

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

REBUTTAL EXPERT REPORT OF MICHAEL J. SAILOR PH.D, FRSC, FNAI

EXHIBIT LIST FOR EXPERT REPORT OF MICHAEL J. SAILOR PH.D, FRSC, FNAI

EXHIBIT NO.	DESCRIPTION
Ex. 01	U.S. Patent No. 7,394,547 (SBAI-ITC0000001 – SBAI-ITC0000017)
Ex. 02	U.S. Patent No. 7,445,887 (SBAI-ITC0000018 – SBAI-ITC0000039)
Ex. 03	U.S. Patent No. 7,728,982 (SBAI-ITC0000040 – SBAI-ITC0000057)
Ex. 04	U.S. Patent No. 8,305,585 (SBAI-ITC0000058 – SBAI-ITC0000075)
Ex. 05	U.S. Patent No. 5,804,453 (GATOR_SAR0002838 - GATOR_SAR0002858) (“Chen”)
Ex. 06	Provisional Application No. 60/518,068 (GATOR_SAR0003604 - GATOR_SAR0003612) (“’068 provisional”)
Ex. 07	Provisional Application No. 60/558,381 (GATOR_SAR0002645 – GATOR_SAR0002675)
Ex. 08	Terminal Disclaimer In a Patent or Proceeding In View of Another Patent, disclaiming the terminal part of the term of U.S. Patent No. 8,305,585 that extends beyond the expiration of U.S. Patent No. 7,728,982, dated May 1, 2023 (“’585 Terminal Disclaimer to ’982 Patent”)
Ex. 09	Prosecution History for Appl. No. 10/981,901 (SBAI-ITC0000076 - SBAI-ITC0000532) (“’901 Application Prosecution History”)
Ex. 10	Prosecution History for Appl. No. 12/099,751 (SBAI-ITC0000993 - SBAI-ITC0001249) (“’751 Application Prosecution History”)
Ex. 11	Prosecution History for Appl. No. 12/790,736 (SBAI-ITC0001250 - SBAI-ITC0001602)
Ex. 12	Declaration of Michael J. Sailor Ph.D. In Support of Sartorius’s Opening Claim Construction Brief, dated April 5, 2023
Ex. 13	Joint Chart Of Agreed And Disputed Claim Terms For Construction dated March 22, 2023
Ex. 14	Yang et al., <i>Direct monitoring of antigen-antibody interactions by optical fiber bioprobe</i> Proceedings of the SPIE (GATOR_SAR0002755- GATOR_SAR0002763) (“Yang”)
Ex. 15	Sun et al., <i>Fiber Optic Direct-Sensing Biosensor Applied in Detecting Biolayer Thickness of Nanometer Grade</i> , ACTA PHOTONICA SINICA (June 2002) (translated by Gator Bio) (GATOR_SAR0003220 - GATOR_SAR0003224) (“Sun”)
Ex. 16	Yu et al., <i>Reflectometry Interference Spectroscopy in Detection of Hepatitis B Surface Antigen</i> , Clinical Chemistry (2000) (GATOR_SAR0002125- GATOR_SAR0002169) (“Yu”)
Ex. 17	“Metrotek Catalog” (AAATesters.com) (GATOR_SAR0002875 - GATOR_SAR0002910) (“Metrotek Catalog”)

