

THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GATOR BIO, INC.,

Petitioner,

v.

SARTORIUS BIOANALYTICAL INSTRUMENTS, INC.,

Patent Owner.

IPR2025-00633

U.S. Patent No. 8,647,588

**OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL**

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EXHIBIT LIST¹

Exhibit	Description
1001	U.S. Patent No. 8,647,588 (“588 patent”)
1002	Declaration of Dr. Laird Forrest
1003	Curriculum Vitae of Laird Forrest, Ph.D.
1004	Certified File History of U.S. Patent No. 8,647,588 (“588 FH”) (copies of prior art references omitted)
1005	U.S. Patent No. 4,087,248 (“Miles”)
1006	Yuxiao Yang et al., <i>Direct monitoring of antigen-antibody interactions by optical fiber bioprobe</i> , PROCEEDINGS OF SPIE, THIRD INT’L CONFERENCE ON PHOTONICS AND IMAGING IN BIOLOGY AND MEDICINE, 5254:431-436 (2003), copy obtained from British Library (“Yang”)
1007	U.S. Patent No. 4,676,377 (“Rainin”)
1008	PCT Publication No. WO 2005/047854 A2 (“WO854”)
1009	U.S. Patent No. 5,804,453 (“Chen”), which is incorporated by reference into WO854
1010	Yan Sun et al., <i>Fiber Optic Direct-Sensing Biosensor Applied in Detecting Biolayer Thickness of Nanometer Grade</i> , ACTA PHOTONICA SINICA, 31(6):657-661 (June 2002), copy obtained from British Library
1011	Certified English Translation of EX1010, Yan Sun et al., <i>Fiber Optic Direct- Sensing Biosensor Applied in Detecting Biolayer Thickness of Nanometer Grade</i> , ACTA PHOTONICA SINICA, 31(6):657-661 (June 2002) (“Sun”)

¹ Unless otherwise stated, citations in this Petition are to the original page, column, and line numbers in the exhibits. Brackets ([]) are used in citations to refer to the sequential page numbers added in the footer to exhibits.

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1012	Excerpted Transcript of May 25, 2023 Deposition of Michael Sailor, ITC Inv. No. 337-TA-1344 (“Sailor”)
1013	U.S. Patent No. 5,827,745 (“Astle”)
1014	U.S. Patent No. 5,475,610 (“Atwood”)
1015	U.S. Patent No. 3,356,462 (“Cooke”)
1016	U.S. Patent No. 5,674,047 (“Lapeus”)
1017	U.S. Patent No. 6,019,225 (“Kalmakis”)
1018	Fang Yu et al., <i>Reflectometry Interference Spectroscopy in Detection of Hepatitis B Surface Antigen</i> , CLINICAL CHEMISTRY, 46(9):1489-1490 (September 2000) (“Yu”), copy obtained from U.S. Library of Congress
1019	Weiping Qian et al., <i>Immobilization of Antibodies on Ultraflat Polystyrene Surfaces</i> , CLINICAL CHEMISTRY, 46(9):1456-1463 (2000) (“Qian”)
1020	Rudolf Lequin, <i>Enzyme Immunoassay (EIA)/Enzyme-Linked Immunosorbent Assay (ELISA)</i> , CLINICAL CHEMISTRY, 51(12):2415-2418 (2005) (“Lequin”)
1021	Corning, <i>ELISA Technical Bulletins - Nos. 1 & 2</i> (July 2001), available at https://www.labcluster.com/news4_2/Corning_elisa1_2.pdf (“Corning”)
1022	U.S. Patent No. 5,799,792 (“Abrums”)
1023	U.S. Patent No. 4,848,579 (“Barnes”)
1024	U.S. Patent Appl. Publ. No. 2006/0186014 A1 (“Ramanujam”)
1025	U.S. Patent No. 4,027,778 (“Tupper”)
1026	Joseba Zubia et al., <i>Plastic Optical Fibers: An Introduction to Their Technological Processes and Applications</i> , Optical Fiber Technology, 7:101-140 (2001) (“Zubia”)

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1027	Excerpt of Patent Owner’s Preliminary Sur-Reply (Paper 18), dated April 25, 2023, in IPR2023-00215 (“PO Surreply”)
1028	Excerpt of Patent Owner’s Prehearing Brief, in <i>Certain Bio-Layer Interferometers and Components Thereof</i> , ITC Inv. No. 337-TA-1344 (“PHB”)
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1036	Roy Manns, <i>History of Microplates</i> , Plastics Historical Society, available at https://plastiquarian.com/?page_id=14361 (“Manns”)
1037	U.S. Patent Appl. Publ. No. 2004/0171087 A1 (“Rech-Weichselbraun”)
1038	U.S. Patent No. 5,759,774 (“Hackett”)
1039	Gilson, Inc., <i>Manual Liquid Handling Catalog</i> (2004), available at https://web.archive.org/web/20040523093106/http://www.gilson.com:80/Products/prodPDF.asp?pID=106&pdftid=BRO (archived May23, 2005) (“Gilson”)
1040	Thomas Astle, <i>Recollections of Early Microplate Automation</i> , J. ASSOC. FOR LABORATORY AUTOMATION, 5:30-31 (2000) (“Astle-2000”)
1041	American National Standards Institute (ANSI) & Society for Laboratory Automation and Screening (SLAS), <i>for Microplates – Well Positions</i> , ANSI SLAS 4-2004 (R2012) (“ANSI/SLAS”).

