

***PUBLIC VERSION***

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

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

**In The Matter Of**

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

**Investigation No. 337-TA-1344**

**THE COMMISSION INVESTIGATIVE STAFF'S INITIAL  
POSTHEARING BRIEF**

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Staff's Pre-Hearing Brief and Statement (337-1344)

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**I. INTRODUCTION**

In accordance with the procedural schedule issued in Order No. 29 and with Ground Rule 14, the Commission Investigative Staff (“Staff”) respectfully submits this initial posthearing brief. For the reasons set forth below, the evidence does not show that a Section 337 violation has occurred.

**A. Procedural History**

Complainant Sartorius Bioanalytical Instruments, Inc. (“Complainant” or “Sartorius”) filed a complaint on October 25, 2022 (*see* 86 Fed. Reg. 65824), and Sartorius amended the complaint on the same day. *See* EDIS Doc. ID 784388 (the “Complaint”). The sole Respondent named in the Complaint is Gator Bio, Inc. (“Respondent” or “Gator Bio”). Compl. at ¶ 18.

The Commission instituted the Investigation on all grounds on November 11, 2022. *See* 87 Fed. Reg. 73329 (Nov. 29, 2022); Notice of Institution of Investigation (“NOI”), EDIS Doc. ID 785140 (Nov. 11, 2022).

The Complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, 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 by reason of the infringement of certain claims of U.S. Patent No. 7,394,547 (“the ’547 patent”); U.S. Patent No. 7,445,887 (“the ’887 patent”); U.S. Patent No. 7,728,982 (“the ’982 patent”); and U.S. Patent No. 8,305,585 (“the ’585 patent”). *See* NOI, at 1.

On January 20, 2023, Gator Bio moved, pursuant to 19 U.S.C. § 1337(c) and 19 C.F.R. § 210.21(c), to partially terminate this Investigation as to certain products that contain a “registration plate” (referred to herein as the “Registration Plate Instruments”) based on a consent order. *See* Motion Dkt. No. 1344-003. That motion was granted on February 24, 2023, *See* Order No. 8 (“ID”); EDIS Doc. ID 793046 (Consent Order). On March 23, 2023, the

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“simply claimed that it was impossible to conduct a price differential analysis” and “should not benefit from a lack of any effort to identify” relevant pricing information).

The evidence shows that a [REDACTED] is appropriate for the GatorPrime and a [REDACTED] bond is appropriate for the GatorPlus, based on the ASP to consumers of the GatorPrime [REDACTED] GatorPlus [REDACTED] and Complainant’s purported comparable R-8 [REDACTED] instruments. Tr. (Schwartz) 789:3-790:7, 790:12-791:15; CPX- 0065C, CPX-0029C, CX-0376C. Respondent’s economist did not contest this analysis. Tr. (Vander Veen) 532:18-25.

As for the GatorPro instrument, the evidence showed that Gator Bio had only sold one GatorPro, and for less than [REDACTED] Tr. (Tan) at 348:12-349:1. Thus, a [REDACTED] is appropriate [REDACTED]  
[REDACTED] Tr. (Schwartz) 790:12-791:15; CX-0370C.

## **VII. PUBLIC INTEREST CONSIDERATIONS**

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 involved in an investigation are “bad actors,” or whether a party’s actions have harmed the public. The public interest analysis is 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 even if neither side presents any evidence 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

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purpose is to determine the effect of an exclusion order and/or cease and desist order on four statutory public interest factors. 19 U.S.C. § 1337(d)(1).

For the reasons discussed above, Sartorius will not be able to establish a Section 337 violation. However, if a violation is found, Staff submits that with respect to the particular articles at issue—BLI devices and biosensors/probes—the evidence will support a finding that public interest concerns warrants the remedy discussed above with respect to a LEO (either no LEO or a specifically tailored LEO) and CDO (only to the four accused Gator Bio probes). In Staff’s view, based on the evidence presented at the hearing, the remedy discussed above would alleviate the public interest concerns.

**A. The Public Health and Welfare**

The evidence shows that Gator Bio’s BLI instruments and biosensors are used for basic research as well as a range of clinical and industry applications to develop new drugs, therapies, and diagnostics, such as gene therapy applications, antibody drugs, COVID-19 research and other applications. Tr. 393:20-397:25; CX-0624C. Mr. Zuk and Dr. Vander Veen testified that Gator Bio’s products are used by, among many others, researchers at the University [REDACTED] [REDACTED] University [REDACTED] University [REDACTED], University [REDACTED] [REDACTED], University [REDACTED] biotech companies, the National Institutes of Health (NIH), the Centers for Disease Control, the U.S. Army, United States Military Academy, and [REDACTED] General Hospital to study diseases including COVID-19, hemorrhagic fever (with a 40 percent mortality rate), and to develop antibodies, including through work supported by the U.S. Department of Energy, NIH, and Military Infectious Disease Research Program. Tr. 393-397; Tr. 499-500; RX-0081-0086. RPostHBr. at 67-68. The evidence shows that Gator Bio’s public university customers such as [REDACTED] run programs under government grants or

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contracts. Tr. (Tan) at 321-22. The evidence shows that Gator Bio's customers include government agencies, government labs, university labs, hospitals, and large, medium, and small biotech companies, such as [REDACTED], and many more. Tr. (Tan) 321:1-8; CX-0055C; CX-0073C.0009; Tr. 497:21-498:3. Thus, the evidence shows that, at a minimum, Sartorius' requested relief would disrupt the research conducted by users of the Accused Products. For example, Dr. Tan testified that if a customer had Gator Bio probes and kits (including universities and government labs), they could not use them with Sartorius instruments and that it would be either very difficult or impossible for customers to switch from a Gator Bio BLI system to a Sartorius BLI system. Tr. (Tan) 317:1-318:7, (Forrest) at 1063:17-25.