EXHIBIT NO.	DESCRIPTION
Ex. 18	“Metrotek Website” April, 2001 (GATOR_SAR0008090- GATOR_SAR0008094) (“Metrotek Website”)
Ex. 19	U.S. Patent Publication No. US 2002/0127565 A1, published September 12, 2002 (GATOR_SAR0005201-GATOR_SAR0005289) (“Cunningham”)
Ex. 20	Yu et al., <i>Assay of HIV-1 protease activity by use of crude preparations of enzyme and biotinylated substrate</i> , Journal of Virological Methods (1995) (GATOR_SAR0004905 - GATOR_SAR0004915) (“Yu 1995”)
Ex. 21	W. Rudolf Seitz & Michael J. Sepaniak, <i>Chemical Sensors Based on Immobilized Indicators and Fiber Optics</i> , Analytical Chemistry (1988) (GATOR_SAR0002680 - GATOR_SAR0002719) (“Seitz”)
Ex. 22	Khraltsova et al., <i>An enzyme-linked lectin assay for alpha1,3-galactosyltransferase</i> , Anal Biochem. (2000) (GATOR_SAR0005192 - GATOR_SAR0005200) (“Khraltsova”)
Ex. 23	Fiber Optic Association Reference Guide Article (GATOR_SAR0002676 - GATOR_SAR0002679) (“FOA Internet Article”)
Ex. 24	Hayes, J., <i>Fiber Optics Technician's Manual</i> (2nd ed.) (2000) (GATOR_SAR0003416 -GATOR_SAR0003436) (“Hayes”)
Ex. 25	Fiber Optic Connector identifier retrieved May 4, 2023, from https://www.thefoa.org/tech/connID.htm (“FOA Fiber Optic Connector Identifier”)
Ex. 26	A. Brecht, G. Gauglitz, <i>Optical probes and transducers</i> , Biosensors and Bioelectronics (1995) (SBAI-ITC0014834 - SBAI-ITC0014847) (“Brecht 1995”)
Ex. 27	Deposition Transcript of Hong Tan
Ex. 28	Exhibit 4 to the Deposition of Hong Tan
Ex. 29	Deposition Transcript of Robert Zuk
Ex. 30	Brecht, A. et al., <i>Recent Developments in Optical Transducers for Chemical or Biochemical Applications</i> , Sensors and Actuators B (1997) (GATOR_SAR0002738 – GATOR_SAR0002744) (“Brecht 1997”)
Ex. 31	Brecht, A. et al., <i>Direct Monitoring of Antigen-Antibody Interactions by Spectral Interferometry</i> , Sensors & Actuators, vol. B5 (1992) (SBAI-ITC0000157 – SBAI-ITC0000161) (“Brecht 1992”)
Ex. 32	Prosecution History for Appl. No. 11/326,689 (SBAI-ITC0000533 – SBAI-ITC0000992) (“’887 Patent Prosecution History”)
Ex. 33	Donald Voet and Judith G Voet, <i>Biochemistry</i> , 71-75, 89-96 (2 nd ed. 1995) (“Voet Biochemistry”)
Ex. 34	Sigma Aldrich Product Webpage – 4-Chloro-1-naphthol (last accessed May 5, 2023) (https://www.sigmaaldrich.com/US/en/product/sigma/c6788) (“Sigma Aldrich – 4-Chloro-1-naphthol”)



I. INTRODUCTION

1. I have been retained by Haug Partners LLP (“Haug Partners” or “counsel”), counsel to Complainant Sartorius BioAnalytical Instruments, Inc. (“Sartorius”).

2. I have been asked by Haug Partners to review and respond to the opinions set forth in the Opening Expert Report of David Schaafsma, Ph.D. dated April 21, 2023 (the “Schaafsma Rep.”) and the Opening Expert Report of Laird Forrest, Ph.D. dated April 21, 2023 (the “Forrest Rep.”). These reports generally concern the validity of U.S. Patent Nos. 7,394,547 (“the ’547 patent”), 7,728,982 (“the ’982 patent”), 8,305,585 (“the ’585 patent”), and 7,445,887 (“the ’887 patent”) (collectively, the “Asserted Patents”).¹ In particular, I have been asked to review the Asserted Patents and the prosecution histories of the Asserted Patents, review the prior art cited by Dr. Schaafsma and Dr. Forrest, and offer an opinion about the validity or invalidity of the challenged claims. I have also been asked to respond to Dr. Schaafsma and Dr. Forrest’s other opinions with respect to validity, such as their opinions that the claims are invalid for lack of enablement, lack of written description, and lack of utility.

3. The opinions contained herein are based upon the information presented to me as of the date of this report as well as my education and experience, and are therefore subject to supplementation, amendment, and/or revision. All citations in this report are meant to be exemplary.