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1042	Peter B. Luppá et al., <i>Immunosensors- principles and applications to clinical chemistry</i> , CLINICA CHIMICA ACTA, 314:1-26 (2001) (“Luppá”)
1043	Jay L. Bock, <i>The New Era of Automated Immunoassay</i> , AM. J. CLIN. PATHOL., 113:628-646 (2000) (“Bock”)
1044	B.H. Schneider et al., <i>Highly sensitive optical chip immunoassays in human serum</i> , BIOSENSORS & BIOELECTRONICS, 15:13-22 (2000) (“Schneider”)
1045	U.S. Patent No. 4,511,534 (“Bennett”)
1046	Andreas Brecht & Günter Gauglitz, <i>Recent developments in optical transducers for chemical or biochemical applications</i> , SENSORS AND ACTUATORS B, 38-39:1-7 (1997) (“Brecht”)
1047	Oliver Birkert & Günter Gauglitz, <i>Development of an assay for label-free high-throughput screening of thrombin inhibitors by use of reflectometric interference spectroscopy</i> , ANAL. BIOANAL. CHEM., 372:141-147 (2001) (“Birkert”)
1048	Fisher Scientific, Inc. <i>Fisher Catalog 2004/05</i> (2004) (“Fisher”)
1049	Bio-Tek Instruments, Inc., <i>Precision™ Microplate Pipetting System, Liquid Handling - Automated Microplate Pipetting Systems</i> , available at https://web.archive.org/web/20050405215350/http://www.biotek.com/products/product_print.php?pid=119 (archived April 5, 2005) (“Biotech Precision Webpage”)
1050	Excerpt of Bio-Tek Instruments, Inc., <i>Precision Microplate Pipetting System, Operator’s Manual</i> , Rev. D1 (Jan. 2005), available at https://assets.fishersci.com/TFS-Assets/CCG/EU/Biotek-Instruments/manuals/BTK011_EN%20Precision_Op_Man_Rev_D1.pdf (“Bio-Tek Precision Manual”)
1051	Seahorse Bioscience, <i>How Does XF Technology Work?</i> , available at https://web.archive.org/web/20041212090403/http://www.seahorsebioscience.com/xf_work.html (archived Dec. 12, 2004) (“Seahorse”)
1052	U.S. Patent Appl. Publ. No. 2005/0054028 A1 (“Teich”)

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1053	Thomas R. Clem et al., <i>Practical Colorimeter for Direct Measurement of Microplates in Enzyme Immunoassay Systems</i> , J. CLIN. MICROBIOL. 7(1):55-58 (1978) (“Clem”)
1054	Günther Viehhauser, <i>Simple Procedure for Large-Scale Assays for Chick Interferon</i> , APPLIED & ENVIRON. MICROBIOL., 33(3):740-743 (1977) (“Viehhauser”)
1055	Brian Law et al., <i>Chapter 7: Enzyme-Linked immunosorbent assay (ELISA) development and optimization</i> , in IMMUNOASSAY, A PRACTICAL GUIDE (1996) (“Law”)
1056	Bartels Legionella Urinary Antigen ELISA Test, 501(k) Premarket Notification (March 30, 1999), available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/K991074.pdf (“Bartels”)
1057	Fiber Optics Association Reference Guide, <i>Connector Identifier</i> , available at https://www.thefoa.org/tech/connID.htm (“FOA Reference Guide”)
1058	MetroTek, <i>Bare Fiber Adapters & Kits</i> , available at https://web.archive.org/web/20010411055716/http://metrotek.com:80/mtekbfa.htm (archived April 11, 2001) (“MetroTek Website”)
1059	Metrotek, MetroTek Catalog, Issue No. 8 (2004) (“MetroTek Catalog”)
1060	Defendants’ Notice and Stipulation re: Challenged Claims in IPR2025-00633, No. 5:22-cv-01417-EJD (N.D. Cal. Apr. 24, 2025), ECF No. 79
1061	Docket Sheet, in <i>Sartorius Bioanalytical Instruments, Inc. v. Gator Bio, Inc. and Hong Tan</i> , No. 5:22-cv-01417 (N.D. Cal.)
1062	Excerpt of Second Amended Complaint, Dkt. 59, in <i>Sartorius Bioanalytical Instruments, Inc. v. Gator Bio, Inc. and Hong Tan</i> , No. 5:22-cv-01417 (N.D. Cal.)
1063	Excerpt of Gator Bio’s Motion to Dismiss Second Amended Complaint, Dkt. 67, in <i>Sartorius Bioanalytical Instruments, Inc. v. Gator Bio, Inc. and Hong Tan</i> , No. 5:22-cv-01417 (N.D. Cal.)

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1064	Excerpted Transcript of May 1, 2025 Hearing, in <i>Sartorius Bioanalytical Instruments, Inc. v. Gator Bio, Inc. and Hong Tan</i> , No. 5:22-cv-01417 (N.D. Cal.)
1065	Excerpt of Staff's Initial Post-Hearing Brief, in <i>Certain Bio-Layer Interferometers and Components Thereof</i> , ITC Inv. No. 337-TA-1344
1066	Additional Excerpt of March 8, 2024 Final Initial Determination, in <i>Certain Bio-Layer Interferometers and Components Thereof</i> , ITC Inv. No. 337-TA-1344 (public version dated March 26, 2024)
1067	Excerpt of June 26, 2024 Commission Decision, in <i>Certain Bio-Layer Interferometers and Components Thereof</i> , ITC Inv. No. 337-TA-1344 (public version dated July 16, 2024)
1068	Excerpt of Transcript of Evidentiary Hearing, in <i>Certain Bio-Layer Interferometers and Components Thereof</i> , ITC Inv. No. 337-TA-1344
1069	Email from D. Doshi to H. Santhanam dated December 6, 2024
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1071	DocketNavigator Time to Milestones for Judge Edward Davila
1072	DocketNavigator Statistics for Motion Success for Stay Pending IPR (Post-Institution) for Northern District of California
1073	DocketNavigator Statistics for Motion Success for Stay Pending IPR (Post-Institution) for Judge Edward Davila
1074	Gator Bio Brochure, Gator Next-Gen Biolayer Interferometry, available at https://www.gatorbio.com/wp-content/uploads/2023/10/Gator%C2%AE-Family-Brochure-3.pdf
1075	Gator Bio Brochure, Gator Label-Free Analysis Systems (Exhibit CX102 in ITC case)
1076	Yiqi Luo et al., <i>Kinetics of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antibody Avidity Maturation and Association with Disease Severity</i> , CLINICAL INFECTIOUS DISEASE, 73(9):e3095-97 (2021) (Exhibit RX81 in ITC case)

