is focused on design, development, manufacturing, research and development, quality

[19] The Octet line currently includes the Octet SF3 instrument (introduced in 2022), which is not a bio-layer interferometry instrument, and which has not been identified as a domestic industry instrument. *See* Tr. (Kang) at 127:11–128:2; Tr. (Barnabei) at 205:9–16; and Tr. (Bailey) at 629:3–14.

[redacted]

control, logistics, and engineering activities primarily with respect to Sartorius's Octet line of products. Tr. (Lessler) at 68:6–10; and Tr. (Barnabei) 204:11–205:16 and 212:14–213:22. Sartorius manufactures all of its Octet instruments, all Octet kits (including the anti-CHO HCP detection kit), and certain standalone Octet probes (e.g., the streptavidin and SAX2) in the United States at its Fremont facility. Tr. (Lessler) at 69:23–70:1; and Tr. (Barnabei) at 212:14–18, 216:2–5, 218:1–18, and 223:9–224:2. Most of Sartorius's standalone probes, that is, probes to which surface chemistry has not yet been added, are manufactured in Shanghai. Tr. (Lessler) at 70:21–24; Tr. (Barnabei) at 216:9–13 and 224:3–5 (approximately 5 percent of Sartorius's standalone probes are manufactured in Fremont). For such Shanghai-manufactured probes/kits, Sartorius performs the biocoating step in the United States. Tr. (Barnabei) at 218:1-18; and Tr. (Lessler) at 70:21–24. Sartorius is in the process of replicating its overseas probe manufacturing facility in the United States. Tr. (Barnabei) at 237:7–22; CPX-0034C; and Tr. (Kang) at 140:20–22. Sartorius performs all Octet research and development work in the United States. Tr. (Kang) 145:20–24; Tr. (Barnabei) 213:10–22, 215:13– 15; and Tr. (Schwartz) at 776:23–777:23.

Mr. Lessler described Sartorius's Fremont facility as follows:

> In 2019, when we did our first visit, it was a suite of about 40,000 square feet, mostly dedicated to manufacturing and product development, research and development activities. There was additional space allocated for office workers; so the purchasing team, customer service, some more customer-facing activities.
>
> Then in 2021, we leased an additional connecting suite, expanding it another 40,000 square feet, which ultimately opened in 2022, really for expanding product development of the Octet product line as well as some space dedicated, again, for more customer-facing, small showrooms, some application labs.

Tr. (Lessler) at 70:9–20.

Sartorius's product development team for its Octet line, including research and development, is located at its Fremont facility. Tr. (Kang) at 145:22–24; and Tr. (Lessler) 68:6–

[redacted]

10. Sartorius also performs quality control, warehousing, and logistics there. Tr. (Barnabei) at 213:4–13.

B. Sartorius's Allocations

Sartorius does not specifically track its expenses on a product-by-product basis and instead tracks expenses incurred at cost centers, which it identifies using eight-digit cost center codes. Sartorius Br. at 61; Tr. (Lessler) at 80:6–20, 83:16–22, 90:11–13, and 97:5–7. Sartorius's economic expert, Dr. Schwartz, relied on thirteen such cost centers, listed in the table below, in opining on Sartorius's cognizable investments in its domestic industry products. He considered those costs during what Sartorius calls the "DI Period," from May 2020, when Sartorius acquired the Octet line, through December 2022, a month after Sartorius filed its amended complaint. Sartorius Br. at 60; and Tr. (Lessler) at 68:22–69:2. Those cost centers are identified below:

- **Attachment C-1** (CX-0337C)
  DI Cost Centers Basis for Allocating to DI Products

Cost Center Number	Cost Center Description	Allocation Basis Description	
26401588	Cost of Sales - BioA	Net sales	→ COGS (materials costs)
26402401	Dir Lab Inst. FRE	Production output value (instruments)	Manufacturing Cost Centers
26402402	Dir Lab R&C FRE	Production output value (consumables)	
26402501	OPS OH Inst. FRE	Production output value (instruments)	
26402502	OPS OH R&C FRE	Production output value (consumables)	
26402503	OPS OH Quality	Production output value (instruments + consumables)	
26402505	Ops Mgt & Qlty FRE	Production output value (instruments + consumables)	
26402602	Purchasing/Whs FRE	Net sales	→ Purchasing/Distribution Cost Center
26405101	PD Management FRE	Project hours and net sales	Product Development Cost Centers
26405102	PD Assay FRE	Project hours and net sales	
26405103	PD Hardware FRE	Project hours and net sales	
26405104	PD Software FRE	Project hours and net sales	
26406501	Building FRE	Investments get allocated to cost centers above and then to DI Products	→ Fremont Building Cost Center (rent/building expenses)

CX-0337C; Tr. (Schwartz) at 755:17–757:11; *see also* CPX-0032C; CPX-0028C; CPX-0027C; CX-0158C; CX-0159C; CX-0160C; Tr. (Lessler) at 70:25–71:20 (regarding CPX-0032C, gross profitability report), 72:15–25 (same), 80:6–87:13 (regarding CPX-0028C, cost center report), 90:11–93:11 (regarding CPX-0027C, fixed asset register), 97:5–98:15 (regarding CX-0158C,

employee headcount report), 99:1–8 (regarding CX-0159C, employee headcount report), and 99:9–18 (regarding CX-0160C, employee headcount report).

Dr. Schwartz grouped the thirteen cost centers into five categories, which he color-coded to indicate the cost allocation methodology he used for that category: (1) cost of goods sold or materials (green); (2) manufacturing (blue); (3) purchasing/distribution (green); (4) product development (peach); and (5) rent and building expenses for the Fremont facility (red). Tr. (Schwartz) at 755:17–757:11. Commission precedent recognizes that different allocation methodologies may be appropriate. "[A] complainant is not obligated to use a particular allocation methodology." *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 65 (Aug. 23, 2021) (EDIS Doc. ID 750094). An allocation methodology may be appropriate to a complainant's circumstances "as supported by evidence in the record." *Certain Mobile Device Holders and Components Thereof*, Inv. No. 337-TA-1028, Comm'n Op. at 18 (Mar. 22, 2018) (EDIS Doc. ID 639588). "[A]ll that is required is the use of reasonable allocations for the purposes of establishing the economic prong of the domestic industry requirement." *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 21 (June 29, 2018) (EDIS Doc. ID 649139).

The allocation methodologies used in Sartorius's cost center groupings are addressed below.

1. Fremont Building Cost Center

The expenses of the Fremont building cost center, number 26406501, identified in red in CX-0337C above, were allocated to the other 12 cost centers that use those facilities. Tr. (Schwartz) at 757:4–7. That allocation was done according to actual headcount for 2020 (CX-

[redacted]

0158C) and planned headcount for 2021 and 2022 (CX-0159C and CX-0160C). Tr. (Lessler) at 97:5–98:15, 99:1–18, and 100:2–102:15; and Tr. (Schwartz) at 759:6–760:4. The allocation percentages for the Fremont building cost center to the other 12 cost centers is shown below:

Allocation Percentages for Fremont Building Cost Center (26406501) Investments

Cost Center Number	Cost Center Description	2020	2021	2022
SART/26401588	Cost of Sales - BioA	-	-	-
SART/26402401	Dir Lab Inst. FRE	13%	11%	18%
SART/26402402	Dir Lab R&C FRE	5%	7%	15%
SART/26402501	OPS OH Inst. FRE	1%	-	4%
SART/26402502	OPS OH R&C FRE	-	-	2%
SART/26402503	OPS OH Quality	6%	2%	-
SART/26402505	Ops Mgt & Qlty FRE	8%	11%	1%
SART/26402602	Purchasing/Whs FRE	12%	11%	14%
SART/26405101	PD Management FRE	2%	2%	2%
SART/26405102	PD Assay FRE	13%	14%	10%
SART/26405103	PD Hardware FRE	18%	24%	21%
SART/26405104	PD Software FRE	16%	16%	13%

CX-0338C; *see also* CPX-0028C; CPX-0061C; CX-0158C; CX-0159C; and CX-0160C.

2. Product Development Cost Centers

For the product development cost centers (26405101, 26405102, 26405103, and 26405104), identified in peach in CX-0337C above, Dr. Schwartz allocated by project hours, and then further allocated according to the net sales of the domestic industry products. Tr. (Schwartz) at 756:24–757:3. In particular, Dr. Schwartz considered hours reported by Sartorius employees to individual projects, identified products associated with each project, and then allocated to those products based on net sales. Tr. (Schwartz) at 766:19–768:2; CX-0343C; CX-0344C; CX-0345C; CX-0346C; and CX-0347C; *see also* CPX-0031C; CPX-0055C; and CPX-0056C.

[redacted]

The evidence shows that Sartorius's product development cost center employees logged 35,238 hours for March through December 2021 and 40,429 hours in 2022 on projects identified as relating to domestic industry products. Tr. (Schwartz) at 769:3–9; and CX-0343C. Dr. Schwartz allocated these investments as follows: (i) next-generation domestic industry instrument projects were allocated to that instrument (if launched between May 2020 and December 2022) and launched biosensors that could take advantage of the new instrument; (ii) new biosensor projects were allocated to that biosensor (if launched between May 2020 and December 2022) and existing launched domestic industry instruments with which the biosensor could be used; and (iii) general bio-layer interferometry projects, like software, were allocated between domestic industry products. CX-0344C; CX-0345C; CX-0346C; CX-0347C; Tr. (Schwartz) 768:3–769:2; Tr. (Kang) 153:11–19. Dr. Schwartz summarized the percentages he applied to allocate investments from the different cost centers to individual domestic industry products, as shown in the table below:

Attachment C-12
Allocation Percentages for DI Cost Centers to DI Products

Product Type	Product Name	Cost of Sales - 26401588	Dir Lab Inst. FRE 26402401	Dir Lab R&C FRE 26402402	OPS OH Inst. FRE 26402501	OPS OH R&C FRE 26402502	OPS OH Quality 26402503	Ops Mgt & Qlty FRE 26402505	Purchasing/ Whs FRE 26402502	PD Management 26405101	PD Assay FRE 26405102	PD Hardware 26405103	PD Software FRE 26405104
% allocated to DI products		93.4%	97.7%	50.1%	97.7%	50.1%	96.3%	96.3%	93.4%	7.9%	56.2%	42.5%	65.8%
% allocated to DI Instruments		76.3%	97.7%	-	97.7%	-	94.9%	94.9%	76.3%	6.4%	50.4%	14.2%	43.3%
% allocated to DI Biosensors		17.1%	-	50.1%	-	50.1%	1.4%	1.4%	17.1%	1.4%	5.8%	28.3%	22.5%
Instrument	HTX/RH96	18.9%	21.9%		21.9%		21.3%	21.3%	18.9%	1.6%	12.5%	3.5%	10.6%
Instrument	N1/BLItz	1.3%	1.6%		1.6%		1.6%	1.6%	1.3%	0.1%	0.9%	0.2%	0.7%
Instrument	QKe	0.9%	0.8%		0.8%		0.8%	0.8%	0.9%	0.1%	0.6%	0.2%	0.5%
Instrument	R2	2.8%	4.3%		4.3%		4.2%	4.2%	2.8%	0.2%	1.8%	0.5%	1.6%
Instrument	R4	3.6%	5.2%		5.2%		5.1%	5.1%	3.6%	0.3%	2.4%	0.7%	2.1%
Instrument	R8	24.4%	35.3%		35.3%		34.3%	34.3%	24.4%	2.1%	16.2%	4.6%	14.1%
Instrument	RED384/RH16	13.2%	16.6%		16.6%		16.2%	16.2%	13.2%	1.1%	8.7%	2.4%	7.4%
Instrument	RED96	0.1%	-		-		-	-	0.1%	0.0%	0.1%	0.0%	0.1%
Instrument	RED96e	11.1%	11.9%		11.9%		11.5%	11.5%	11.1%	0.9%	7.3%	2.0%	6.2%
Biosensors	Anti-AAVX (AAVX)	0.0%	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Biosensors	Anti-CHO HCP (CHO)	0.3%	-	-	-	-	-	-	0.3%	0.0%	0.1%	0.5%	0.4%
Biosensors	Anti-hIgG Fc Capture (AHC2)	0.2%	-	-	-	-	-	-	0.2%	0.0%	0.1%	0.2%	0.2%
Biosensors	Mannose Screening (GlyM)	0.0%	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Biosensors	Octet Amine Reactive 2nd Generation (AR2G)	0.7%	-	9.0%	-	9.0%	0.3%	0.3%	0.7%	0.1%	0.3%	1.2%	1.0%
Biosensors	Octet Aminopropylsilane (APS)	0.1%	-	-	-	-	-	-	0.1%	0.0%	0.0%	0.1%	0.1%
Biosensors	Octet Anti-Glutathione-S-Transferase (GST)	0.1%	-	-	-	-	-	-	0.1%	0.0%	0.0%	0.2%	0.1%
Biosensors	Octet Anti-HIS (HIS2)	0.4%	-	-	-	-	-	-	0.4%	0.0%	0.1%	0.6%	0.5%
Biosensors	Octet Anti-Human Fac-CH1 2nd Generation (FAB2G)	0.4%	-	-	-	-	-	-	0.4%	0.0%	0.1%	0.7%	0.5%
Biosensors	Octet Anti-Human Fc Capture (AHC)	1.9%	-	-	-	-	-	-	1.9%	0.2%	0.7%	3.2%	2.5%
Biosensors	Octet Anti-Human IgG Quantitation (AHQ)	0.3%	-	-	-	-	-	-	0.3%	0.0%	0.1%	0.5%	0.4%
Biosensors	Octet Anti-Mouse Fc Capture (AMC)	0.9%	-	-	-	-	-	-	0.9%	0.1%	0.3%	1.4%	1.1%
Biosensors	Octet Anti-murine IgG Quantitation (AMQ)	0.1%	-	-	-	-	-	-	0.1%	0.0%	0.0%	0.1%	0.1%
Biosensors	Octet Anti-Penta-HIS (HIS1K)	1.2%	-	-	-	-	-	-	1.2%	0.1%	0.4%	2.0%	1.6%
Biosensors	Octet High Precision Streptavidin (SAX)	1.5%	-	-	-	-	-	-	1.5%	0.1%	0.5%	2.5%	2.0%
Biosensors	Octet High Precision Streptavidin 2.0 (SAX2)	0.4%	-	27.8%	-	27.8%	0.8%	0.8%	0.4%	0.0%	0.1%	0.7%	0.5%
Biosensors	Octet Ni-NTA (NTA)	1.0%	-	-	-	-	-	-	1.0%	0.1%	0.3%	1.6%	1.3%
Biosensors	Octet Protein A (ProA)	2.8%	-	5.3%	-	5.3%	0.2%	0.2%	2.8%	0.2%	1.0%	4.7%	3.7%
Biosensors	Octet Protein G (ProG)	0.5%	-	-	-	-	-	-	0.5%	0.0%	0.2%	0.8%	0.6%
Biosensors	Octet Protein L (ProL)	0.1%	-	-	-	-	-	-	0.1%	0.0%	0.1%	0.2%	0.2%
Biosensors	Octet Super Streptavidin (SSA)	0.3%	-	-	-	-	-	-	0.3%	0.0%	0.1%	0.5%	0.4%
Biosensors	Residual Protein A (RPA)	0.1%	-	6.6%	-	6.6%	0.2%	0.2%	0.1%	0.0%	0.0%	0.2%	0.2%
Biosensors	Sialic Acid Screening (GlyS)	0.0%	-	1.3%	-	1.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
Biosensors	Streptavidin (SA)	3.8%	-	0.2%	-	0.2%	0.0%	0.0%	3.8%	0.3%	1.3%	6.4%	5.1%

CX-0348C; Tr. (Schwartz) at 769:10–20; and CDX-0003.30C.

3. Manufacturing Cost Centers

The allocations of manufacturing cost centers (26402401, 26402402, 26402501, 26402502, 26402503, and 26402505), identified in blue in CX-0337C above, were performed according to the value of the manufactured output. Tr. (Schwartz) at 756:18–23. Dr. Schwartz calculated the relative production output value of products manufactured in Fremont from May 2020 through December 2022. CX-0341C; CX-0342C; CDX-0003.20C; and Tr. (Schwartz) at 763:3–764:14. He multiplied the production units for each domestic industry product (CPX-0063C (instruments), CPX-0058C (probes/kits)) by Sartorius's average selling price for that product (CX-0340C), noting that "[t]he prices of consumables and instruments vary very greatly....So the way to put everything on a common foundation would be to do it in dollar terms." Tr. (Schwartz) at 764:1–9. Between May 2020 and December 2022, domestic industry instruments accounted for [redacted] (97.7%) of production output value of instruments manufactured at Fremont. *Id.*, 764:15–766:6; CX-0341C; and CDX-0003.21C.

The production output value for individual domestic industry instruments, as calculated by Dr. Schwartz, is shown below:

[redacted]

Production Output Value for DI Instruments: May 2020–December 2022

Product	May 2020 – December 2020	2021	2022	May 2020 – December 2022			
	Unit Output [A]	Unit Output [B]	Unit Output [C]	Unit Output [D]	ASP [E]	Output Value [F]	% of Total [G]
HTX/RH96	22	38	55	115	[redacted]		21.9%
N1/BLItz	51	62	77	190			1.6%
QKe	10	7	-	17			0.8%
R2	-	41	62	103			4.3%
R4	-	28	36	64			5.2%
R8	-	133	152	285			35.3%
RED384/RH16	30	46	60	136			16.6%
RED96	-	-	-	-			0.0%
RED96e	94	43	-	137			11.9%
Total Instrument DI Products	207	398	442	1,047			97.7%
Total instruments	249	429	466	1,144			100.0%

CX-0341C.

4. Cost of Sales Cost Center and Purchasing Cost Center

The cost of sales cost center (26401588) and the purchasing cost center (26402602), both identified in green in CX-0337C, above, were allocated based on relative net sales. Tr. (Schwartz) at 757:8–11. Dr. Schwartz used net sales to allocate these costs because sales are tracked as an activity in these cost centers. *Id.* at 766:12–14. Dr. Schwartz allocated the cognizable investment amount for the domestic industry products by allocating these cost centers according to sales of individual domestic industry products. *Id.* at 766:15–18.

Dr. Schwartz used Sartorius's sales data from May 2020 through December 2022 (CPX-0032C), which were primarily intercompany sales to Sartorius's customer-facing affiliates. Tr. (Lessler) at 71:3–20 (regarding CPX-0032C, gross profitability report), 72:10–25 (same), and 73:16–74:8 (describing intercompany sales as arm's length transactions managed by a group tax department and regularly audited); and Tr. (Barnabei), 244:12–18 (describing intercompany sales). Dr. Schwartz identified sales of Sartorius products as follows:

[redacted]

Summary of Sartorius Intercompany Net Sales of DI Products

Product Type	Product	May 2020 – Dec 2022			
		Net Sales [A]	Units [B]	ASP [C]	Net Sales % [D]
Instrument	HTX/RH96	[redacted]			18.9%
Instrument	N1/BLItz				1.3%
Instrument	QKe				0.9%
Instrument	R2				2.8%
Instrument	R4				3.6%
Instrument	R8				24.4%
Instrument	RED384/RH16				13.2%
Instrument	RED96				0.1%
Instrument	RED96e				11.1%
Biosensors	Anti-AAVX (AAVX)				0.0%
Biosensors	Anti-CHO HCP (CHO)				0.3%
Biosensors	Anti-hIgG Fc Capture (AHC2)				0.2%
Biosensors	Mannose Screening (GlyM)				0.0%
Biosensors	Octet Amine Reactive 2nd Generation (AR2G)				0.7%
Biosensors	Octet Aminopropylsilane (APS)				0.1%
Biosensors	Octet Anti-Glutathione-S-Transferase (GST)				0.1%
Biosensors	Octet Anti-HIS (HIS2)				0.4%
Biosensors	Octet Anti-Human Fac-CH1 2nd Generation (FAB2G)				0.4%
Biosensors	Octet Anti-Human Fc Capture (AHC)				1.9%
Biosensors	Octet Anti-Human IgG Quantitation (AHQ)				0.3%
Biosensors	Octet Anti-Mouse Fc Capture (AMC)				0.9%
Biosensors	Octet Anti-murine IgG Quantitation (AMQ)				0.1%
Biosensors	Octet Anti-Penta-HIS (HIS1K)				1.2%
Biosensors	Octet High Precision Streptavidin (SAX)				1.5%
Biosensors	Octet High Precision Streptavidin 2.0 (SAX2)				0.4%
Biosensors	Octet Ni-NTA (NTA)				1.0%
Biosensors	Octet Protein A (ProA)				2.8%
Biosensors	Octet Protein G (ProG)				0.5%
Biosensors	Octet Protein L (ProL)				0.1%
Biosensors	Octet Super Streptavidin (SSA)				0.3%
Biosensors	Residual Protein A (RPA)				0.1%
Biosensors	Sialic Acid Screening (GlyS)				0.0%
Biosensors	Streptavidin (SA)				3.8%
Total DI products					93.4%
Total products					100.0%

CX-0340C.

Dr. Schwartz identified sales of domestic industry products totaling [redacted] out of [redacted] or 93.4% of net sales. CX-340C; CPX-0032C; Tr. (Schwartz) at 755:1–15 and 766:7–18; CDX-0003.9C and 23C. Of those, Sartorius had sales of [redacted] of domestic industry instruments (76.3% of sales) and sales of [redacted] of its Anti-CHO HCP detection kit (0.3% of sales).

C. The Domestic Industry Probes/Kits

Gator Bio argues that Sartorius did not narrow its domestic industry products or claimed investments to account for narrowing of patents or products, making its claimed investments overbroad. Gator Bio Reply at 63 (citing Tr. (Schwartz) at 798:2–14; and Tr. (Vander Veen) at 516:1–8). As noted, Sartorius has not shown that its anti-CHO HCP detection kit is representative of its other probes that do not contain HRP. As a result, expenses for all of Sartorius's probes/kits should not be included when assessing economic domestic industry. In the analysis below, as to Sartorius's probes/kits, only expenses as to Sartorius's Anti-CHO HCP detection kit will be credited.

D. Plant and Equipment

Dr. Schwartz identified the following investments in plant and equipment: (1) domestic plant and equipment investments made by the Fremont building cost center; (2) direct plant and equipment investments made by the other 12 domestic industry cost centers (discussed above and shown in CX-0337C); and (3) plant and equipment investments relating to Sartorius's Project Vanguard. Tr. (Schwartz) at 757:12–24; CDX-0003.31C; CX-0349C; CX-0350C; CX-0351C; CX-0352C; CX-0363C; CX-0353C; and CX-0348C. Each is discussed in turn below.

1. Freemont Building Cost Center

Dr. Schwartz identified plant and equipment purchases by the Fremont Building Cost Center (26406501) from May 2020 through December 2022 attributable to buildings, lease improvement, machinery, equipment, and furniture, etc., and prepared the following table:

[redacted]

Plant & Equipment Purchases by Fremont Building Cost Center (26406501) (May 2020–December 2022)

Period	May 2020 – December 2022											
	131000 Land	131150 Buildings (RE-FX)	131300 Lease Improvements	131400 Machinery	131600 Equipment	131650 Equipment (RE-FX)	131700 Furniture	131900 Computer Equipment	132000 Other Electronics	132150 Vehicles (RE-FX)	139000 Down Payments	139100 AUC Tangible	Total
May 2020 – Dec 2020	[redacted]												
2021													
2022													
Total													

CX-0349C; CPX-0027C; Tr. (Schwartz) at 757:25–759:5; Tr. (Lessler) at 90:14–24; and CDX-0003C.0014. As shown, Dr. Schwartz identified [redacted] in plant and equipment purchases by the Fremont building cost center. As explained by Dr. Schwartz, these expenses include assets such as "the capitalized value of the leasehold, a dehumidifier system, and as well as the construction/buildout of the second building . . . at 47669 Fremont Boulevard." Tr. (Schwartz) at 758:22–759:2.