II. SUMMARY OF QUALIFICATIONS AND BACKGROUND

A. PROFESSIONAL EXPERIENCE

4. I am currently the Director of the University of California, San Diego, Materials Research Science and Engineering Center. I have held this position since 2020. I am also the

¹ See Exs. 1-4.

Hayes teaches that the most common end-faces for fiber optic connectors are the domed or PC types that create physical contact.¹⁴⁹ I agree with the explanations and conclusions in Hayes.

165. Back reflection from gaps in the SMA connectors would have been of particular concern to a POSA constructing an apparatus like the one described in Yang. A POSA would be focused on effective light transmission, and would not want the connection point to introduce additional light interference that would be difficult to filter out. Uniquely, out of the many uses for fiber optics, an interferometer is measuring the reflection of light from a sample. A POSA would not have found it desirable to introduce spurious reflections into the system. For these reasons, a POSA reading Yang would not have assumed the presence of an air gap in the SMA connector shown in Fig. 3.

166. I understand that Dr. Schaafsma relies on a sentence in the FOA Internet Article to the effect that early SMA connectors “always had an air gap between the connectors to prevent them rotating.”¹⁵⁰ I respectfully disagree with the term “always.” To me, the author of this internet article was being a bit loose with the terminology. The sentence also refers to an air gap between “the connectors,” when it should have been discussing the gap between the fibers. As I stated earlier, I can take an SMA-905 connector, and use a mating adapter to connect it to a fiber so that there is no air gap present. In fact, the very next sentence points out that the “air gap between the fibers causes a reflection when the light encounters the change in refractive index from the glass fiber to air in the gap.”¹⁵¹

167. As I explained, a POSA constructing an interferometer in 2003 would have worked hard to eliminate an air gap in the connection. In addition to creating physical contact, a

¹⁴⁹ Ex. 24, Hayes at GATOR_SAR0003421.

¹⁵⁰ Ex. 23, FOA Internet Article at GATOR_SAR0002677.

¹⁵¹ Ex. 23, FOA Internet Article at GATOR_SAR0002677.

POSA would have considered using an index matching liquid to replace the air in the gap. The Fiber Optic Association describes the Deutsch 1000, pictured below, as follows:

Deutsch 1000 was probably the first commercially successful fiber optic connector. The nose piece is spring loaded and was pushed back when the connector was inserted into a mating adapter. The fiber stuck out into a drop of index matching fluid on a plastic lens. This solution was state of the art in the late 70s, yielding about 3 dB loss.¹⁵²



Thus, even if an SMA-type connection had a gap between the optical fibers, that gap would not necessarily be filled with air. It could easily have been filled with an index matching liquid, given that a POSA would understand that an air gap can negatively impact signal, and using an index matching liquid to remove this air gap can obviate this concern.

168. Finally, Dr. Schaafsma contends that even if the “Y-shaped optical fiber and the optical fiber portion of the probe in Sun’s RIfS setup” were in physical contact, an air gap of less than 100nm would be present.¹⁵³ Dr. Schaafsma attributes this position to Sartorius’s infringement contentions. I disagree for several reasons. First, while it may be true in some cases that connections appearing to have physical contact to the naked eye could in reality

¹⁵² Ex. 25, FOA Fiber Optic Connector Identifier.

¹⁵³ Schaafsma Rep. FN 118, 151 (and throughout the appendices).

- Claims 1-6 and 8-19 of the '585 patent are not invalid.

392. If asked and allowed, I expect to testify about my background, qualifications, and professional experience. I also expect to testify, if asked and permitted, about the content of my expert report, which may include my opinions and conclusions, as well as the bases for such opinions and conclusions. If asked, I am prepared to provide a tutorial to the Administrative Law Judge that may assist in understanding the technology described in this declaration.

393. I reserve the right to supplement or amend this report as appropriate. I may supplement or amend the statements in this expert report based on additional information that I might receive, including information not yet provided by Gator Bio or third parties. I further reserve the right to respond to Gator Bio's experts' opinions regarding this report and their opinions regarding the Asserted Patents and the asserted claims.

Dated: May 5, 2023



Michael J. Sailor, Ph.D, FRSC, FNAI