Exhibit	Description
1077	Allison Titong et al., <i>First-in-class trispecific VHH-Fc based antibody with potent prophylactic and therapeutic efficacy against SARS-CoV-2 and variants</i> , SCIENTIFIC REPORTS, 12:4163 (2022) (Exhibit RX84 in ITC case)
1078	Mary Prahl et al., <i>Evaluation of transplacental transfer of mRNA vaccine products and functional antibodies during pregnancy and infancy</i> , NATURE COMMUNICATIONS, 13:4422 (2022) (Exhibit RX86 in ITC case)
1079	Ian Durie et al., <i>Structural characterization of protective non-neutralizing antibodies targeting Crimean-Congo hemorrhagic fever virus</i> , NATURE COMMUNICATIONS, 13:7298 (2022) (Exhibit RX82 in ITC case)
1080	Bo Wang et al., <i>A novel IgG Fc by computer-aided design enhances heavy-chain heterodimerization in bi- or trispecific antibodies</i> , ANTIBODY THERAPEUTICS, 5(3):216-225 (2022) (Exhibit RX83 in ITC case)
1081	Letter from P. Yu to L. Barton, Secretary to the U.S. International Trade Commission, dated April 4, 2024
1082	Letter from Z. Suo to L. Barton, Secretary to the U.S. International Trade Commission, dated April 5, 2024
1083	Letter from J. Wang to L. Barton, Secretary to the U.S. International Trade Commission, dated April 5, 2024
1084	DocketNavigator 5YR Time to Milestones for Judge Edward Davila
1085	Excerpt of Rebuttal Expert Report of Michael J. Sailor, Ph.D. FRSC, FNAI, dated May 5, 2023
1086	Excerpt of Sartorius Stedim Biotech, <i>Universal Registration Document 2022 Including the Annual Financial Report</i> (Feb. 2023), available at https://www.sartorius.com/download/1379314/ssb-annual-report-2022-e-data.pdf

I. Introduction

Patent Owner Sartorius Bioanalytical Instruments, Inc. (“PO” or “Sartorius”) largely complains that Hong Tan and Robert Zuk, two of the named inventors of U.S. Patent No. 8,647,588 (“’588 patent”), are principals of Petitioner Gator Bio, Inc. (“Petitioner” or “Gator Bio”). Because assignor estoppel does not apply to IPRs, PO tries to cast the issue as weighing on the Director’s discretion, while ignoring the many compelling, overarching considerations—including PO’s own “unfair dealings,” the extraordinary public interests at stake, and the strength of the petition—that set this IPR apart from nearly all others and warrant institution.

First, even if assignor estoppel were a proper consideration, numerous factual issues make it unsuitable to address in this IPR, including post-assignment developments such as PO’s misleading statements during prosecution to obtain allowance of the ’588 patent claims and PO’s litigation positions as to those claims, none of which the named inventors could have possibly anticipated. And contrary to PO’s narrative, this is *not* a scenario where the named inventors simply assigned a patent and went off to sell infringing products. To be sure, Dr. Tan and Mr. Zuk helped develop PO’s biolayer interferometry (“BLI”) technology while they were employed by one of PO’s predecessors (FortéBio) during the 2000s. But after they left the company in 2008, PO failed to carry forward the technology. In 2011, *three years later* and still clinging to its old technology, PO filed the application that would

issue as the '588 patent. And *nearly a decade later*, Dr. Tan and Mr. Zuk founded Gator Bio to address a critical, unmet need for *next-generation* BLI products.

Second, the Patent Office has a significant interest in instituting IPR here to discourage PO's unfair and dilatory litigation tactics, which inform the "settled expectations of the parties" and any "unfair dealings." Indeed, unable or unwilling to innovate, PO has sought to use its aging patents to harass and destroy Gator Bio, with little regard for the merits. In March 2022, PO sued Gator Bio in the Northern District of California, asserting four patents (notably not including the '588 patent). EX1061, Dkt. 1. But failing to plausibly allege any infringement, PO forced Gator Bio to twice move to dismiss. *Id.*, Dkts. 20 & 29. PO then took its dispute to the International Trade Commission ("ITC"), asserting all four patents there, while the district court case was stayed. *Id.*, Dkt. 38; EX1066, 1. After full discovery on those patents, PO itself saw fit to dismiss three of the patents. *Id.*, 2. And after an evidentiary hearing (trial) on the fourth patent, the Administrative Law Judge ("ALJ") issued a determination of *no violation in Gator Bio's favor* that was ultimately upheld by the Commission in June 2024. *Id.*, 3, 178; EX1067, 2.

The settled expectations of the parties thus was that their dispute was over—PO lost. PO, in fact, remained radio silent for *nearly six months* after the Commission decision and did not inform the district court that the ITC case had concluded even after its appeal deadline passed. And in the *nearly three years of litigation* between

the parties involving Gator Bio's BLI products, PO never once mentioned the '588 patent or even so much as hinted that *those same products* infringed the '588 patent.

But in December 2024, apparently dissatisfied with its ITC result, PO finally broke its silence and informed Gator Bio that it would press forward in the district court with three patents it had lost on or dropped from the ITC case. EX1069. And *for the first time*, PO indicated it would seek to amend its district court complaint to add the '588 patent. *Id.* PO has yet to explain why it waited *years* to identify or assert the '588 patent. But either (a) PO was lying in wait to assert the '588 patent, strategically concealing it from Gator Bio, or (b) having lost at the ITC on its best patents, PO delayed going back to the district court so it could find *something* to prop up its case. Because Congress intended for IPRs to be an efficient alternative to litigation, IPR institution is warranted here to discourage PO's dilatory tactics. Indeed, had PO identified the '588 patent when it filed suit in 2022, Gator Bio would have long ago filed this IPR, and the Board already would have resolved it.²

PO also has taken unfairly inconsistent positions before the Patent Office and in litigation that warrant the Board's expertise. Indeed, despite asserting that Gator Bio's BLI probes infringe the '588 patent's claims—all of which require an optical sensing assembly (BLI probe) comprising an “optical fiber” as a result of PO's claim

² Gator Bio did just that when it filed IPR2023-00215 challenging one of PO's other asserted patents just shortly after PO filed its ITC complaint in 2022.

amendments and arguments during prosecution—PO recently told the district court that the accused Gator BLI probes do *not* comprise an optical fiber in an effort to avoid prosecution disclaimer on another patent. EX1064, 30:10-17 (“we don’t” “characterize[s] their optical probes as optical fiber”). If so, PO had no legitimate basis to assert the ’588 patent and is applying the claims in some unsupported fashion that the named inventors could not have possibly contemplated.