After identifying the [redacted] in purchases by the Fremont Building Cost Center, Dr. Schwartz then allocated this amount to the other 12 cost centers according to the percentages table below, using allocation percentages identified in CX-0338C, shown and discussed above. Tr. (Schwartz) at 759:15–19. This resulted in the following allocations of plant and equipment by the Fremont building cost center to the other 12 cost centers:

[redacted]

Allocation of Plant & Equipment Purchases by Fremont Building Cost Center (26406501) to DI Cost Centers

Description		May – Dec 2020	2021	2022	Total
P&E Investments by 26406501		[redacted]			
SART/26401588	Cost of Sales - BioA				
SART/26402401	Dir Lab Inst. FRE				
SART/26402402	Dir Lab R&C FRE				
SART/26402501	OPS OH Inst. FRE				
SART/26402502	OPS OH R&C FRE				
SART/26402503	OPS OH Quality				
SART/26402505	Ops Mgt & Qlty FRE				
SART/26402602	Purchasing/Whs FRE				
SART/26405101	PD Management FRE				
SART/26405102	PD Assay FRE				
SART/26405103	PD Hardware FRE				
SART/26405104	PD Software FRE				

CX-0350C; Tr. (Schwartz) at 760:6–16; and CDX-0003.17C.

Dr. Schwartz applied the allocation percentages in CX-0338C to the 12 cost centers to arrive at his calculation of what he asserted were Sartorius's cognizable investments in plant and equipment purchases of [redacted] in purchases allocated to the 12 cost centers. Tr. (Schwartz) at 760:10–16. Based on the percentages in CX-0348C, Dr. Schwartz allocated [redacted] in plant and equipment purchases to domestic industry products. Of that [redacted] was allocated to domestic industry instruments and [redacted] was allocated to what Dr. Schwartz identified as domestic industry probes/kits, as shown below.

[redacted]

Domestic P&E Investments Attributable to DI Products Summary

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
P&E purchases for Fremont building cost center (26406501)	[B]	
Direct P&E Purchases by DI Cost Centers	[C]	
Project Vanguard Allocation	[D]	
Amount allocated to DI Instruments	[E]	
P&E purchases for Fremont building cost center (26406501)	[F]	
Direct P&E Purchases by DI Cost Centers	[G]	
Project Vanguard Allocation	[H]	
Amount allocated to DI Biosensors	[I]	
P&E purchases for Fremont building cost center (26406501)	[J]	
Direct P&E Purchases by DI Cost Centers	[K]	
Project Vanguard Allocation	[L]	

CX-0354C and Tr. (Schwartz) at 754:9–19.

The evidence supports Dr. Schwartz's allocation of [redacted] to plant and equipment expenses of the Fremont building cost center expenses. Because not all of the Sartorius probes/kits that Dr. Schwartz considered are domestic industry products, the entirety of the [redacted] Dr. Schwartz identified cannot be credited. Dr. Schwartz, however, performed a product-specific breakdown of this allocation to each specific instrument and probe. That breakdown shows an allocation of [redacted] in plant and equipment purchases by the Fremont building cost center for Sartorius's Anti-CHO HCP detection kit. CX-0353C; and Tr. (Schwartz) at 770:4–23. The evidence supports that this amount is properly credited as a plant and equipment expense.

2. Domestic Industry Cost Centers

Dr. Schwartz next identified plant and equipment purchases made directly by the other 12 cost centers, totaling [redacted], as shown below:

[redacted]

Fremont Location Plant & Equipment Purchases by DI Cost Centers (May 2020–December 2022)

Cost Center Number	Cost Center Description	May 2020 – December 2022												
		131000 Land	131150 Buildings (RE-FX)	131300 Lease Improvements	131400 Machinery	131600 Equipment	131650 Equipment (RE-FX)	131700 Furniture	131900 Computer Equipment	132000 Other Electronics	132150 Vehicles (RE-FX)	139000 Down Payments	139100 AUC Tangible	Total
26401588	Cost of Sales - BioA	[redacted]												
26402401	Dir Lab Inst. FRE													
26402402	Dir Lab R&C FRE													
26402501	OPS OH Inst. FRE													
26402502	OPS OH R&C FRE													
26402503	OPS OH Quality													
26402505	Ops Mgt & Qlty FRE													
26402602	Purchasing/Whs FRE													
26405101	PD Management FRE													
26405102	PD Assay FRE													
26405103	PD Hardware FRE													
26405104	PD Software FRE													
Total														

Tr. (Schwartz) at 760:17–761:10; CX-0351C; CPX-0027C; and CDX-0003C.0018. These purchases included items such as refrigerators, freezers, incubators, and an ellipsometer. Tr. (Schwartz) at 761:11–17. Based on the product-specific allocations in CX-0348C, of that amount, Dr. Schwartz allocated [redacted] to domestic industry products for the other 12 cost centers. CX-0354C; CX-0348C. Of this, [redacted] was allocated to domestic industry instruments and [redacted] was allocated to what Dr. Schwartz identified as domestic industry probes/kits, as shown below:

Domestic P&E Investments Attributable to DI Products Summary

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
P&E purchases for Fremont building cost center (26406501)	[B]	
Direct P&E Purchases by DI Cost Centers	[C]	
Project Vanguard Allocation	[D]	
Amount allocated to DI Instruments	[E]	
P&E purchases for Fremont building cost center (26406501)	[F]	
Direct P&E Purchases by DI Cost Centers	[G]	
Project Vanguard Allocation	[H]	
Amount allocated to DI Biosensors	[I]	
P&E purchases for Fremont building cost center (26406501)	[J]	
Direct P&E Purchases by DI Cost Centers	[K]	
Project Vanguard Allocation	[L]	

CX-0354C. The evidence supports Dr. Schwartz's allocation of [redacted] as plant and equipment expenses of the other 12 cost centers relating to domestic industry instruments. Because Dr. Schwartz did not further allocate the [redacted] he attributed globally to probes/kits to the Anti-CHO HCP detection kit, I do not credit that amount.

3. **Project Vanguard**

The evidence shows that Sartorius has launched what it calls Project Vanguard, a new facility being built in Ann Arbor, Michigan. Tr. (Schwartz) at 777:7–10 and Tr. (Lessler) at 96:2–6 and 111:5–18. The charter for Project Vanguard is to transfer the capacity of manufacturing and finished goods of Octet R Series instruments to the Ann Arbor manufacturing site. Tr. (Barnabei) at 249:7–11 and CPX-0071C. For Project Vanguard, Dr. Schwartz identified [redacted] for the land and [redacted] for the buildout. Tr. (Schwartz) at 761:20–762:24; and CX-0352C. Based on the square footage expected to be used for instruments and probes, Dr. Schwartz allocated 1.9% of that investment to domestic industry products: [redacted] each for instruments and probes. Tr. (Schwartz) at 761:18–762:15; and Tr. (Barnabei) at 242:16–23. The evidence supports Dr. Schwartz's allocation of [redacted] as plant and equipment expenses of Vanguard Project allocated to domestic industry instruments. Because Dr. Schwartz did not further allocate the [redacted] he attributed globally to probes/kits to the Anti-CHO HCP detection kit, I do not credit that amount.

4. Total Investments in Plant and Equipment

The evidence supports that the following are properly allocated to Sartorius's plant and equipment expenses:

Plant and Equipment Activity	**Allocated Amount**
Domestic industry instruments (Fremont)	[redacted]

Domestic industry kit (Anti-CHO HCP)	[redacted]
Plant and equipment purchases (instruments)	[redacted]
Project Vanguard (instruments)	[redacted]
Total	[redacted]

For subsection (A), Sartorius has demonstrated investments reasonably allocated to domestic industry products as [redacted]. CX-0350C; CX-0351C; CX-0352C; CX-0353C; CX-0354C; and Tr. (Schwartz) at 754:4–19, 769:21–770:23, and 821:3–8.

E. Labor and Capital

Dr. Schwartz identified the following categories of investments in labor and capital: (1) domestic labor expenses made by the domestic industry cost centers; (2) rent/building expenses allocated from the Fremont building cost center to the other 12 cost centers; (3) costs associated with packaging/procurement/shipping activities performed at Fremont; and (4) direct materials purchases for raw materials used in the manufacturing activities at Fremont. Tr. (Schwartz) at 771:2–12. Each of these is addressed below.

1. Domestic Labor Expenses

With respect to domestic labor expenses made by the 12 domestic industry cost centers, Dr. Schwartz identified [redacted] in domestic labor expenses from Sartorius's cost center report (CPX-0028C):

[redacted]

Fremont Location Labor Expenses by DI Cost Centers (May 2020–December 2022)

Cost Center Number	Cost Center Description	May 2020 – December 2022				
		SARTSART_3500 Employee benefits ex	SARTSART_3850 Purchased services	SARTSART_944 Temp. Workforce	SARTSART_945 Services Procured (M	Total
26401588	Cost of Sales - BioA	[redacted]				
26402401	Dir Lab Inst. FRE					
26402402	Dir Lab R&C FRE					
26402501	OPS OH Inst. FRE					
26402502	OPS OH R&C FRE					
26402503	OPS OH Quality					
26402505	Ops Mgt & Qlty FRE					
26402602	Purchasing/Whs FRE					
26405101	PD Management FRE					
26405102	PD Assay FRE					
26405103	PD Hardware FRE					
26405104	PD Software FRE					
Total						

CX-0357C; and Tr. (Schwartz) at 771:15–24.

Based on the percentages identified in CX-0348C, Dr. Schwartz allocated [redacted] to domestic industry products of which [redacted] was allocated to domestic industry instruments and [redacted] was allocated to domestic industry probes, as shown below:

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
Fremont rent/building expenses	[B]	
Labor expenses	[C]	
Packaging/procurement/shipping expenses	[D]	
Direct materials purchases	[E]	
Amount allocated to DI Instruments	[F]	
Fremont rent/building expenses	[G]	
Labor expenses	[H]	
Packaging/procurement/shipping expenses	[I]	
Direct materials purchases	[J]	
Amount allocated to DI Biosensors	[K]	
Fremont rent/building expenses	[L]	
Labor expenses	[M]	
Packaging/procurement/shipping expenses	[N]	
Direct materials purchases	[O]	

[redacted]

CX-0360C.

Because expenses relating to only the anti-CHO HCP detection kit should be used in considering expenses allocated to probes/kits and Dr. Schwartz did not further allocate the probe/kit expenditures he determined globally and using Dr. Schwartz's calculations from CPX-0028C and CX-0348C, the properly allocated domestic labor expenses (attributable to domestic industry instruments) total [redacted]. CX-0360C.

2. Rent/Building Expenses from Fremont Building Cost Center

With respect to rent/building expenses, Dr. Schwartz allocated [redacted] in monthly expenses in rent and building expenses of the Fremont building cost center to the other 12 cost centers from March 2020 to December 2022. CX-0360C; CX-0356C; CPX-0028C; CPX-0061C; CX-0159C; CX-0160C; and Tr. (Schwartz) at 772:9–773:8 and 775:23–776:4.

Allocation of Rent/Building Expenses from Fremont Building Cost Center (26406501) to DI Cost Centers

Description		May – Dec 2020	2021	2022	Total
Rent/Building Expenses for 26406501		[redacted]			
SART/26401588	Cost of Sales - BioA				
SART/26402401	Dir Lab Inst. FRE				
SART/26402402	Dir Lab R&C FRE				
SART/26402501	OPS OH Inst. FRE				
SART/26402502	OPS OH R&C FRE				
SART/26402503	OPS OH Quality				
SART/26402505	Ops Mgt & Qlty FRE				
SART/26402602	Purchasing/Whs FRE				
SART/26405101	PD Management FRE				
SART/26405102	PD Assay FRE				
SART/26405103	PD Hardware FRE				
SART/26405104	PD Software FRE				

CX-0356C.

Gator Bio contends that there was potential double-counting of investments in fixed assets related to building expenses. Gator Bio Reply at 68. Dr. Schwartz explained, however, that he distinguished the rent and building expenses included in labor and capital from the capitalized values associated with plant and equipment. Tr. (Schwartz) at 772:14–18; *also compare* CPX-

0027C (capitalized expenses, e.g., "Fremont, CA Additional Space / Building Lease") *with* CPX-0028C (monthly expenses, e.g., "Rent Assessment"). The evidence shows, however, that Dr. Schwartz assigned the capitalized value of the leasehold to plant and equipment under subsection (A), *see* Tr. (Schwartz) at 758:22–759:2, and that the monthly payments for the lease were included under subsection (B), *see id.* at 772:14–18. *See Certain Gas Spring Nailer Products and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 79, n.17 (Apr. 28, 2020) (EDIS Doc. ID 709073), *vacated on other grounds*, *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369 (Fed. Cir. 2022). The evidence thus supports that there was no inappropriate double counting.

