

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN BIO-LAYER
INTERFEROMETERS AND
COMPONENTS THEREOF

Investigation No. 337-TA-1344

COMMISSION OPINION

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I. INTRODUCTION

The Commission has determined to review in part the final initial determination (“FID”) issued by the presiding Administrative Law Judge (“ALJ”) on March 8, 2024, and, on review, to affirm with modification the FID’s finding of no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”). Accordingly, the investigation is terminated with a finding of no violation of section 337.

This opinion sets forth the Commission’s reasoning in support of its determinations. The Commission affirms all findings in the FID that are not inconsistent with this opinion.

II. BACKGROUND

A. Procedural History

On November 29, 2022, the Commission instituted this investigation under section 337 based on a complaint filed by complainant Sartorius Bioanalytical Instruments, Inc. (“Sartorius” or “Complainant”) of Bohemia, New York. *See* 87 FR 73329-30 (Nov. 29, 2022). The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of “bio-layer interferometers, biosensors, and kits containing biosensors and reagents” by reason of the infringement of certain claims of U.S. Patents Nos. 7,445,887 (“the ’887 patent”); 7,394,547 (“the ’547 patent”); 7,728,982 (“the ’982 patent”); and 8,305,585 (“the ’585 patent”). *Id.* The notice of investigation names Gator Bio, Inc. (“Gator Bio” or “Respondent”) of Palo Alto, California as the respondent. *Id.* The Office of Unfair Import Investigations (“OUII”) is also a party to the investigation. *Id.*

The Commission previously terminated the investigation as to the ’547, ’982, and ’585 patents and claims 1-5, 7, 9-14, and 16-18 of the ’887 patent based on the withdrawal of the complaint as to those patents and claims. *See* Order No. 14 (May 15, 2023), *unreviewed by*

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Comm’n Notice (June 9, 2023); Order No. 26 (June 29, 2023), *unreviewed by* Comm’n Notice (July 20, 2023); Order No. 37 (Oct. 26, 2023), *unreviewed by* Comm’n Notice (Nov. 27, 2023). Claim 8 of the ’887 patent (“asserted claim”) remains pending in this investigation.

On May 31, 2023, the ALJ issued a claim construction order construing certain terms of the ’887 patent. Order No. 16 (May 31, 2023). On June 26, 2023, the ALJ issued a supplemental claim construction order. Order No. 22 (June 26, 2023). In particular, the ALJ declined to correct the term “the layer of enzyme binding molecules,” and found the remaining asserted claims to be indefinite on that basis. *See id.* Accordingly, on June 30, 2023, the ALJ issued an ID granting summary determination that the asserted claims are invalid for indefiniteness, thereby terminating the investigation with a finding of no violation of section 337. *See* Order No. 27 (June 30, 2023). On August 16, 2023, the Commission determined to reverse the ALJ’s indefiniteness finding. *See* Comm’n Notice (Aug. 16, 2023). Specifically, the Commission corrected the term “the layer of enzyme binding molecules,” which included an obvious and minor clerical error, and construed it as “the layer of *analyte* binding molecules.” *Id.*¹ The Commission also remanded the investigation to the ALJ for further proceedings consistent with the Commission’s determination. *See id.*

On September 16, 2022, the ALJ issued the FID finding no violation of section 337. Specifically, the FID finds the accused products do not infringe claim 8 of the ’887 patent, and that the domestic industry products do not practice that claim, and thus Sartorius has failed to satisfy the technical prong of the domestic industry requirement. *See* FID at 59-88, 97-110.

¹ Commissioner Johanson dissented from the majority’s decision to reverse the ALJ’s indefiniteness finding and to construe the term “the layer of enzyme binding molecules” to mean “the layer of analyte binding molecules.” *See* Comm’n Op. at 2 n.1 (Aug. 24, 2023) (public version).