Third, the strength of the petition—which PO does not meaningfully challenge—warrants institution. Notably, PO does not (and cannot) assert that the combinations and arguments in the petition were previously considered by the Patent Office. During prosecution, PO successfully obtained allowance of the claims by convincing the examiner that the prior art did not disclose BLI probes—even though it was aware of several such references. The grounds here identify prior art that not only discloses BLI probes (Yang and WO854) but also motivates the use of tip trays to package such probes (Miles). The grounds are further supported by the admissions of *PO’s own expert* that the cited prior art discloses such BLI probes. EX1012.

Fourth, the status of the district court case fully supports institution. That case is still at the pleading stage because it was stayed pending the ITC case PO chose to bring. EX1061. Upon learning of PO’s new claim based on the ’588 patent, Gator Bio diligently prepared the instant IPR petition and filed it *less than a week* after PO amended its complaint to add the patent. *Id.*, Dkt. 59. Because PO lacks basis to

continue asserting the patents from the ITC case, Gator Bio has moved to dismiss those patents, and it may be weeks or months before the court rules on that motion or even holds a scheduling conference. *Id.*, Dkt. 67. Even then, the median time to trial in this district is 31.8 months, and before the presiding judge, Edward Davila, it is even longer at 49.9 months. EX1070; EX1071. Cases in the district and before Judge Davila also are routinely stayed post-institution. EX1072; EX1073. Thus, a trial on the '588 patent is unlikely to occur until long after a final written decision here. To minimize overlap, Gator Bio also has stipulated that it will not raise invalidity defenses under 35 U.S.C. §§ 102 or 103, if this IPR is instituted. EX1060.

Finally, and significantly, because PO seeks to enjoin or otherwise prevent Gator Bio from offering its critical, next-generation BLI products, it is difficult to overstate the public interests that warrant institution. Notably, in the ITC case, the agency staff made the extraordinary recommendation that any remedy be set aside or severely limited given the adverse impact that limiting access to Gator Bio's products would have on the public interest. EX1065, 84-91. As the staff recognized, the public health and welfare would be harmed because "Gator Bio's BLI instruments and biosensors [probes] 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." *Id.*, 85. And "the prospect of eliminating Gator Bio (one of two

suppliers) in the BLI marketplace,” the staff explained, “would harm competitive conditions in the U.S. economy.” *Id.*, 88. The staff’s concerns are backed up by letters submitted by leading-edge laboratories warning of the adverse impact on their critical research efforts if they were to lose access to Gator Bio’s BLI products. EX1080-EX1083. Rarely will an IPR involve such express recognition of the public interests at stake by the independent staff of a sister agency and by the general public.

II. Background

A. Gator Bio and Its Next-Generation BLI Products

Gator Bio is a biotechnology startup company specializing in BLI products. Dr. Hong Tan and Robert Zuk co-founded Gator Bio in 2017 to address a need for innovation in BLI instruments and biosensors (probes) that had gone unmet by PO’s existing BLI products. EX1068, 286:22-287:18 (Tan), 384:14-21 (Zuk). Applying innovations that they had independently developed over the previous decade in the clinical-diagnostics space with respect to instrument and sensor design, Dr. Tan and Mr. Zuk (through Gator Bio) have since developed a portfolio of next-generation BLI products. *Id.*, 287:19-288:2 373:11-375:7 (Tan), 385:5-13 (Zuk). These products provide superior performance and features and cater to a broad range of applications, including the development, testing, and manufacture of antibody therapies, gene therapies, and pharmaceuticals, as well as a range of life-sciences

research applications such as investigation of COVID-19 and other infectious diseases. *Id.*, 310:19-311:16 (Tan); 393:20-397:15 (Zuk).

Gator Bio's product portfolio currently includes five next-generation BLI instruments (Pilot, Prime, Plus, Pivot, and Pro) that range in throughput and features. Ex. 1074 at 9-10. Gator Bio also offers a suite of nearly two-dozen BLI probes and kits that can be used with those instruments to study the binding interactions of a virtually infinite universe of molecules, including antibodies, proteins, DNAs, RNAs, small molecule compounds, and viral and bacterial particles.

Full Suite of Biosensors for Diverse Applications				
Probes	Function	Applications	Dynamic Range	Regeneration
ProA	IgG titer	Q	0.02-2000 µg/mL	Yes
ProG	IgG titer	Q	0.02-2000 µg/mL	Yes
ProL	Kappa light chain titer	Q	0.02-2000 µg/mL	Yes
SA	Biotinylated and Avi-tagged molecules	K/EP	Protein dependent	No
SA XT	Biotinylated proteins and large molecules	K	Protein dependent	No
Flex SA	Reusable SA kit	K	Protein dependent	Yes
SMAP	Measurement of small molecules, peptides (<150 Da)	K	Protein dependent	No
HFC	Human IgG characterization	Q/K/QKR/EP	0.05-300 µg/mL	Yes
HFCII	Advanced human IgG characterization	Q/K/QKR/EP	0.3-6000 µg/mL	Yes
MFC	Mouse IgG characterization	Q/K/QKR/EP	0.02-6000 µg/mL	Yes
Anti-FAB	F(ab), F(ab)2	Q/K/QKR/EP	0.3-3000 µg/mL	Yes
APS	Direct adsorption	K	Protein dependent	No
AR	Amine coupling immobilization	K/EP	Protein dependent	No
His	His-tagged proteins	Q/K/QKR/EP	Protein dependent	Yes
Ni-NTA	His-tagged proteins through Ni-NTA	Q/K/QKR/EP	0.25-1000 µg/mL	Yes
Strep-Tactin XT	Proteins with Twin-Strep-tag®	Q/K	Protein dependent	Yes
Anti-PEG	PEGylated lipid-based molecules	Q/K	Analyte dependent	No
Anti-GST	GST-tagged proteins	Q/K	0-100% full	No for Q
AAVX	Direct binding titer (AAV1-10)	Q/K	Protein dependent	Yes
AAV9	Direct binding titer (AAV9)	Q/K	1x10 ² - 1x10 ¹³ vp/mL	No
HS AAV	High sensitivity titer (AAV1-8, 10)	Q	3x10 ² - 1x10 ¹³ vp/mL	No
HS AAV9	High sensitivity titer (AAV9)	Q	1x10 ² -5x10 ¹⁰ vp/mL	No
AAV Ratio	Empty vs Full Ratio Determination	Ratio	1x10 ² -1x10 ⁹ vp/mL	No

Id., 4; EX1068, 293:5-16 (Tan); 391:12-392:12 (Zuk).