Based on the percentages identified in CX-0348C, Dr. Schwartz allocated [redacted] to domestic industry products of which [redacted] was allocated to domestic industry instruments and [redacted] was allocated to domestic industry probes, as shown below:

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
Fremont rent/building expenses	[B]	
Labor expenses	[C]	
Packaging/procurement/shipping expenses	[D]	
Direct materials purchases	[E]	
Amount allocated to DI Instruments	[F]	
Fremont rent/building expenses	[G]	
Labor expenses	[H]	
Packaging/procurement/shipping expenses	[I]	
Direct materials purchases	[J]	
Amount allocated to DI Biosensors	[K]	
Fremont rent/building expenses	[L]	
Labor expenses	[M]	
Packaging/procurement/shipping expenses	[N]	
Direct materials purchases	[O]	

CX-0360C.

As explained above, only the anti-CHO HCP detection kit should be used in calculating labor and employment expenses. Conservatively only accounting for domestic industry instruments and using Dr. Schwartz's calculations from CPX-0028C and CX-0348C, the allocated rent/building expenses allocated from the Fremont building cost center to the 12 other cost centers are [redacted]. Tr. (Schwartz) at 776:2–4; CX-0356C; CX-0338C; CX-0378C; CPX-0028C; CPX-0061C; CX-0159C; CX-0160C; and CX-0360C.

3. Packaging/Procurement/Shipping

With respect to packaging/procurement/shipping expenses, Dr. Schwartz identified [redacted] in expenses, as shown below:

Fremont Logistics and Direct Materials Expenses

Description	Source	Amount
Procurement/freight in expenses	[A]	[redacted]
Packaging/freight out expenses	[B]	
Direct materials costs for production (May 2020 through Feb 2021)	[C]	
Direct materials costs for production (March 2021 through Dec 2022, instruments only)	[D]	

CX-0358C (item [A] plus item [B]). Because those expenses were based on net sales, Dr. Schwartz used the allocation percentages from CX-0340C to allocate [redacted] to domestic industry products, of which [redacted] was allocated to domestic industry instruments and [redacted] was allocated to domestic industry probes/kits, as shown below:

[redacted]

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
Fremont rent/building expenses	[B]	
Labor expenses	[C]	
Packaging/procurement/shipping expenses	[D]	
Direct materials purchases	[E]	
Amount allocated to DI Instruments	[F]	
Fremont rent/building expenses	[G]	
Labor expenses	[H]	
Packaging/procurement/shipping expenses	[I]	
Direct materials purchases	[J]	
Amount allocated to DI Biosensors	[K]	
Fremont rent/building expenses	[L]	
Labor expenses	[M]	
Packaging/procurement/shipping expenses	[N]	
Direct materials purchases	[O]	

CX-0360C; Tr. (Schwartz) at 773:9–19; CPX-0028C; and CDX-0003C.36.

Because only the anti-CHO HCP detection kit should be used in calculating labor and employment expenses, only the [redacted] allocated to domestic industry instruments will be credited.

4. Direct Material Purchases

With respect to direct material purchases, Dr. Schwartz identified [redacted], as shown below:

Fremont Logistics and Direct Materials Expenses

Description	Source	Amount
Procurement/freight in expenses	[A]	[redacted]
Packaging/freight out expenses	[B]	
Direct materials costs for production (May 2020 through Feb 2021)	[C]	
Direct materials costs for production (March 2021 through Dec 2022, instruments only)	[D]	

[redacted]

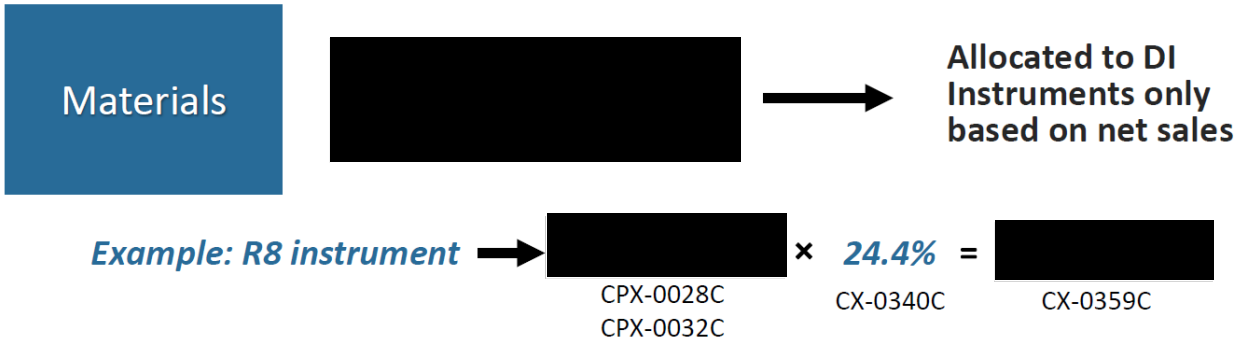
CX-0358C (item [C] plus item [D]); CPX-0028C; and CPX-0032C. Using the allocation percentages identified in CX-0340C based on net sales, Dr. Schwartz allocated [redacted] to domestic industry instruments, as shown below:

Description	Source	Value
Amount allocated to DI Products	[A]	[redacted]
Fremont rent/building expenses	[B]	
Labor expenses	[C]	
Packaging/procurement/shipping expenses	[D]	
Direct materials purchases	[E]	
Amount allocated to DI Instruments	[F]	
Fremont rent/building expenses	[G]	
Labor expenses	[H]	
Packaging/procurement/shipping expenses	[I]	
Direct materials purchases	[J]	
Amount allocated to DI Biosensors	[K]	
Fremont rent/building expenses	[L]	
Labor expenses	[M]	
Packaging/procurement/shipping expenses	[N]	
Direct materials purchases	[O]	

CX-0360C. Dr. Schwartz testified that "These costs were allocated to DI instruments only. Nothing to biosensors, just to the DI instruments. And the allocation was done on the basis of net sales." Tr. (Schwartz) at 773:25–774:2.

Dr. Schwartz used the demonstrative below to explain his calculation regarding the materials cost for the Octet R8.

[redacted]



CDX-0003.37C. As shown above, for the R8 alone, the materials cost amounted to [redacted]. CX-0359C. Adding the allocated materials costs for all domestic industry instruments (HTX/RH96, N1/Blitz, QKe, R2, R4, R8, RED384/RH16, RED96, and RED96e), CX-0359C, Dr. Schwartz arrived at a total value of [redacted], all attributable to domestic industry instruments. *See id*.

5. Investments in Labor and Capital

The evidence supports that the following are properly allocated to Sartorius's labor and capital expenses:

Labor and Capital Activity	**Allocated Amount**
Domestic labor expenses	[redacted]
Rent/Building expenses	[redacted]
Packaging/Procurement/Shipping Expenses	[redacted]

Direct Material Purchases	[redacted]
Total	[redacted]

As shown in the above table, Sartorius's allocated domestic labor and capital investments in the domestic industry products during the domestic industry period are [redacted]. CX-0360C; Tr. (Schwartz) at 775:14–776:21 and 821:3–8; CDX-0003.38C; and CX-0359C.

F. Gator Bio's Objections

Gator Bio's expert, Dr. Vander Veen, did not perform an independent analysis of Sartorius's economic domestic industry. Gator Bio, however, lodges various objections to Sartorius's analysis, many of them scattershot and several of them difficult to understand. Gator Bio Reply at 63–68. They are addressed below.

Gator Bio first contends that because Sartorius's "calculations are directed to all DI products, they are overstated." Gator Bio Reply at 64. As detailed above, however, to the extent not properly identified specifically with respect to Sartorius's Anti-CHO HCP detection kit, I have not credited expenses relating to probes/kits globally and have instead credited expenses to domestic industry instruments.

Gator Bio contends that certain investments in "sales, marketing, and IP" should be excluded, citing testimony of Dr. Vander Veen. Gator Bio Reply at 65. There, he testified:

> So we heard testimony from Mr. Lessler and Mr. Barnabei, I believe, that at least one of the R&D projects was a rebranding project, and that appeared to be a marketing project, a rebranding project, and that, I think, would fall within the category of a sales and marketing expenditure.

Tr. (Vander Veen) at 517:20–26.

Dr. Vander Veen, however, did not identify what costs should be excluded. Nor does Gator Bio. Gator Bio also cites (but does not explain the relevance of) testimony from Mr. Lessler. Gator

Bio Reply at 65, *citing* Tr. (Lessler) at 112:18–113:5. There, Mr. Lessler testified that tab 2022 of CPX-0028C at row 311 identified "patent expenses" and that he expected that those would include "patent applications and fees and things of that nature." That portion of CPX-0028C identifies patent expenses as part of cost center 26405101. CPX-0028C. Based on the allocation percentages in CX-0348C, Dr. Schwartz allocated [redacted] in 2022 to cost center 2640501. CX-0350C; and CDX-0003C.17. CX-0348 indicates that Dr. Schwartz allocated 6.4% from cost center 2640501. If the [redacted] in row 311 was included in the total that was then allocated, [redacted] would be deducted from the [redacted] allocated for cost center 26405101 for 2022. That amount, which Gator Bio does not even specifically identify, does not materially impact Dr. Schwartz's overall analysis. *Certain Stringed Musical Instruments and Components Thereof,* Inv. No. 337-TA-586, Comm'n Op. at 25–26 (May 16, 2008) (EDIS Doc. ID 300615) ("[T]here is no need to define or quantify the industry itself in absolute mathematical terms."); *Certain Movable Barrier Operator Sys. and Components Thereof,* Inv. No. 337-TA-1118, Comm'n Op. at 28 (Jan. 12, 2021) (EDIS Doc. ID 730303) (explaining that Commission precedent does not require a "precise accounting" of expenditures).

Gator Bio next contends that expenses relating to warehousing and distribution of probes that are manufactured in Shanghai should be excluded. Gator Bio Reply at 65–66, citing Tr. (Vander Veen) at 518:4–11. As noted above, however, expenses relating to probes have not been credited, except when specifically related to the Anti-CHO HCP detection kit, which as noted above, is manufactured in the United States and is properly identified as a domestic industry product.

Gator Bio also notes Commission precedent that sales and marketing activities may be indistinguishable from the activities of a mere importer. Gator Bio Reply at 66. The Commission,

however, has stated that "[w]hile marketing and sales activity, alone, may not be sufficient to meet the domestic industry test, those activities may be considered as part of the overall evaluation of whether or not a Complainant meets the economic prong." *Certain Solid State Storage Drives, Stacked Elec. Components, and Prods. Containing Same*, Inv. No. 337-TA-1097, Comm'n Op. at 22 (June 29, 2018) (EDIS Doc. ID 649139), *quoting Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Order No. 24 at 34 (Apr. 21, 2010).

Gator Bio next argues that Sartorius's [redacted] investment in raw materials, including cost of materials manufactured outside the United States, through cost centers SARTSART_941 and 26401588 are not reflective of domestic activities. Gator Bio Reply at 66–67, *citing* Tr. at (Lessler) at 114:15–115:15; Tr. (Vander Veen) at 518:16–519:9; and Tr. (Kang) at 216:6–218:6 (biosensors, instrument parts, hubs, tip trays, fiber optic bundles sourced from China). Raw material costs, however, are properly included when they are essential and fundamentally a part of the manufacturing process that leads to the finished instrument. *See Lelo Inc. v. Int'l Trade* Comm'n, 786 F.3d 879 at 884–85 (Fed. Cir. 2015) and Tr. (Schwartz) at 775:10–12. Dr. Schwartz testified that from an economic perspective, raw materials costs are important because they are used in the domestic manufacture of Sartorius's instruments. *Id.* at 774:16–23. Such costs are cognizable. *Certain Electrochemical Glucose Monitoring Sys. and Components Thereof*, Inv. No. 337-TA-1075, Order No. 32 (Initial Determination) at 7 (Jun. 22, 2018) (EDIS Doc. ID 648485) (finding raw material cost associated with manufacture, processing, and packaging cognizable), *modified on other grounds*, Comm'n Notice (Jul. 5, 2018) (EDIS Doc. ID 649481).