The evidence, however, also shows that (1) Complainant's instruments are capable of and have been used for the same research (Tr. (Kang) 126:4-6; Tr. (Zuk) 393:2-15; Tr. (Vander Veen) 500:8-13, 552:2-553:13; RX-0082); (2) "Gator systems are very similar" to Octet, and while those who need to switch "may need to recreate the standard curve for the concentrations, but other than that, the data that was generated using the Gator system should still be useable" (Tr. (Kang) 171:22-172:12); and (3) Complainant offers reasonable substitutes for all of the Accused Products, discussed below. CIPostHBr. at 80.

In Staff's view, the potential harm to the public health and welfare would be avoided with either no LEO or a specifically tailored LEO (with the standard certification provisions as well as certain exemptions), and CDO that would be directed only to the four accused Gator Bio probes, discussed above.

**B. Competitive Conditions in the United States Economy**

In assessing competitive conditions in the U.S. 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*, 337-TA-796, Comm’n Op. at 120 (Sept. 6, 2013). The evidence shows that the market for BLI products is a two-player market with only Sartorius and Gator Bio, and that Gator Bio entered the market in 2019 with its Gator Prime instrument. Tr. (Tan) at 316:4-20, (Vander Veen) at 502:20-505:4; (Schwartz) at 799:25-800:17; Tr. (Tan) at 294:3-7. The evidence also shows that Gator Bio’s entry into the market [REDACTED]

[REDACTED]  
CIPostHBr. at 76-77 (citing Tr. (Tan) 345:23-346:9, 346:20-22; Tr. (Vander Veen) 536:4-15, 537:2-544:12; CX-0087; CPX-0065C; CX-0386; *see also* Tr. (Kang) 166:1-6; CX-0412C); RIPostHBr. at 70-71 (citing Tr. (Tan) 318:12-17; CX-0264; RX-0014; CX-0104C; CX-0107C; CX-0199; CX-0109C; CX-0112C-CX-0115C; CX-0129C-CX-131C; Tr. (Zuk) 409:1-7; Tr. (Kang) 191:5-12; Tr. (Forrest) 1060:22-1062:6; Tr. (Tan) at 318:15-24; 369:22-370:8.

Therefore, an exclusion order against Gator Bio instruments would leave only Sartorius with zero competition and no choice for consumers. Tr. (Vander Veen) 504:10-505:4.

The only substitutes to Gator Bio’s accused products adduced at the hearing are Sartorius’ products. The evidence shows that Complainant offers comparable instruments to the GatorPrime and GatorPlus. Tr. (Tan) 296:21-23, 366:15-25; Tr. (Vander Veen) 503:9-19. The evidence suggests that Complainant’s RH96 can run the same number of samples as the GatorPro, and can run *up to 96 channels* simultaneously [REDACTED]

[REDACTED]. Tr. (Kang) 166:12-167:2; Tr. (Bailey) 633:2-7; CX-386. Gator

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Bio's contention that Sartorius does not offer anything comparable to the GatorPro instrument is undercut by the fact that Gator Bio has only sold one GatorPro instrument as a trade in, discussed above, suggesting the perceived advantages of the GatorPro may not be important to customers.

With respect to biosensors, the evidence shows that for the accused AAV9 probe, Complainant offers an AAVX probe capable of detecting AAV9, among other serotypes. Tr. (Bailey) 659:12-20. The evidence also shows that in addition to the off-the-shelf probes,

[REDACTED]

[REDACTED] Tr. (Kang) 161:23-162:10. The evidence shows that a [REDACTED]

[REDACTED]

[REDACTED] Tr. (Kang) 162:11-18. The evidence shows that [REDACTED]

[REDACTED] with technical and/or application notes, such as by converting ELISA assays into Octet quantitation assays using any of Complainant's probes, including streptavidin, APS, AR, or any analyte-specific biosensor (*id.*, 158:14-23; CX-502), or creating custom probes for wholesale protein detection using streptavidin biosensors by following technical notes (*id.*, 160:5-17). The evidence also shows that customers can customize the High-Precision Streptavidin (SAX) probe to any AAV serotype by following Complainant's application notes, CX-0516. Tr. (Bailey) 659:23-660:11; Tr. (Kang) 169:1-24.