Although wide-ranging in applications, Gator Bio's BLI products are used in four major areas: (1) biotherapeutic development, including antibody and other

protein therapeutics; (2) gene-therapy development and manufacture; (3) traditional drug discovery and development, including small molecules and peptides; and (4) life-sciences research carried out by private and public labs at biotech companies, hospitals, universities, and government agencies.



EX1075, 2; EX1068, 311:1-16 (Tan).

Gator Bio’s innovations in the BLI space are reflected in numerous patent applications and issued patents across at least a dozen patent families. Many of Gator Bio’s products are also industry firsts. For example, the most common approach for gene therapy is to use the protein shell (capsid) of an adeno-associated virus (“AAV”) as a vector to deliver genetic material to a patient’s cells. EX1068, 398:4-23 (Zuk). Beginning in 2021, Gator Bio launched its AAV probes and kits (e.g.,

AAVX, AAV9, HS-AAV, HS-AAV9, Ratio), which provide effective tools for quantifying the viral capsid concentration and the ratio of capsids that are empty versus full of genetic material—all critical measurements for bioprocess development and optimization as well as large-scale production. *Id.*, 404:24-405:4, 409:11-410:10, 420:10-13 (Zuk), 1060:17-1062:6 (Forrest). Knowing the empty-to-full ratio also is quite important because the consequences of administering too much AAV in gene therapy can be fatal. *Id.*, 1062:7-1063:2 (Forrest).

Following Gator Bio's lead, PO finally launched a gene-therapy product, an AAVX probe, in 2023. But as its own corporate representative and expert have acknowledged, PO does not offer any product specifically tailored to the AAV9 virus serotype, any product for determining the ratio of empty-to-full virus capsids, or any combination of products that provide the same sensitivity or dynamic range as Gator Bio's gene-therapy products. *Id.*, 191:5-12 (Kang), 717:2-4, 717:22-25, 719:16-720:1 (Bailey); *see also id.*, 409:1-7, 418:21-23 (Zuk). Beyond gene-therapy products, PO has also been unable to match Gator Bio's SA XT and Flex SA biosensors/kits, which provide many advantages including greater sensitivity, better performance, and lower costs. *Id.*, 318:15-24; 369:22-370:8 (Tan).

Further still, Gator Bio offers the first and only BLI instrument (the Gator Pro) that provides 32-channels using 32 spectrometers. *Id.*, 295:32-296:23, 367:4-19, 503:15-19 (Vander Veen); 951:21-954:21(Schaafsma). The more channels

available, the more samples that can be measured in parallel, meaning higher throughput. PO does offer an instrument that multiplexes 16 spectrometers to achieve 96 channels, but due to the multiplexing, it has a slower data acquisition rate than the 32-spectrometer Gator Pro, which can more reliably measure fast interactions of small molecules. *Id.*

B. Litigations Between the Parties

PO sued Gator Bio and Hong Tan in March 2022 in the Northern District of California, asserting infringement of four patents: U.S. Patent Nos. 7,394,547; 7,728,982; 8,305,585; and 7,445,887. EX1061, Dkt. 1. Notably, PO did not assert or otherwise identify the '588 patent as being at issue, even though it was accusing then the same Gator Bio BLI products that it now accuses of infringing the '588 patent. Because PO failed to plausibly allege infringement of any of the asserted patents, Gator Bio moved to dismiss the complaint. *Id.*, Dkt. 20. PO responded by filing an amended complaint that failed to correct these deficiencies (*id.*, Dkt. 28), forcing Gator Bio to file another motion to dismiss PO's amended complaint (*id.*, Dkt. 29).

In October 2022, after Gator Bio's second motion to dismiss was fully briefed, PO initiated an ITC case asserting the same four patents. EX1066, 1. Again, PO accused the same Gator Bio BLI products but did not assert or otherwise identify the '588 patent as being at issue. The district court in turn stayed all proceedings before it pending final resolution of the ITC case. EX1061, Dkt. 38.

In instituting the ITC case, the Commission recognized at the outset the potential impact of any remedy on the public interest and thus delegated authority to the ALJ to take evidence and hear argument on public-interest considerations. The Commission further appointed the independent staff of the Office of Unfair Importation Investigation (“OUII”) as a party to represent the public interest. As addressed below in § III.A.3, the OUII staff ultimately found the potential adverse impact on public interest to be significant, and in a rare and extraordinary move, the staff recommended that any remedial order be set aside or severely limited to minimize disruptions in access to Gator Bio’s BLI products. EX1065, 84-91.

During the ITC case, PO took discovery on its infringement claims as to all four asserted patents but ultimately terminated (dismissed) three patents just shortly before the evidentiary hearing (trial) was to take place. EX1066, 2. Then, after Commission review of an indefiniteness issue relating to the fourth patent (No. 7,445,887), the ALJ held an evidentiary hearing on that patent in November 2023. *Id.*, 2-3. In March 2024, the ALJ issued a final initial determination of no violation, concluding that Gator Bio did not infringe the fourth patent. *Id.*, 178. After PO sought further review, the Commission issued a decision in June 2024, in which it modified but ultimately affirmed the determination of no violation. EX1067, 2.

Then, for nearly six months after the Commission decision, PO remained radio silent. Even after PO’s deadline for filing a notice of appeal passed in August

2024, PO did not notify the district court that the ITC case had concluded, giving the impression that the dispute between the parties was over.

But apparently dissatisfied with its ITC loss, PO broke its silence in December 2024, when it informed Gator Bio that it would press forward with the district court case. EX1069. PO indicated that it would continue to assert three of the patents from the ITC case, including the patent it tried unsuccessfully before the ALJ and two others that it saw fit to dismiss. *Id.* And for the first time, PO identified and indicated that it would seek to amend the district court complaint to assert the '588 patent. *Id.* PO provided no explanation why it did not earlier identify the '588 patent out of the sizable portfolio it purports to have or otherwise assert it back in 2022, either when it initially filed suit in the district court or when it initiated the ITC case.³ *Id.*

Upon learning of PO's new claim based on the '588 patent, Gator Bio diligently prepared the instant IPR petition challenging the '588 patent and filed it on February 24, 2025, less than a week after PO amended its district court complaint to assert the '588 patent. EX1061, Dkt. 59. Gator Bio also has filed in the district court a motion to dismiss PO's claims based on the three patents it previously unsuccessfully asserted in the ITC case. *Id.*, Dkt. 67. The district court held a hearing on Gator Bio's motion in May 2025 but did not indicate when it expects to issue a

³ For 2022, the year it sued Gator Bio, Sartorius boasted having a portfolio of 4,067 patents and trademarks, having added 267 that year. EX1086.

decision. *Id.*, Dkt. 86. Until the court issues a decision, it is not expected to hold a scheduling conference or otherwise enter a case schedule.