[redacted]

Gator Bio next contends that costs from "speculative projects" should be excluded. Gator Bio Reply at 67; *see also id*. at 68 (identifying "future facility").[20] Gator Bio does not identify Project Vanguard by name as such a project and does not specifically identify what expenses should be excluded. Gator Bio does include a citation to testimony from Dr. Vander Veen though it provides no explanation or argument as to that testimony. *Id*. at 67, *citing* 519:15–519:6 (which should presumably be 519:15–520:6). There, Dr. Vander Veen addressed Project Vanguard, stating, "[o]f course, we don't know exactly how that new facility is going to be used in relationship to the domestic industry products." Dr. Schwartz, however, testified about how the facility will be used and allocated expenses for that facility to Sartorius's domestic industry instruments. Dr. Schwartz also allocated expenses to domestic industry probes, but because only Sartorius's Anti-CHO detection kit is asserted as being used with respect to claim 8, those expenses have not been credited.

Gator Bio also cites testimony from Mr. Kang, arguing that it relates to a "speculative project." Gator Bio Reply at 67, *citing* Tr. (Kang) at 150:11–13. There, Mr. Kang testified that Project Hercules is an [redacted] Dr. Vander Veen testified that it was not clear that future products would "necessarily be domestic industry products." Tr. (Vander Veen) at 521:9–11. Dr. Schwartz testified that the RH16 and RH96 are domestic industry instruments, Tr. (Schwartz) at 820:2–4, and the evidence supports that

[20] Gator Bio also cites testimony it asserts is from Dr. Schwartz at "212:21–4" and contends that it supports that "no RED96 or RED96E instruments produced in DI period." Gator Bio Reply at 67. Gator Bio does explain its argument or identify what expenses should be excluded. And in the cited testimony, Mr. Barnabei testified that "[w]e also in Fremont do assay kits, reagent kits, you might call them, that are -- have a biosensor as a base. And then we put ancillary reagents around them to offer a turnkey approach to customers so they can run a specific assay turnkey." The testimony Gator Bio cites does not support the parenthetical for which it was offered.

testimony. CX-0340C and CPX-0032C. Indeed, Dr. Schaafsma (Gator Bio's technical expert) identified the RH16 and RH96 as domestic industry instruments. *See* RDX-0006.59. It stands to reason that the next generation of those products will also be domestic industry products and there is no evidence otherwise.

Gator Bio also cites to several pages of Dr. Schwartz's testimony, stating that certain projects were not released and that expenses related to probe development were allocated to existing instruments while expenses related to instrument development were allocated to existing probes. Gator Bio Reply at 67–68, *citing* Tr. (Schwartz) at Tr. 808:25–812:20. Gator Bio states that "taking project investments already devoted to a specific product and allocating them to entirely different products is not necessary or appropriate, particularly where the project product is not a DI product and does not yet exist." Gator Bio Reply at 67–68.

Gator Bio does not explain its argument (at all) and does not identify what expenses were improperly included based on Dr. Schwartz's testimony. As a result, I have no real way of assessing what if any argument Gator Bio is making. *See Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 90 and 92 (rejecting argument that pointed out statistics but provided no explanation). As far as can be understood from the argument Gator Bio *may* be making, Dr. Schwartz testified that in considering product development hours by project and cost center, in considering hours spent on development of next-generation instruments, he allocated costs to existing biosensors and for hours spent on development of next-generation biosensors, he allocated costs to existing instruments. Tr. (Schwartz) at 767:15–768:22. He testified that he did so because the probes and instruments operate as a system and that future instruments would operate with existing probes and future probes would operate with existing instruments. *Id*. Notwithstanding that Sartorius's Anti-CHO HCP detection kit is the only domestic

industry probe/kit, Dr. Schwartz's allocation methodology is sound. And Gator Bio provides no argument, evidence, expert analysis, or caselaw suggesting it is not.

Gator Bio also cites *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same II*, Inv. No. 337-TA-1073, Comm'n Op. at 7 (Aug. 12, 2019) (EDIS Doc. ID 684974) for the proposition that estimates of future sales are too speculative to be credited. Gator Bio Reply at 68. There, however, the Commission considered whether significant and unusual circumstances existed that would warrant "departing from the general rule that the domestic industry is assessed at the time of the filing of the complaint." That is not the case here. Sartorius relies on expenses incurred between May 2020 and December 2022, that latter date being just a month after Sartorius filed its amended complaint. Tr. (Schwartz) at 753:17–25. Further, while Sartorius relies on product development expenses (which will presumably result in future product sales), those expenses are not speculative, and the evidence supports that they relate to domestic industry instruments.

Gator Bio also relies on *Certain In-Line Roller Skates with Ventilated Boots and In-Line Roller Skates with Axle Aperture Plugs*, Inv. No. 337-TA-348, Order No. 10 (Jun. 30, 1993) for the proposition that a complainant's future intentions are not relevant to whether a domestic industry existed when the complaint was filed. Gator Bio Reply at 68. There, the ALJ denied discovery into the complainant's future plans to move functions outside the United States, finding such plans irrelevant. Here, by contrast, the evidence supports expenses already made by Sartorius to a facility it is building in the United States and Sartorius properly allocated a portion of those expenses to its domestic industry instruments.

Gator Bio's various objections do not impact the evidence demonstrating Sartorius's investments in plant and equipment or in labor and capital.

[redacted]

G. Significance of Sartorius's Investments

I find that Sartorius's investments in plant and equipment and labor and capital related to its domestic industry products are significant, both quantitatively and qualitatively. As Dr. Schwartz testified:

> Fremont is the critical location for all of the activities that are related to the DI products. Everything happens there.
>
> Moreover, during this period, [Sartorius] has expanded its domestic footprint. The additional facility at Fremont that we heard about yesterday, the construction that's ongoing in connection with Project Vanguard in Ann Arbor.
>
> The investments and employment of labor and capital, the same, basic story holds. The employees that are at Fremont are performing essential functions. They cover the full range of activities associated with the production of the DI products, ranging from the product design and the development through the manufacturing and the quality control process through the logistics of distribution -- of warehousing, storage, and distribution.
>
> So all of the functions happen there, and these investments are connected to that.
>
> All of the R&D work. All of the work that reflects investments in an ongoing DI industry, or domestic industry, also are done at Fremont.

Tr. (Schwartz) at 777:4–23; and CPX-0027C.

Sartorius's domestic industry instruments and its Anti-CHO HCP detection kit are designed, developed, and manufactured in the United States, at Sartorius's Fremont facility. *See* Tr. (Barnabei) at 212:16–213:9; Tr. (Schwartz) at 777:4–23. As Dr. Vander Veen testified, Sartorius's "assembly occurs in the United States." Tr. (Vander Veen) at 545:14–15.

[redacted]

With respect to quantitative significance, the evidence shows that production of domestic industry instruments increased over time from 207 in 2020 to 442 in 2022, or 83% of total instruments manufactured in 2020 to 95% in 2022. Tr. (Schwartz) at 765:6–14. The sales contribution of the domestic industry instruments represented more than three-quarters of Sartorius's sales. *Id.* at 778:11–14. More than two-thirds of the labor costs for the domestic industry instruments were incurred domestically. *Id.* at 778:15–17. Of Sartorius's plant and equipment investments, over 13.5% were attributable to the domestic industry instruments. CX-0353C; and CX-0366C. Of Sartorius's total domestic labor expenses, 27.2% were attributable to the domestic industry instruments. CX-0360C; and CX-0367C. Comparing Sartorius's domestic industry investments to its net sales of the domestic industry products [redacted], plant and equipment investments [redacted] were 3.75% of sales, and labor and capital investments [redacted] were 19.2% of sales. Tr. (Schwartz) at 779:7–18; CX-0340C; and CPX-0032C. These various comparisons demonstrate the quantitative significance of Sartorius's investments.

Gator Bio argues that Sartorius should not have used inter-company data for the denominator in comparing sales data. Gator Bio Reply at 69. However, Dr. Schwartz explained that intercompany sales are the proper measure to contextualize Sartorius's investments because "these are the sales that are made by SBAI."[21] Tr. (Schwartz) at 779:19–780:6; and Tr. (Lessler) at 73:16–25 (Sartorius makes only arm's length intercompany sales to affiliates). However, even accepting Gator Bio's proposed figure of [redacted], representing net sales to customers, Gator Bio Reply at 69, *citing* Tr. (Vander Veen) at 523:1–526:9, plant and equipment investments were 2.63% of customer sales, and labor and capital investments were 13.4% of customer sales. Even

[21] SBAI refers to Sartorius BioAnalytical Instruments, Inc., i.e., complainant Sartorius.

[redacted]

under the higher figure proposed by Gator Bio, Sartorius has demonstrated the quantitative significance of its investments in both plant and equipment and labor and capital. The evidence thus demonstrates that Sartorius's investments in the relevant domestic industry are significant, both quantitatively and qualitatively.

Gator Bio argues that Sartorius's domestic industry investments relate to non-practicing, non-HRP products and instruments that are overwhelmingly used in non-practicing ways, because the instruments are only alleged to practice claim 8 when used with the anti-CHO HCP detection kit, which only constitutes 0.3% of sales of Sartorius's products. Gator Bio Reply at 68–69.

Gator Bio cites *Certain Printing and Imaging Devices*, Inv. No. 337-TA-690, Comm'n Op. at 28 (Feb. 17, 2011) (EDIS Doc. ID 444708), but that reliance is inapt because there, the "complainant failed to submit evidence to substantiate the nature and significance of its activities with respect to the articles protected by the patent." *Id.* at 30 ("[C]omplainant submitted no evidence to show how its activities were important to the articles protected by the asserted patents in the context of the company's operations, the marketplace, or the industry in question, or whether complainant's undertakings had a direct bearing on the practice of the patent."). Here, as explained above, Sartorius has submitted substantial evidence demonstrating the nature and significance of its activities. In *Certain Printing and Imaging Devices*, the complainant's services and repairs were purely post-sale and there was no evidentiary proof that such activities added value to the imported articles. *Id.* at 33. Sartorius, however, has shown that its Fremont facility performs essential functions, ranging from product design and development through manufacturing and quality control. Tr. (Schwartz) at 777:3–23; and CPX-0027C.

Gator Bio's reliance on *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 42–43 (Aug. 1, 2007) (EDIS Doc. ID 279161) is likewise misplaced. Gator Bio

[redacted]

Reply at 69. There, the Administrative Law Judge found that the complainant had not demonstrated an industry in the United States when the goods at issue were substantially manufactured overseas but finished for production in the United States. Comm'n Op. at 45. In reversing the Administrative Law Judge on this issue, the Commission found that the complainant established a domestic industry because the unfinished imported products were "not saleable to the consumer as imported." *Id.* at 42. The complainant completed the manufacture of the goods, including the addition of components required for "the practice of certain patent claims." *Id.* There is no dispute here, however, that Sartorius's U.S. activities are directed to manufacturing domestic industry instruments and the Anti-CHO HCP detection kit used for allegedly practicing claim 8 of the '887 patent.

Gator Bio contends that Sartorius's investments are insignificant because they have substantial non-infringing uses, and Sartorius only asserts practice of the asserted claim when Sartorius's domestic industry instruments are used with its anti-CHO HCP detection kit. Gator Bio Reply at 68–69. *Certain Male Prophylactic Devices* does not support this proposition, however, because that case examined the nature of domestic and foreign manufacture when a product is substantially manufactured overseas and then finished in the United States.

Gator Bio also cites *Certain Concealed Cabinet Hinges and Mounting Plates* as supporting the Commission giving less weight to a complainant's investments relating to adding optional features to the imported product "[b]ecause of the indirect bearing on the patented features of the [product]." Gator Bio Reply at 69, *quoting* Inv. No. 337-TA-289, Comm'n Op. 1990 WL 10608981 at *11 (Jan. 8, 1990). In *Certain Cabinet Hinges*, however, "the only product covered by the [asserted patent], [was] not 'assembled' in the United States in accordance with the procedure described in the complaint." 1990 WL 10608981 at *3. The complaint described the

[redacted]

"assembly process" for the hinges at issue in general terms and asserted that such assembly included a dowel-addition procedure performed on fully-assembled hinges. *See id.* The dowel-addition procedure was not required, however, both because it was not performed on a substantial portion of the subject hinges, and because many of the complainant's customers performed the dowel-addition procedure themselves. *Id.* The Commission therefore found that "the subject wide-angle hinge is imported as a completed product." *Id.* at *11. That is not the case here, where Sartorius manufactures its instruments and its Anti-CHO HCP detection kit at its Fremont facility.