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Additionally, the FID finds that the importation requirement is satisfied regarding the accused Gator Bio instruments but is not satisfied with respect to the accused probes and kits, and that the Commission lacks *in rem* jurisdiction over those probes and kits. *See id.* at 16-17. The FID does not address whether the accused instruments are “articles that infringe” under section 337(a)(1)(B) reasoning that “the record on this issue is undeveloped and because [the ALJ] ha[s] found that the use of Gator Bio’s GatorPrime instruments with one of its HRP probes does not practice claim 8.” *Id.* at 89. The FID further finds that claim 8 of the ’887 patent is not invalid based on obviousness-type double patenting and that assignor estoppel bars Gator Bio’s assertions of invalidity based on obviousness and obviousness-type double patenting. *See id.* at 114-22. The FID also rejects as moot Gator Bio’s assertions of invalidity based on patent ineligibility, indefiniteness, lack of written description, and lack of enablement, which are premised on Sartorius’s construction for the term “air gap,” which the FID does not adopt. *See id.* at 122. Lastly, should the Commission find that the technical prong of the domestic industry requirement is in fact satisfied, the FID finds that the economic prong of the domestic industry requirement is also satisfied with respect to the ’887 patent. *See id.* at 122-58.

The FID includes a Recommended Determination (“RD”) recommending, should the Commission find a violation of section 337, that the Commission issue: (1) a limited exclusion order against certain bio-layer interferometers and components thereof that are imported into the United States, sold for importation, or sold within the United States after importation by or on behalf of Gator Bio; and (2) a cease and desist order against Gator Bio. The RD recommends no (zero percent) bond during the period of Presidential review against Gator Bio’s infringing probes/kits but recommends that the Commission set a bond of 100 percent with respect to the

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infringing GatorPrime instruments, 54.6 percent bond with respect to the infringing GatorPlus instruments, and 100 percent with respect to infringing GatorPro instruments.

On March 22, 2024, Sartorius petitioned for Commission review of certain FID findings, including with respect to: (1) importation and *in rem* jurisdiction; (2) whether the accused instruments are “articles that infringe”; (3) claim construction; (4) infringement; (5) the technical prong of the domestic industry requirement; and (6) assignor estoppel.² On the same day, Gator Bio filed a contingent petition for review of certain FID findings, including with respect to: (1) infringement; (2) invalidity; and (3) the domestic industry requirement (economic prong and technical prong).³ On April 3, 2024, the parties and OUII filed responses to the petitions.⁴

On April 8 and 9, 2024, respectively, Sartorius and Gator Bio filed statements on the public interest pursuant to Commission Rule 210.50 (19 C.F.R. § 210.50). On April 5, 2024, the Commission received public interest submissions from Paul Yu, Jordon Wang, and Zucui Suo in response to its post-RD *Federal Register* notice. *See* 89 Fed. Reg. 18667 (Mar. 14, 2024).

B. The Asserted Patent

The ’887 patent relates to measurements of enzyme activity using bio-layer interferometry (“BLI”).⁵ The specification of the ’887 patent explains that enzyme assays of the

² *See* Complainant’s Combined Petition for Review and Contingent Petition for Review of the Final Initial Determination (Mar. 22, 2024) (“Complainant’s Pet.”).

³ *See* Respondent Gator Bio Inc.’s Contingent Petition for Review (Mar. 22, 2024) (“Respondent’s Pet.”).

⁴ *See* Complainant’s Response to Respondent Gator Bio, Inc.’s Contingent Petition for Review of the Initial Determination Finding of No Violation of Section 337 (Apr. 3, 2024) (“Complainant’s Resp.”); Respondent Gator Bio, Inc.’s Response to Complainant’s Petition for Review and Contingent Petition for Review of Initial Determination (Apr. 3, 2024) (“Respondent’s Resp.”); The Commission Investigative Staff Combined Response (Apr. 3, 2024) (“OUII’s Resp.”).

⁵ The earliest effective filing date for the ’887 patent is January 7, 2005, and therefore the patent is subject to the pre-AIA (“America Invents Act”) patentability provisions of the Patent Act.

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V. CONCLUSION

The Commission has determined to review in part the FID and, on review, affirms with modification the FID's finding of no violation of section 337. Accordingly, the investigation is terminated with a finding of no violation of section 337.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy oval shape.

Lisa R. Barton
Secretary to the Commission

Issued: July 16, 2024