C. The '588 Patent and Its Alleged Invention

The '588 patent and the challenged claims are generally directed to a “tip tray” apparatus for packaging sensor probes (referred to as “optical sensing assemblies” in the patent) to facilitate their use with standard microtiter plates.

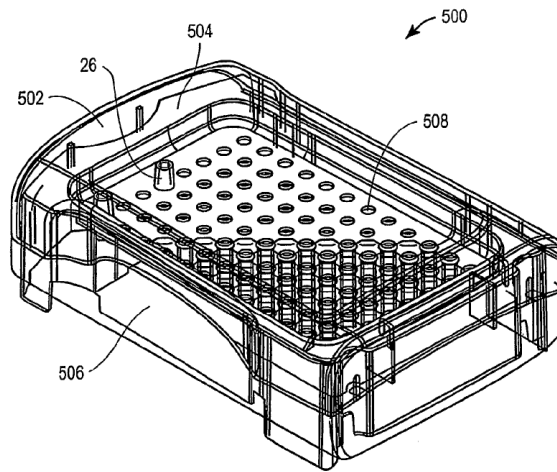


FIG. 5

EX1001, title, 1:19-22, claim 1, Fig. 5. During prosecution, the examiner repeatedly rejected the claims, reasoning that a tip tray for probes was neither novel nor nonobvious. *E.g.*, EX1004, [132]-[136]. To overcome those rejections, PO amended the claims to recite features of BLI probes (also known as “reflectometric interference spectroscopy” or “RIfS” probes), including “an optical fiber and a transparent optical element having...first and second reflecting surfaces separated by at least 50 nm.” *Id.*, [218], [236]. Pointing to the amendments, PO argued that the prior art failed to disclose BLI probes having these claimed elements. *E.g.*, [208]-

[209], [239]-[240]. And mistakenly relying on PO's assertions, the examiner ultimately allowed the claims. *Id.*, [252].

III. Discretionary Denial Is Not Warranted

A. The Factors Outlined in the Director's Memorandum or Otherwise Addressed by Patent Owner Do Not Warrant Discretionary Denial, and to the Contrary, Support Institution

Principally raising an assignor-estoppel argument, PO asserts that various considerations support discretionary denial, including those outlined in the Acting Director's March 26, 2025 memorandum regarding "Interim Processes for PTAB Workload Management" ("Director's Memorandum"). PO's assertions not only lack merit but also ignore the many compelling considerations—including PO's own unfair dealings, the extraordinary public interests, and the strength of the petition grounds—that distinguish this IPR from nearly all others and support institution.

1. Assignor estoppel does not apply to IPRs and in any event does not warrant discretionary denial

As a threshold matter, controlling precedent from both the Federal Circuit and the Board holds that assignor estoppel does *not* apply to IPRs. In *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 801, 803-04 (Fed. Cir. 2018), the Federal Circuit held that the Board's determination of whether assignor estoppel applies at the institution stage was reviewable and then affirmed the Board's conclusion that assignor estoppel in fact did not apply to IPRs as a matter of law. As the Federal Circuit explained, the enabling statute for IPRs, 35 U.S.C. § 311(a), provides that "a

person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent” and thus “unambiguously leaves no room for assignor estoppel in the IPR context.” *Id.* at 803. The Board likewise has held in a precedential decision that assignor estoppel does not apply to IPRs. *Athena Automation Ltd. v. Husky Injection Molding Sys. Ltd.*, IPR2013-00290, Paper 18, at 12-13 (PTAB Oct. 25, 2013) (precedential); *see also Frameless Hardware Co. LLC v. C.R. Laurence Co., Inc.*, IPR2022-00620, Paper 8, at 8-10 (PTAB Sept. 13, 2022).

PO acknowledges (at 1-2, 8) that assignor estoppel does not apply to IPRs and instead couches it as a factor weighing on discretionary denial, citing the Acting Director’s decision in *Tessell, Inc., v. Nutanix, Inc.*, IPR2025-00322, Paper 14, at 2-3 (PTAB June 12, 2025). There, as part of a “holistic assessment of all the evidence and arguments presented,” the Acting Director found that the fact that the IPR was brought by named inventors who “applied for and were issued” the challenged patent was relevant as “unfair dealings” that “tip[ped] the balance to exercising discretion to deny institution.” *Id.* PO argues that the same unfair dealings exist here but fails to address the underlying factual complexities and the numerous other compelling considerations that were not present in *Tessell* and that support institution here.

Even to the extent assignor estoppel may be considered in an IPR, PO’s assertion of assignor estoppel here is steeped in factual issues that are not suitable to

resolve in an IPR, let alone at the institution stage.⁴ In *Minerva Surgical, Inc. v. Hologic, Inc.*, 594 U.S. 559, 576-77 (2021), the Supreme Court held that 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.” “[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 576. And post-assignment developments must be considered, because they can bear on whether assignor estoppel applies. *Id.* at 577.

Here, unlike in *Tessell* and contrary to PO’s assertions (at 1, 20-24), Dr. Tan and Mr. Zuk did not apply for, obtain, or even specifically assign the ’588 patent. Nor were they involved in the prosecution of the ’588 patent. Rather, in January 2007, they assigned an earlier application in the same family (U.S. Application No. 13/101,112). EX2007. It was not until May 2011—*more than four years after* Dr. Tan and Mr. Zuk made the assignment in question and *nearly three years after* they had left PO’s predecessor company—that PO filed the application that would

⁴ Gator Bio disputes that assignor estoppel is a relevant discretionary consideration because the Patent Office may not foreclose through its discretionary authority under § 314(a) what Congress expressly allowed under § 311(a). To the extent *Tessell* suggests otherwise, the Director should reconsider or clarify that decision.

later issue in 2014 as the '588 patent. Though PO offers much speculation, it does not identify any plausible basis to suggest that Dr. Tan or Mr. Zuk even knew of the '588 patent. These circumstances undermine PO's false narrative of Dr. Tan and Mr. Zuk having knowingly assigned a patent and gone on to develop infringing products. To the contrary, as addressed in § II.A, Dr. Tan and Mr. Zuk co-founded Gator Bio nearly a decade after they left PO's predecessor to address a critical need for innovative, next-generation BLI products that PO had failed to meet.