Gator Bio essentially argues that *Certain Cabinet Hinges* supports its contention that Sartorius's domestic industry should be discounted to the proportion of times that the instruments are in fact used with the anti-CHO HCP detection kit. However, "a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009). I decline to reduce the value of Sartorius's domestic investments as proposed by Gator Bio.

Gator Bio also cites *Certain Plastic Encapsulated Integrated Circuits* as supporting that the "significance inquiry included whether activities relate to something covered by the patent." Gator Bio Reply at 69, *citing* Inv. No. 337-TA-315, Initial Determination at 90, USITC Pub. No. 2574 (Nov. 1992). Like *Certain Cabinet Hinges* and *Certain Male Prophylactic Devices*, *Certain Plastic Encapsulated Integrated Circuits* addresses the issue of the location of production—whether the article protected by the patent was produced abroad or in the United States. *See id.* at 87–88. Indeed, the Administrative Law Judge in *Certain Plastic Encapsulated Integrated Circuits* contrasted the circumstances of that investigation with those of *Certain Cabinet Hinges* in finding cognizable domestic industry investments:

> The circumstances in this investigation are distinguishable from those in *Cabinet Hinges*. Here, TI practices the entire process claimed in the [asserted patent] in the United States. Unlike the product in *Cabinet Hinges* which was produced partially in the United States and partially overseas, an integrated circuit encapsulated by the [patented] process is not partially encapsulated overseas and partially encapsulated domestically. Rather, 100% of the value created by the encapsulation of an integrated circuit at the [facility] is created domestically. Accordingly, it is not possible to conduct a relative assessment of the importance of two segments of a single operation as was done in *Cabinet Hinges*.

Id. at 88–89. As in *Certain Plastic Encapsulated Integrated Circuits*, Sartorius manufactures its instruments in the United States, for use with its anti-CHO HCP detection kit that is also manufactured in the United States. Sartorius's manufacturing operations in the United States are directly related to activities alleged to be covered by the '887 patent.

I further find that Sartorius's domestic investments in plant and equipment and employment of labor and capital relating to its domestic industry instruments and Anti-CHO HCP detection kit are qualitatively significant. Sartorius's activities are core manufacturing activities that produce instruments and probes/kits that are alleged to perform the patented method. Such activities are consistently recognized as demonstrating an economic domestic industry. *Certain Toner Supply Containers and Components Thereof I*, Inv. No. 337-TA-1259, Comm'n Op. at 13 (Aug. 19, 2022) (EDIS Doc. ID 778370) (affirming finding of qualitative significance because complainant's activities "are core manufacturing activities that produce patented articles, converting parts and materials into saleable, useful products" and that "[s]uch activities have long been recognized as a domestic industry within the meaning of section 337").

Based on the evidence presented, I find that Sartorius has satisfied the economic prong of the domestic industry requirement under section 337(a)(3)(A) based on significant investments of at least [redacted] in plant and equipment related to the domestic industry products. *See* CX-0349C; CX-0350C; CX-0351C; CX-0352C; CX-0353C; CX-0354C; and Tr. (Schwartz) at 754:4–

19, 769:21–770:23, and 821:3–8. I further find that Sartorius has satisfied the economic prong of the domestic industry requirement under section 337(a)(3)(B) based upon significant investment of at least [redacted] in employment of labor and capital related to its domestic industry products. *See* CX-0360C; Tr. (Schwartz) at 775:14–776:21 and 821:3-8; CDX-0003.38C; and CX-0359C. The Staff agrees that these expenditures under sections 337(a)(3)(A) and (B) are significant. *See* Staff Br. at 74–75. In view of its significant expenditures related to the domestic industry products alleged to be covered by claim 8 of the '887 patent, I find that Sartorius has satisfied the economic domestic industry requirement under sections 337(a)(3)(A) and (B).

XI. CONCLUSIONS OF LAW

1. The Commission has statutory jurisdiction.

2. The Commission has personal jurisdiction over the parties.

3. The Commission has *in rem* jurisdiction over the accused instruments.

4. The Commission does not have *in rem* jurisdiction over the accused probes.

5. The importation requirement is satisfied for the accused instruments.

6. Claim 8 of the '887 patent has not been shown to be infringed.

7. Assignor estoppel bars Gator Bio's allegations of invalidity under 35 U.S.C. § 103.

8. Assignor estoppel bars Gator Bio's allegations of invalidity for obviousness-type double patenting.

9. Claim 8 of the '887 patent has not been shown to be invalid.

10. The technical prong of the domestic industry requirement has not been satisfied.

11. The economic prong of the domestic industry requirement has been satisfied.

XII. PUBLIC INTEREST

In the Notice of Investigation, the Commission directed me to take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest and provide the Commission with findings of fact and a recommended determination on this issue, limited to the statutory public interest factors in 19 U.S.C. § 1337(d)(1), (f)(1), and (g)(1). 87 Fed. Reg. 73330.

Before issuing a remedy for a violation of section 337, the Commission must consider the effect of the remedy on the following public interest factors: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) production of like or directly competitive articles in the United States; and (4) United States consumers. 19 U.S.C. §§ 1337(d)(1), (f)(1). The purpose of a public interest analysis is not to determine whether any of the parties is a bad actor, or whether a party's actions have harmed the public. The public interest analysis is also not an equitable defense to patent infringement. It is, instead, an element of the trade statute from which the Commission's authority is derived, one that the Commission is specifically required to consider whether or not any evidence is presented on the subject. *See Certain Hybrid Vehicles and Components Thereof*, Inv. No. 337-TA-688, Ltr. from ALJ Essex to Counsel of Record (Jan. 15, 2010) (EDIS Doc. No. 417576). Its purpose is to determine the effect of an exclusion order and/or cease and desist order on the four statutory public interest factors. 19 U.S.C. § 1337(d)(1). For the reasons discussed above, Sartorius has not established a section 337 violation. However, if a violation is found, public interest concerns warrant tailoring the imposed remedy.

The statute does not place the burden on any party to an investigation of proving that a public interest concern precludes a remedy or requires tailoring of a remedy. *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 29 (Jan. 10, 2020) (EDIS Doc. ID 698855). To

the extent that Sartorius suggests otherwise, the burden is not on Gator Bio with respect to public interest. Sartorius Br. at 77.

When the Commission delegates public interest to the ALJ, it has stated that it expects "the development of a fulsome evidentiary record on the public interest, especially direct evidence from the third parties in the United States that are likely to be impacted." *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 29–30. In particular, "where public interest is delegated to the ALJ, it is important, even if not technically required, that all parties to the proceeding—complainant, respondent, and OUII—seek factual information and statements from knowledgeable sources, including interested third parties, during fact discovery, and present this information and evidence subject to cross-examination and rebuttal at the hearing so that the ALJ's RD will provide a complete and reliable factual record on the statutory public interest considerations." *Id.* at 30, n.26. The parties here, however, did not offer into the evidentiary record before me any information or evidence from any third party relating to public interest. Nonetheless, as required, I consider below the issues and evidence presented by the parties in view of the four statutory public interest factors.

A. The Public Health and Welfare

Basic scientific research is "precisely the kind of activity intended by Congress to be included when it required the Commission to consider the effect of a remedy on the public health and welfare." *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 31, *quoting Certain Inclined-Field Acceleration Tubes and Components Thereof*, Inv. No. 337-TA-67, Comm'n Op. at 22, USITC Pub. No. 1119 (Dec. 1980) (EDIS Doc. ID 217920). The evidence supports that Gator Bio's instruments and probes are used for basic scientific research as well as a range of clinical and industry applications to develop new drugs, therapies, and diagnostics, including gene

[redacted]

therapy applications, antibody drugs, and COVID-19 research, some of which is funded by the government. Tr. (Zuk) at 393:8–397:25; Tr. (Vander Veen) at 499:3–500:13; and RX-0081–RX-0086; *see* Gator Bio Br. at 67–68.

Sartorius agrees that bio-layer interferometry is used for basic scientific research, Sartorius Br. at 79, but contends that Gator Bio's accused products are "not the kind the Commission has found to raise public health or welfare concerns" because they are not "necessary medical equipment" "or equipment needed for clinical diagnostics purposes." *Id*. at 78–79. Sartorius, however, describes its own bio-layer interferometry strategy as creating products "for protein characterization that help scientists accelerate development of vital medicines to cure diseases." CX-0412C.11. There is no reason that this is not also true with respect to Gator Bio's bio-layer interferometry instruments and probes and the evidence supports that it is.

The evidence thus supports that the public health and welfare may be impacted by remedial orders directed to Gator Bio's accused products. There is, however, no direct evidence in the record from any third party indicating whether or how their research or operations may be impacted by any remedial orders. That significantly differentiates this investigation from *Microfluidic Devices* in which the Commission considered extensive third-party evidence when tailoring relief based on the impact of remedial orders on public health and welfare. Comm'n Op. at 31–48. Such evidence simply does not exist here.

Both Gator Bio and the Staff argue the negative impact of the potential unavailability of Gator Bio probes/kits to existing research in arguing harm to the public health and welfare and other public interest factors. Gator Bio Br. at 70–72 (addressing AAV probes/kits, SA XT biosensors, and Flex SA biosensors/kits), 76–77 (quoting testimony from Dr. Vander Veen that Gator Bio's production in the United States "would certainly be reduced, potentially to zero, as

customers would no longer be able to purchase the biosensors"); Tr. (Vander Veen) at 510:14–511:4))[22]; and Staff Br. at 86. This concern, however, appears to be unwarranted. Commission remedial orders do not extend to domestically-manufactured, non-imported products, such as Gator Bio's probes/kits. *Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 77. There is no serious dispute here, and the evidence supports, that Gator Bio's accused probes/kits—indeed all of its probes/kits—are manufactured in the United States and are not imported. *See* section IV. Because a Commission remedy cannot reach such probes/kits, there is no public interest concern with respect to the availability of such probes/kits for ongoing research using existing Gator Bio instruments.

The issue, therefore, is the impact on the public health and welfare of potential remedial orders directed to Gator Bio's instruments. As to those instruments, Commission remedial orders will not reach previously-deployed instruments currently used for research (or other uses). And Gator Bio's domestically-manufactured probes/kits will continue to be available for use with those instruments, contrary to Gator Bio's assertion. Gator Bio Br. at 75.

The evidence shows that bio-layer interferometry is a two-player market—Sartorius and Gator Bio. Tr. (Tan) at 316:11–20; Tr. (Vander Veen) at 503:20–24; and Tr. (Schwartz) at 800:14–17. The evidence shows that Gator Bio is a relatively new entrant to the market and has around 5% market share. CX-0386C; and Tr. (Schwartz) at 801:9–16. The evidence also shows that Gator

[22] Gator Bio also argues that Sartorius's expert, Dr. Schwartz, admitted that "an exclusion order would . . . have the effect of limiting the accompanying Gator Bio's [sic] biosensors and consumables that Gator Bio develops and manufactures" in the United States. Gator Bio Br. at 76, *quoting* Tr. (Schwartz) at 803:2–12. For the reasons explained below, this argument is not supported by the record. It is also contradicted by Gator Bio's argument that Dr. Schwartz's testimony regarding any requested remedial orders should not be credited because Dr. Schwartz was "apparently unaware what remedial orders Sartorius seeks." Gator Bio Br. at 78.

[redacted]

Bio would not be eliminated from the market if remedial orders issue because Gator Bio offers bio-layer interferometry instruments (the GatorPivot and GatorPilot) that Sartorius has represented will not be included within the scope of any requested remedial order. Sartorius Reply at 53. ("Respondent/Staff completely ignore Respondent's introduction in October 2023 of two new instruments (GatorPilot and GatorPivot) that would not be impacted by the requested LEO, which means consumers can stay within Respondent's ecosystem if they so choose"); *see also* Tr. (Tan) at 293:20–294:2 and 354:20–355:4. Thus, even with a two-player market, the evidence supports relatively small harm to the public health and welfare because Gator Bio has such a small market share and because new customers will have certain Gator Bio instrument options available for their use along with the full suite of Gator Bio probes/kits for those instruments. *See Certain Two-Way Radio Equip. and Sys., Related Software and Components Thereof*, Inv. No. 337-TA-1053, Comm'n Op. at 42 (Dec. 18, 2018) (EDIS Doc. ID 664543) (noting small market share of respondent and ability of respondent to continue to supply the market as weighing against public interest concerns).

