

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.

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.

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,

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

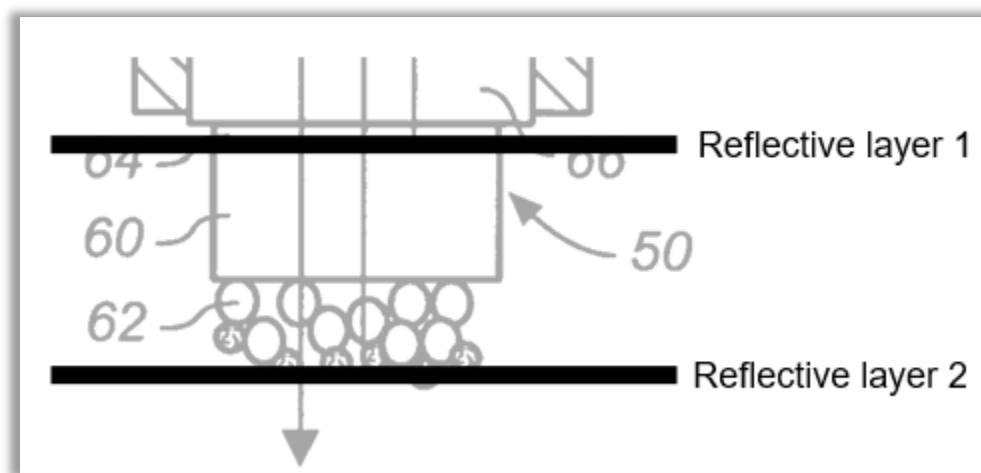
Sartorius is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 565 Johnson Avenue, Bohemia, New York, 11716. Amended Complaint, ¶ 24. Sartorius was incorporated on December 2, 2019. *Id.* Sartorius is a subsidiary of Sartorius AG, the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



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.

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.

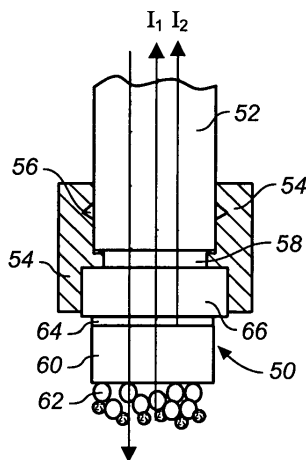
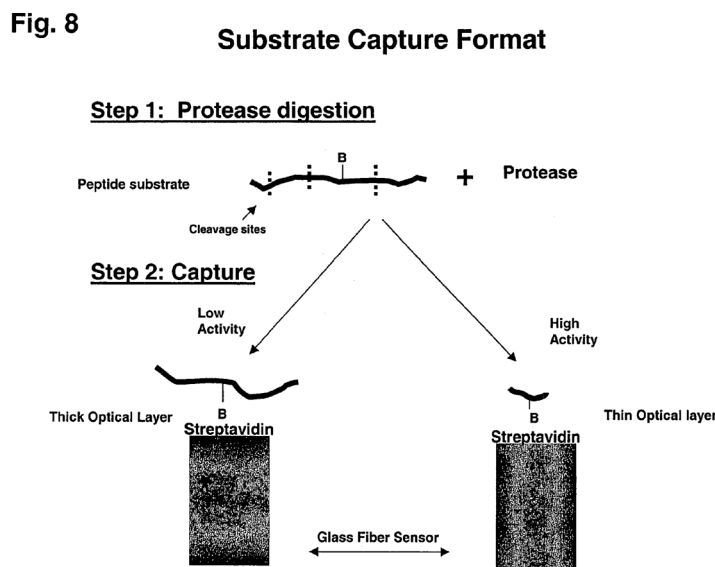


FIG. 4

'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.

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.,

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.

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:



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]

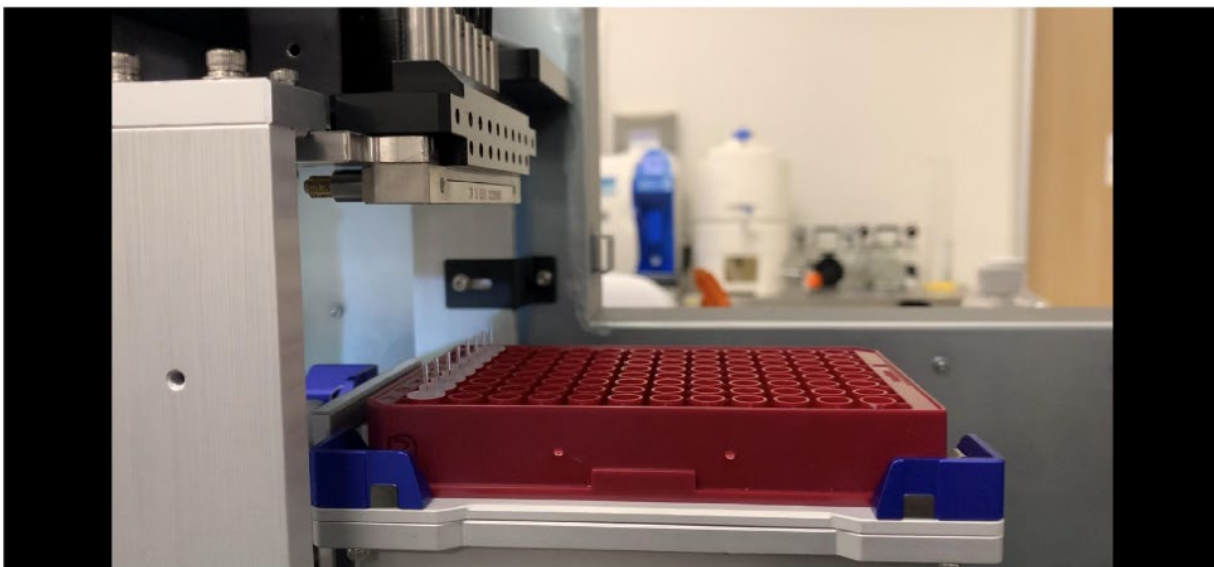
Claim 8 recites “a method for assaying enzyme activity.” Because the analysis of element [8pre] is related to the analysis of element [8H], I address the preamble with element [8H].

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]

[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:

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

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.

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.

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

);”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

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

“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