Moreover, unlike in *Tessell*, factual issues relating to post-assignment developments inform and complicate any application of assignor estoppel here. Notably, during the prosecution of the '588 patent, PO successfully obtained allowance of the claims by amending them to recite specific features of BLI probes, including “an optical fiber and a transparent optical element having...first and second reflecting surfaces separated by at least 50 nm.” EX1004, [218], [236]. PO further repeatedly argued that the prior art failed to disclose BLI probes having these elements (*id.*, [208]-[209], [239]-[240])—all the while knowing that myriad references including Yang (EX1006), WO854 (EX1008), and Sun (EX1010/11) disclosed precisely such probes, as its *own expert* confirmed in the ITC case. Pet. 35-38; EX1012. Dr. Tan and Mr. Zuk could not have possibly anticipated that PO would take such positions when they executed their 2007 assignment. And because

the petition grounds seek to correct the error that occurred during prosecution—as a result of *PO's misleading representations*—they should be allowed to proceed.

PO also has taken unfairly inconsistent positions in the related district court case that inform the scope of the '588 patent claims in a manner that (again) Dr. Tan and Mr. Zuk could not have possibly anticipated when executing their 2007 assignment. As addressed below, despite asserting that Gator Bio's BLI probes infringe the '588 patent claims—all of which require a probe comprising an “optical fiber” as PO repeatedly emphasized during prosecution—PO has told the district court that Gator Bio's probes do *not* comprise an optical fiber, in an effort to avoid prosecution disclaimer on a different patent. *See* § III.A.2.b. PO's position not only raises serious questions about its basis for asserting the '588 patent but also underscores the need for the Board's expertise in holding PO to a consistent position.

Further still, to the extent unfair dealings are relevant, the Director should also consider the other relevant factors—including PO's unfair dealings in litigation, the extraordinary public interests at stake, and the strength of the petition grounds—all of which set this IPR apart and holistically support institution. Not only has PO taken inconsistent positions in litigation as noted above, but PO also has engaged in unfair and dilatory tactics, including strategically delaying identifying or asserting the '588 patent for *nearly three years* while the parties litigated PO's other patents. *See* § III.A.2.a. Meanwhile, the public interests at stake cannot be overstated because

Gator Bio’s next-generation BLI products that PO seeks to eliminate are critical to not only basic research but also wide-ranging clinical and industry applications, including the development of new drugs, therapies, and diagnostics and research into diseases such as COVID-19 and hemorrhagic fever (40% mortality rate). *See* § III.A.3. The grounds here also are strong and supported by *PO’s own expert* who confirmed that the cited prior art discloses BLI probes having the very elements that PO argued during prosecution were missing from the prior art. *See* § III.A.4; *Eunsung Global Corp. v. Hydrafacial LLC*, IPR2025-00453, Paper 14, at 2 (PTAB July 10, 2025) (error in prosecution sufficient to overcome any settled expectations).

Given these numerous, overarching, and compelling considerations that were not present in *Tessell*, the Director should not apply assignor estoppel or otherwise rely on the doctrine here to discretionarily deny IPR.

2. Patent Owner’s unfair dealings and the settled expectations of the parties strongly support institution

a. The Patent Office has a significant interest in discouraging Patent Owner’s unfair and dilatory litigation tactics

Unable to compete through innovation, PO has sought to use its aging patents to harass and destroy Gator Bio through a litigation campaign that has had very little regard for the merits and has been grounded in unfair and dilatory tactics that inform the “settled expectations of the parties” and any relevant “unfair dealings.”

As discussed in § II.B, PO sued Gator Bio and Dr. Tan in March 2022 in the Northern District of California, asserting that Gator Bio's BLI products infringed four patents, notably not including the '588 patent. EX1061, Dkt. 1. Because it failed to allege any plausible infringement, PO forced Gator Bio to twice move to dismiss, before PO took its dispute to the ITC in October 2022 and asserted all four patents there. *Id.*, Dkts. 20 & 29; EX1066, 1. After full discovery at the ITC on its infringement claims, PO itself dropped three of the asserted patents, and it ultimately lost after a trial on the fourth patent, with the ALJ and the Commission both determining that Gator Bio did *not* infringe. EX1066, 178; EX1067, 2.

Even as the parties spent years litigating PO's unsuccessful infringement claims against Gator Bio's BLI products, PO did not once breathe a word about the '588 patent, let alone suggest that those same products infringed the '588 patent. PO also remained radio silent for nearly six months after the Commission issued its decision in June 2024, indeed without informing the district court that the ITC case had concluded even after PO's appeal deadline passed. Thus, the reasonable and settled expectations of the parties was that the dispute was over—PO had lost.

It was not until December 2024 that PO broke its silence, stating that it would press forward in the district court by asserting three patents that it had lost on or dropped from the ITC case and indicating *for the first time* that it intended to assert the '588 patent. EX1069. And it was not until February 2025 that PO amended its

complaint to add the '588 patent. EX1061, Dkt. 59; EX1062, 2 (¶3). Notably, PO still has not explained why it waited so long to identify or assert the '588 patent. But the reality is that either (a) PO was lying in wait to assert the '588 patent, all the while strategically concealing it from Gator Bio, or (b) PO delayed going back to the district court so that it could find *some* patent to prop up its district court case.

These circumstances dispel PO's false narrative that Dr. Tan and Mr. Zuk somehow knowingly delayed seeking IPR of the '588 patent and also lay bare PO's attempt to blame them for the patent's looming expiration. The circumstances here also are readily distinguishable from *iRHYTHM Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10, at 3 (PTAB June 6, 2025), where the petitioner was aware of the patent application that issued as the challenged patent, cited it in its own patent applications relating to its products, and failed to seek IPR.