That said, in Staff's view, the prospect of eliminating Gator Bio (one of two suppliers) in the BLI marketplace would harm competitive conditions in the U.S. economy. Again, however, the potential harm to competitive conditions would be avoided with either no LEO or a specifically tailored LEO (as described above) and a CDO that would be directed to only the four accused Gator Bio probes, discussed above.

**C. Production of like or directly competitive articles in the United States**

The evidence shows that Sartorius offers alternatives to Gator Bio's accused products, discussed above. The evidence also shows that Sartorius has sufficient capacity to meet any increase in demand. As argued by Sartorius,

[REDACTED]

CIPostHBr. at 81-82. However, the evidence shows that Sartorius' future facility [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. (Vander Veen) at 513:6-15.

In view of the evidence adduced at the hearing, in Staff's view, it appears plausible that Complainant could meet the demand for the Accused Products. Even if they could not, the potential harm to the production of like or directly competitive articles would be avoided with either no LEO (or a specifically tailored LEO) and a CDO directed to only the four accused Gator Bio probes, discussed above.

**D. United States Consumers**

The evidence shows that U.S. consumers would suffer harm if they were not permitted to purchase, use, or service Gator Bio BLI instruments and consumables. The evidence shows that

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BLI devices must undergo a validation process before it can be used for many applications. Tr. (Zuk) 414:25-415:8; (Forrest) 1065:2-8; (Vander Veen) 497:12-20, 501:17-502:16; CX-0139.0027. The evidence shows that the FDA requires certain features and data. Tr. (Kang) 126:4-6. The evidence shows that gene therapies are regulated by the FDA and that is a major consideration and demand with respect to certifications and reproducibility. Tr. (Zuk) at 414. The evidence shows that in this regulated environment, it is “extremely difficult [] to switch if they have already validated an analytical method” and may have to repeat their studies or clinical trials, and that validation steps can be complex and time consuming. Tr. (Zuk) at 415:1-8. The evidence shows that Gator Bio’s customers would have to validate an entirely new BLI system and could not simply purchase Sartorius probes to use with their existing Gator Bio instruments. Tr. (Vander Veen) at 500:17-502:16. The evidence shows, and it is undisputed, that Gator Bio probes are custom made for the Gator Bio BLI devices and are not compatible with Sartorius’ devices, nor are the Sartorius probes compatible with the Gator Bio BLI devices. Thus, customers would have to validate and purchase an entirely new BLI system to continue their research. The evidence shows, as argued by Gator Bio,

In addition to these disruptions, such an order would be overly burdensome on research entities and companies given the cost of purchasing new BLI devices because many third-party customers of Gator Bio, some of whom are operating on limited budgets as non-profit organizations and/or receive funding from government grants. For example, Gator Bio’s sales documents produced in this Investigation indicate that Gator Bio’s instruments sold for between [REDACTED] *Id.* These expensive instruments have to be written into grants years before. Tr. 1063:17-1065:8. After making these initial investments, Gator Bio’s U.S. customers would no longer be able to use these instruments, particularly if relief is expanded improperly to Gator Bio’s probes in the event of an exclusion order. *Id.* ... When consumers purchased their Gator Bio instruments, logically they expected the continued availability of Gator Bio biosensors to use those instruments. In the event of an exclusion order, a U.S. consumer would either not be able to perform important research requiring BLI systems or would have to go through complex steps to validate and purchase a new Sartorius system including

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instruments and consumables. *Id.* Forcing a change in platform would cause researchers to go back and redesign and re-conduct experiments. *Id.* Particularly for regulated studies, revalidation could delay projects “by months, if not, potentially over a year.” *Id.* U.S. customers would incur the time and expense of validation, but also investing in a new Sartorius system would be a large investment. Tr. 506:12-508:9, 509:11-21. The 2023 list prices (i.e., not discounted) of Sartorius’ Octet R2, R4, and R8 are [REDACTED] respectively (or approximately [REDACTED]). CPX-0036C. Mr. Kang admitted that an existing customer would be unable to replace their AAV probes or kits without buying an entirely new Sartorius machine at a cost of up to [REDACTED] Tr. 196:3-15.

RIPostHBr. at 74-75.

Therefore, in Staff’s view, the evidence shows an adverse impact on U.S. consumers if Sartorius’ requested LEO is issued.

On balance, in Staff’s view, if a violation is found, the evidence will show that entry of an LEO could potentially have a significant adverse impact on at least two statutory public interest factors. However, the potential harm to the public interest would be avoided with either no LEO (or a specifically tailored LEO) and a CDO directed to only the four accused Gator Bio probes, discussed above.

## **VIII. CONCLUSION**

For the foregoing reasons, the Staff respectfully submits that the evidence establishes:

- i. the importation requirement of Section 337 is satisfied;
- ii. Respondent’s accused products do not infringe the claim 8 of the ‘887 patent;
- iii. Claim 8 of the ‘887 patent is not invalid under § 103;
- iv. Claim 8 of the ‘887 patent is not invalid under § 101;
- v. Claim 8 of the ‘887 patent is invalid under § 112 if Sartorius’ interpretation of the “air gap” limitation is adopted;

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Dated: November 20, 2023

Respectfully submitted,

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