Gator Bio and the Staff focus on the fact that most uses of Gator Bio's instruments are not infringing because they are implemented with probes/kits that do not use HRP (and are thus not accused). Gator Bio Br. at 64 ("Sartorius seeks an LEO that would bar the importation of ***all*** Gator Bio instruments, even though the vast majority of their use is now for non-accused, non-infringing uses"); Staff Br. at 77–78 ("the overwhelming majority of uses of Gator Bio's instruments do not infringe because 19 of 23 Gator Bio probes are not accused and thus can be used with the Gator Bio instruments without infringement"). As Sartorius points out, however, such uses would continue unabated because existing users would continue to be able to use the Gator Bio instruments they have and would be able to acquire Gator Bio probes/kits for such uses. Sartorius

Br. at 80 ("Given the limited set of Accused Probes and their limited sales, there is no evidence any researcher, let alone any *specific* researcher, would need to replace their existing instrument.") In addition, as agreed by Sartorius, new users would be able to use the GatorPivot or GatorPilot instruments. Sartorius Reply at 53.

In addition, while Gator Bio argues potential harm because of the unavailability of the accused probes/kits for gene therapy research, it provides no evidence of such harm and itself recognizes that "[i]t is unclear whether Sartorius also seeks an LEO directed to biosensors or kits." Gator Bio Br. at 64, n.6; *see also* Gator Bio Br. at 70–71 (arguing harm because of lack of supposed alternatives for its HRP probes/kits used for gene therapy applications). But because those probes/kits are not imported and are instead manufactured in the United States, their continued use will not be impacted by remedial orders. Gator Bio and the Staff's arguments on harm to the public health and welfare as a result of unavailability of Gator Bio HRP probes/kits are therefore baseless.

As for existing Gator Bio instruments and the potential harm to public health and welfare, any harm to ongoing scientific research can be ameliorated by tailoring any remedial orders to allow for existing service, repair, and warranty provisions. The evidence supports the existence of such provisions and inclusion of an exemption for such activities will adequately protect existing users of Gator Bio's instruments with respect to any adverse impact on public health and welfare. Tr. (Tan) at 322:17–324:10; CX-0051C; CX-0437C; and CX-0449C.[23]

[23] Gator Bio also seeks an exemption for replacement of instruments, Gator Bio Br. at 80 and Gator Bio Reply at 74, but has not articulated exactly what replacement parts are necessary, what burdens and expenses would be imposed on third parties, or how long such an exemption would be necessary. *Certain Biometric Scanning Devices, Components Thereof, Associated Software, and Products Containing the Same*, Inv. No. 337-TA-720, Comm'n Op. at 26 (Nov. 10, 2011) (EDIS Doc. ID 463967). As a result, I recommend denying Gator Bio's request. *See* Staff Br. at 80.

[redacted]

Sartorius argues that there should be no such exemption because the specific provisions of Gator Bio's warranty and service contracts were not put into evidence. Sartorius Reply at 51–52. As noted, the evidence supports that such provisions exist. Given the public health and welfare concerns raised by existing Gator Bio customers potentially not being able to continue their scientific research, I recommend an exemption for service, repair, and warranty activities notwithstanding that the details of such provisions were not put into evidence with such exemption being limited to Gator Bio customer-specific provisions. *See Certain Optoelectronic Devices for Fiber Optic Communications, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-860, Comm'n Op. at 33–34, ITC Pub. No. 4852 (Nov. 2018) (EDIS Doc. ID 666446).

As for potential new Gator Bio customers, the evidence does not support harm to the public health or welfare that would suggest either not entering remedial orders or delaying entry of remedial orders, as proposed by both Gator Bio and the Staff. Gator Bio Br. at 81; and Staff Br. at 80. As noted, there is no direct evidence from any third party suggesting that such relief is necessary or appropriate. And though only certain uses of Gator Bio instruments are alleged to infringe, there is no record evidence supporting that the Commission should not issue remedial orders to address that infringement if a violation is found.

Further, the evidence supports that Sartorius offers reasonable alternative products to Gator Bio's instruments. Gator Bio does not dispute that Sartorius offers reasonable alternatives to its GatorPrime and GatorPro instruments. Gator Bio Br. at 72. Gator Bio does contend that Sartorius does not offer an alternative to its GatorPro instrument because "Sartorius does not offer an instrument with 32 spectrometers." *Id*. The evidence shows, however, that Sartorius's RH96 instrument can run the same number of samples as the GatorPro and can run up to 96 channels simultaneously. Tr. (Kang) at 166:12–167:13; Tr. (Bailey) at 633:2–7; Tr. (Schwartz) at 781:5–

25; and CX-0386C. Perfect available substitutes are not required, and the evidence shows that there is a reasonable alternative to the GatorPro. *Certain Access Control Sys. and Components Thereof*, Inv. No. 337-TA-1016, Comm'n Op. at 38–39 (Aug. 21, 2018) (EDIS Doc. ID 653484).

The evidence also supports that Sartorius has the capacity to make up for any exclusion of Gator Bio products from the market because of any remedial orders. Tr. (Barnabei) at 234:2–236:16 (Sartorius can increase its manufacturing capacity by adding shifts); Tr. (Schwartz) at 782:18–783:13; and CX-0164C; *see also* Tr. (Barnabei) at 230:6–25 ([redacted]); CPX-0050C (same); Tr. (Barnabei) at 221:13–222:7 (detailing Sartorius's [redacted]); CPX-0034C; and CPX-0063C. The evidence thus supports that if Gator Bio's accused instruments are subject to remedial orders, Sartorius could increase its production of like or directly competitive goods in the United States.

The evidence also supports that Sartorius offers reasonable alternatives to Gator Bio's probes/kits. *See* Sartorius Br. at 83–85. With respect to Gator Bio's AAV9 probe, the evidence supports that Sartorius offers an AAVX probe capable of detecting AAVP among other serotypes, Tr. (Bailey) at 659:12–20, and that users can customize Sartorius's SAX probe to any AAV serotype using Sartorius's application notes. Sartorius Br. at 85; CX-0516; Tr. (Bailey) at 659:23–660:11; and Tr. (Kang) at 169:1–24. In addition, the evidence demonstrates that Sartorius is [redacted] Tr. (Kang) at 162:19–25 and 191:21–24. For the SA XT and Flex SA probe/kit, customers can use Sartorius's streptavidin probe. Tr. (Kang) at 168:5–21; and Tr. (Bailey) at 658:5–662:20. The evidence also demonstrates that Sartorius provides customer support to assist users in creating custom assays as necessary and can do so within days or weeks.

Tr. (Kang) at 146:8–16 ("any specific customer requests" factors into what Sartorius's project development team works on), 156:7–9, 160:5–162:18, and 158:14–23; and CX-0502. As a result, the evidence supports that new customers will have available alternative Sartorius probes/kits.

Based on the record evidence I find that the public health and welfare in the U.S. will not adversely be affected by an exclusion order that allows for service, repair, and warranty activities for Gator Bio instruments purchased before the effective date of any remedial orders.

B. Competitive Conditions in the United States Economy

In assessing competitive conditions in the United States economy, a relevant inquiry is whether there are "reasonable substitutes for the devices subject to the exclusion order in terms of features, price points, and other pertinent factors." *Certain Electronic Digital Media Devices and Components Thereof*, Inv. No. 337-TA-796, Comm'n Op. at 120 (Sept. 6, 2013) (EDIS Doc. ID 517720). As noted above, the evidence supports that although bio-layer interferometry is a two-party market, Gator Bio's market share is quite small, and it would not be eliminated from the market if remedial orders issue. As a result, the two-party market will continue even if remedial orders issue, thus blunting any impact on competitive conditions in the United States economy. As also noted above, the evidence supports that reasonable alternatives exist from Sartorius for Gator Bio instruments that would be impacted by any remedial orders and for probes/kits used with such instruments. The evidence also supports that the price point differentials between Sartorius's instruments and Gator Bio's instruments are not so different as to harm competitive conditions in the United States economy. Gator Bio Br. at 74–75 ("Gato Bio's sales documents produced in this Investigation indicate that Gator Bio's instruments sold [redacted])" and *id*. at 75 ("The 2023 list prices (i.e., not discounted) of Sartorius' Octet R2, R4, and R8 are [redacted] respectively (or approximately [redacted], and

[redacted]);"[24] and CPX-0036C. Other evidence supports that the average sales price of Sartorius's R-8 instrument is [redacted] Tr. (Schwartz) at 789:3–790:7 and 790:12–791:15; CPX-0065C; CPX-0029C; and CX-0376C.

"[H]igher prices for the same, or analogous, products has not been deemed a basis for prohibiting issuance of an LEO or CDO," *Certain Two-Way Radio Equip.*, Inv. No. 337-TA-1053, Comm'n Op. at 44, especially where the complainant "sells systems at a range of price points." *Certain X-Ray Breast Imaging Devices and Components Thereof*, Inv. No. 337-TA-1063, Initial Determination at 291 (Sept. 13, 2018) (EDIS Doc. ID 655676). Sartorius has demonstrated that it offers replacement instruments at a range of price points. *See* Tr. (Kang) at 198:7–15. In addition, as noted, Gator Bio will continue to be able to sell its GatorPivot and GatorPilot instruments. Sartorius Reply at 53.

Based on the record evidence, I find that there is no evidence that the competitive conditions in the United States economy will be adversely affected by the issuance of remedial orders.

C. Production of Like or Directly Competitive Articles in the United States

As addressed previously, the evidence supports that certain Gator Bio bio-layer interferometry instruments will continue to be available, Gator Bio probes/kits will continue to be available, Sartorius provides reasonable alternatives to Gator Bio's instruments and probes/kits, and Sartorius has the manufacturing capacity to make up for any shortfall in the market due to any remedial orders directed to Gator Bio instruments. As a result, I find that there will be minimal or

[24] Gator Bio does not explain where it obtained its Euro/dollar exchange rate. *See* Gator Bio Br. at 75. As of March 6, 2024, the exchange rate is 1.0894 dollars/Euro. *Bloomberg*, available at https://www.bloomberg.com/quote/EURUSD:CUR?embedded-checkout=true. Using this conversion, those prices respectively are [redacted].

no impact on the production of like or directly competitive articles in the United States as a result of issuance of any remedial orders. *See, e.g.*, *Certain Crystalline Cefadroxil Monohydrate,* Inv. No. 337-TA-293, Comm'n Op. at 46, USITC Pub. No. 2391 (Jun. 1991) (EDIS Doc. ID 217255) (rejecting public interest argument where domestic supply was sufficient to meet demand).

D. United States Consumers

Gator Bio argues that "U.S. consumers would suffer significant harm if they were not permitted to purchase, use, or service Gator Bio BLI instruments and consumables." Gator Bio Br. at 73. As noted, Gator Bio's concern that its customers would not be able to use existing instruments is unwarranted. Commission remedial orders would not reach such instruments and would not reach Gator Bio's domestically-manufactured probes/kits used with such instruments. As a result, Gator Bio's arguments that its existing customers would have to purchase new Sartorius instruments and undergo validation procedures for such instruments are baseless. *See id.* at 73–75. Any concern with respect to United States consumers' use of existing Gator Bio instruments can be addressed by remedial orders allowing service, repair, and warranty activities with respect to such instruments. I therefore agree with Gator Bio and the Staff that any remedial orders should be tailored to allow for such services to protect the interests of United States consumers that purchased Gator Bio instruments before issuance of any remedial orders.

XIII. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission has broad discretion in selecting the form, scope, and extent of any remedy. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986); *see also Hyundai Electronics Industries Co. Ltd. v. Int'l Trade Comm'n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990). By Commission rule, the administrative law judge must issue a recommended determination on the appropriate remedy if the Commission finds a violation of section 337 and

on the amount of bond to be posted by respondents during Presidential review of any Commission remedy. *See* 19 C.F.R. § 210.42(a)(1)(ii). I address these issues below.

A. Limited Exclusion Order

Section 337(d)(1) provides that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). The Commission is required to issue an exclusion order upon the finding of a section 337 violation absent a finding that the effects of any of the statutorily-enumerated public interest factors counsel otherwise. *Spansion v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358 (Fed. Cir. 2010).

Because I do not find a violation of section 337, I do not recommend that a limited exclusion order should issue. However, if the Commission determines that a violation of section 337 has occurred, I recommend that the Commission issue a limited exclusion order barring entry of Gator Bio instruments that infringe claim 8 of the '887 patent.[25] As explained above, the effect of an exclusion order on the public interest factors does not counsel against such a remedy, but such a remedy should be tailored to allow for service, repair, and warranty activities with respect to instruments purchased before entry of any remedial orders.

[25] At Sartorius's request, such a limited exclusion order should specifically exclude the GatorPilot and GatorPivot instruments. Sartorius Reply at 53. ("Respondent/Staff completely ignore Respondent's introduction in October 2023 of two new instruments (GatorPilot and GatorPivot) that would not be impacted by the requested LEO, which means consumers can stay within Respondent's ecosystem if they so choose.").

[redacted]

Gator Bio argues that any limited exclusion order should include several exceptions. Gator Bio Br. at 79–81. First, Gator Bio requests an exception for products sold to or used by the United States Government, as set forth in 19 U.S.C. § 1337(l). *Id.* at 80. That provision states:

> Any exclusion from entry or order under subsection (d), (e), (f), (g), or (i), in cases based on a proceeding involving a patent, copyright, mask work, or design under subsection (a)(1), shall not apply to any articles imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.

19 U.S.C. § 1337(l). Recognizing that such a provision is typically present in Commission exclusion orders, I recommend inclusion of such a provision.

Second, Gator Bio argues that no remedy should reach Gator Bio's domestically-made probes/kits. Gator Bio Br. at 80. The evidence shows that Gator Bio manufactures its accused probes/kits in the United States. Tr. (Schwartz) at 815:9–15; and Tr. (Vander Veen) at 546:10–21. "[I]t is unnecessary to tailor the orders to carve out domestically-manufactured products because the Commission's [orders] apply only to imported products." *Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 77. I therefore recommend not including such a provision.

Third, Gator Bio requests an exemption for existing Gator Bio customers requiring products for continued research. Gator Bio Br. at 80, *citing Microfluidic Devices*, Comm'n Op. at 46–47. However, as discussed above, no evidence was presented from any third party demonstrating a documented need to continue receiving Gator Bio instruments. And since those instruments are expensive pieces of equipment sold in relatively small quantities and used over time to conduct research and experiments, there is no reason to expect that Gator Bio's customers would need a continuous supply of instruments to do their work. In *Microfluidic Devices*, scientists and medical researchers using the accused devices established that they had a documented need to

continue receiving those devices for their ongoing research and that no alternative products existed. *See Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 46. That is not the situation here. I therefore recommend not including such a provision.

Fourth, Gator Bio requests an exemption for service, repair, and warranty activities. Gator Bio Br. at 80–81, *citing* Tr. (Tan) 322:17–324:10; CX-0051C; CX-0437C; and CX-0449C. As discussed above, I find that public interest considerations support such an exemption.

Fifth, Gator Bio requests that any limited exclusion order include a certification provision. *Id.* at 81. The Commission has instructed that "[c]ertification provisions aid U.S. Customs and Border Protection (CBP) in enforcing Commission orders but 'do not mandate that CBP accept certification as proof that the articles in question are not covered' by the limited exclusion order." *Certain Robotic Vacuum Cleaning Devices and Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm'n Op. at 55 (Feb. 1, 2019) (EDIS Doc. ID 665703). "The standard provision does not allow an importer to simply certify that it is not violating the exclusion order. Rather, CBP only accepts a certification that the goods "have been previously determined by CBP or the Commission not to violate the exclusion order" and "it has been Commission practice for the past several years to include certification provisions in its exclusion orders to aid CBP." *Certain Road Milling Machines and Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 15 and n.5 (Aug. 7, 2019) (EDIS Doc. ID 684600) (citations omitted). I recommend that any limited exclusion order include the Commission's standard certification provision. I also recommend that such a certification provision specifically exclude the GatorPivot and GatorPilot instruments because Sartorius stated that they should be excluded from any limited exclusion order. Sartorius Reply at 53.

Gator Bio argues that the standard certification provision should be supplemented with an exemption for researchers for which an alternative product would not meet their needs. Gator Bio Br. at 81. Because there is no evidence from any third party that an alternative product would not meet their needs and because the record supports that Sartorius supplies reasonable alternatives to Gator Bio's products and can make up for any shortfall in the market, I do not recommend the additional certification provision requested by Gator Bio.

Finally, Gator Bio requests a delay in the effective date of any limited exclusion order for at least a period of 12 months to prevent any disruption in research efforts. According to Gator Bio, its consumers require this time to revalidate their systems and obtain funding for replacement products, and to mitigate the harm in the disruption to ongoing research. Gator Bio Br. at 81, *citing* Tr. (Vander Veen) at 508:10–21; and Tr. (Forrest) at 1065:2–8 (revalidation and delay can occur by months, if not, over a year). Because there is no third-party evidence supporting that such a delay is necessary and because of the continued availability of existing instruments and all of Gator Bio's domestically-manufactured probes/kits, I do not recommend any delay in the effective date of any limited exclusion order.

B. Cease and Desist Order

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for violation of section 337. 19 U.S.C. § 1337(f)(1). A cease and desist order is generally issued when a respondent maintains commercially significant inventories in the United States or has significant domestic operations that could undercut the remedy provided by an exclusion order. *Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 4–6 (Feb. 1, 2017) (EDIS Doc. ID 602496). "A complainant seeking a cease and desist

order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order." *Id*. at 5.

A standard cease and desist order prohibits certain conduct only with respect to "imported covered products." It cannot, on its face, extend to products not imported. *See Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 77 (holding that remedial orders do not extend to domestically-manufactured, non-imported products because "the Commission's [exclusion order] and CDOs apply only to imported products."). As a result, because they are not imported, no cease and desist order should issue with respect to any Gator Bio probes/kits.

The parties stipulated that Gator Bio maintains the following domestic industry of accused instruments:

[redacted]

Stipulation on Importation, Sale, and Inventory, at p. 3, ¶ 5 and Ex. A. Sartorius argues that Gator Bio's stipulated inventory of [redacted] is commercially significant. Sartorius Br. at 75–76, *citing* Tr. (Schwartz) at 792:19–793:7.

Despite that stipulation, Sartorius argues that Gator Bio maintains a commercially significant domestic inventory of [redacted]. *Id*. at 75–76, *citing*

Tr. (Schwartz) at 791:16–792:18; CX-0377C; CX-0384C; CPX-0065C; and CX-0098C. Gator Bio argues that Sartorius's identification of [redacted] in inventory is overstated because many of them are unsellable. Gator Bio Reply at 71–72.

Considering just [redacted] Gator Bio instruments that the parties stipulated are in inventory in the United States, I find that Gator Bio maintains a commercially significant inventory in the United States. *See* Tr. (Schwartz) at 792:19–793:7 (16 Gator Bio instruments in inventory represents "months of potential sales"); and Stipulation on Importation, Sale, and Inventory, at p. 3, ¶ 5 and Ex. A. The evidence supports that the stipulated inventory of Gator Bio instruments is commercially significant.

The Staff argues that the Commission should issue a cease and desist order against the four accused Gator Bio probes/kits, even though they are not imported. Staff Br. at 81–82. While recognizing that it is against Commission practice to prohibit Gator Bio from selling its domestically-produced accused sensors, the Staff argues that such a remedy would eliminate the specific infringement that is alleged to occur when those probes are used with the accused instruments. *See id.*, *citing Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 77; *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 4–6 ("A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order"). The Staff argues that a cease and desist order should not be issued against Gator Bio's accused instruments because of their substantial non-infringing uses. *See id.*

The Staff's position is untenable. *See Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1341 (Fed. Cir. 2015) ("If a violation of [section 337] is found, the Commission issues an exclusion

order that bars the importation of some or all of the infringing products and may issue a related cease and desist order unless the Commission finds that certain public interest factors militate against such remedy."). In particular, the Commission has rejected the position that non-infringing uses prevent issuance of a limited exclusion order. *Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Comm'n Op. at 83 ("To the extent the Respondents urge the Commission to exclude their accused products [from remedial orders] because they have substantial non-infringing uses, such a request is contrary to Commission practice."). In addition, Commission remedial orders are directed to imported products and do not reach domestically-manufactured, non-imported products such as Gator Bio's probes/kits.

If the Commission finds a violation of section 337, I recommend issuance of a cease and desist order prohibiting Gator Bio from selling its accused instruments from inventory. I further recommend that any cease and desist order exempt service, repair, and warranty activities associated with Gator Bio instruments purchased before the effective date of such cease and desist order.

C. Bond During Presidential Review

When the Commission enters an exclusion order or a cease and desist order, a respondent may continue to import and sell its products during the 60-day Presidential review period under an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3); and *Certain Automated Put Walls and Automated Storage and Retrieval Systems, Associated Control Software, and Component Parts Thereof*, Inv. No. 337-TA-1293, Comm'n Op. at 46 (Aug. 17, 2023) (EDIS Doc. ID 802614). Sartorius bears the burden of establishing the need for a bond. *Automated Put Walls*, Inv. No. 337-TA-1293, Comm'n Op. at 47.

When reliable price information is in the record, the Commission often sets the bond by eliminating the differential between the domestic product and the imported product. *Id.* at 46. The Commission may also use a reasonable royalty rate to set the bond amount where one can be determined from the record. *Id*. Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a [redacted]. *Id*.

Because Gator Bio's probes/kits are not imported, no bond should be set for those products. As for Gator Bio's accused instruments, Sartorius argues that a [redacted] bond is appropriate for the GatorPrime and a [redacted] bond is appropriate for the GatorPlus, based on the average sales price to consumers of the GatorPrime [redacted], GatorPlus [redacted], and Sartorius's comparable R8 instrument [redacted]. Sartorius Br. at 76, *citing* Tr. (Schwartz) at 789:3–790:7 and 790:12–791:15; CPX-0065C; CPX-0029C; and CX-0376C. The Staff agrees. Staff Br. at 84. Sartorius also argues that a [redacted] bond is appropriate for the GatorPro based on the average sales price to consumers of the comparable RH96 instrument. *Id.* at 77, *citing* Tr. (Tan) at 348:12–349:1; Tr. (Schwartz) at 790:12–791:15; and CX-0370C. The Staff agrees. Staff Br. at 84.

Gator Bio argues that Sartorius overstates its prices, rendering its price differentials unreliable. Gator Bio Reply at 75–76. Gator Bio's expert, however, did not dispute Sartorius's analysis at the hearing and did not provide any opinion on bond. Tr. (Vander Veen) at 532:18–25.

The evidence supports that a [redacted] bond is appropriate for the GatorPrime, and a [redacted] bond is appropriate for the GatorPlus, based on the average sales price to consumers of the GatorPrime [redacted], GatorPlus [redacted], and Sartorius's comparable R8 instrument [redacted]. Tr. (Schwartz) at 789:3–790:7 and 790:12–791:15; CPX-0065C; CPX-0029C; and CX-0376C. As for the GatorPro instrument, a [redacted] bond is appropriate based on the average sales

price to consumers of the comparable RH96 instrument. Tr. (Schwartz) at 790:12–791:15; Tr. (Tan) at 348:23–349:13; and CX-0370C.

XIV. INITIAL DETERMINATION ON VIOLATION

It is my initial determination that a violation of section 337 of the Tariff Act, as amended, has not occurred by the importation into the United States, the sale for importation, or the sale within the United States after importation of certain bio-layer interferometers and components thereof based on infringement of U.S. Patent No. 7,445,887. I hereby certify this Initial Determination and Recommended Determination to the Commission.

The Secretary shall serve the confidential version of this Initial Determination and Recommended Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served on all parties of record later.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review under 19 C.F.R. § 210.43(a) or the Commission orders on its own motion a review of the Initial Determination or certain issues therein under 19 C.F.R. § 210.44.

XV. ORDER

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). The proposed redactions should be made electronically, in a single PDF file using the "Redact Tool" within Adobe Acrobat. The proposed redactions should be submitted as

[redacted]

"marked" but not yet "applied." The proposed redactions should be submitted via email to JohnsonHines1344@usitc.gov and not filed on EDIS.

SO ORDERED.

Doris Johnson Hines
Administrative Law Judge

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, Secretary, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the Commission Investigative Attorney, **Paul Gennari, Esq.**, and the following parties as indicated, on **March 8, 2024**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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