Critically, if PO had asserted the '588 patent in March 2022 when it filed its district court complaint or even in October 2022 when it initiated the ITC case, Gator Bio would have initiated this IPR long ago and well before the Director's Memorandum or the Board's current policies took effect. And the Board already would have reached a final written decision years before the statutory expiration of the '588 patent. Indeed, upon learning of PO's new claim based on the '588 patent,

Gator Bio diligently prepared the instant petition and filed it *less than a week* after PO amended its district court complaint to add the '588 patent.⁵

Because Congress intended for IPRs to provide an efficient and cost-effective alternative to litigation, the Board has a significant interest in instituting IPR here to discourage PO's unfair and dilatory tactics that have unnecessarily drawn out the litigation between the parties. *See* H.R. REP. NO. 112-98, at 39-40 (2011) (AIA was intended to "improv[e] patent quality and provid[e] a more efficient system for challenging patents that should not have issued" and to "limit unnecessary and counterproductive litigation costs").

⁵ As PO boasts a sizable portfolio of over 4,000 patents and trademarks (EX1086), it would not have been feasible for Gator Bio to scour, divine, and seek IPR of every patent that PO might assert, apparently even on dubious grounds (*see* § III.A.2.b). Nonetheless, Gator Bio has had a history of promptly seeking IPR (where appropriate) after being alerted to an infringement assertion. In addition to this IPR, another example is IPR2023-00215, where Gator Bio filed a petition challenging one of PO's other asserted patents in November 2022, *less than a month* after PO filed its ITC complaint and *before* the ITC case was instituted. EX2009.

b. Patent Owner has taken unfairly inconsistent positions that bear on the '588 patent and warrant the Board's expertise

To obtain allowance of the '588 patent, PO made specific representations to the Patent Office that squarely contradict, and are contradicted by, PO's assertions to the district court in the pending litigation and that warrant the Board's expertise.

Notably, in response to the examiner's prior-art rejections, PO amended the claims to specify that the claimed tip-tray apparatus comprises "at least one discrete optical sensing assembly" having features of a BLI probe, including "*an optical fiber* and a transparent optical element having first and second reflecting surfaces." EX1004, [218] (emphasis added). PO further amended the claims to specify other elements of BLI probes, including that "the first and second reflecting surfaces separated by at least 50 nm, wherein the first reflecting surface comprises a layer of analyte binding molecules." *Id.*, [236]. PO also repeatedly relied on these amendments to distinguish the cited prior art. For example, PO distinguished certain prior art as describing a dispensing tip instead of an optical sensing assembly (BLI probe) having the claimed optical fiber and other elements:

Marquiss merely teaches passing fluid through dispensing elements. There is no teaching or suggestion in Marquiss of an apparatus for packaging an optical sensing assembly, the apparatus comprising "at least one discrete optical sensing assembly comprising *an optical fiber* and a transparent optical element having first and second reflecting surfaces."

Id., [209] (emphasis added); *see also id.*, [151]-[152], [238]-[239].

As noted, PO now asserts in the district court case that Gator Bio's BLI probes infringe the '588 patent. EX1062, ¶¶ 151-52. But although the claims of the '588 patent expressly require an optical sensing assembly (BLI probe) comprising an "optical fiber," PO recently told the district court at a hearing on Gator Bio's motion to dismiss that Gator Bio's BLI probes do *not* comprise an optical fiber in an effort to avoid a finding of prosecution disclaimer as to one of the other asserted patents:

[PATENT OWNER'S COUNSEL]: The defendants [Gator Bio and Hong Tan] are incentivized to characterize their optical probes as optical fiber, and in their brief they point to paragraphs 144 and 55 of our complaint and say that we say the probe is fiber, which we don't.

I mean, we look back and nowhere in there do we say fiber.

But interestingly, they also cite to the ITC docket...where the probe is described as a micro glass rod, which is not optical fiber.

THE COURT: Is that the same thing as optical fiber? Is it something else?

[PATENT OWNER'S COUNSEL]: We claim it is distinct.

THE COURT: You don't know what they're talking about.

[PATENT OWNER'S COUNSEL]: Yes, your honor. And that is why it will require discovery, and it's a fact determination, are these two distinct things? Are the probes actually optical fiber? And we posit it would be inappropriate to make a determination and assume based on the position that is advantageous to them for their entire disclaimer argument to apply, that the probe is optical fiber, when...they put the weight that they put in the lower proceedings, they described it as micro glass rod.

EX1064, 30:6-31:7. Doubling down on its assertion, PO analogized an optical fiber in this context to the “bundle of fiberoptic cables” that consumers use for digital cable TV connections and argued that they are “visually distinct...from what the [Gator Bio] probes look like.” *Id.*, 31:21-25.⁶

PO’s representation to the district court that the Gator Bio BLI probes lack an optical fiber cannot be squared with its assertion that the same probes infringe the ’588 patent claims—all of which require a probe comprising an optical fiber based on PO’s claim amendments and arguments during prosecution. If true, PO had no legitimate basis to assert the ’588 patent and is applying the claims in some unsupported fashion that the named inventors could not have possibly contemplated when they executed the 2007 assignment on which PO relies to complain of “unfair

⁶ Further underscoring PO’s unfair dealings, PO’s inconsistent positions as to the ’588 patent arise out its attempt to evade its positions in IPR2023-00215 challenging U.S. Patent No. 8,305,585, one of the ITC patents PO continues to assert. There, PO successfully convinced the Board to deny institution under § 325(d) by disclaiming the BLI arrangement described in petition grounds and arguing that it was substantially similar to prior art considered during prosecution. EX1063, 8-11, 16-19. But before the district court, PO has accused Gator Bio’s BLI products having that same arrangement of infringing the same patent. *Id.*; EX1064, 7-14.

dealings.” Either way, institution is warranted so that the Board may apply its expertise to hold PO to a consistent position.

3. The extraordinary public interests at stake distinguish this IPR from nearly all others and strongly support institution

Given the critical applications in which Gator Bio’s BLI products are used and PO’s ongoing litigation effort to eliminate access to these products, this IPR invokes significant public interests that set it apart from nearly all others. Notably, in the ITC case, the Commission recognized at the outset the potential impact of the remedy sought by PO and appointed the independent OUII staff to represent the public interest. After full discovery and an evidentiary hearing (trial) addressing the public interest, the OUII staff took the extraordinary step of recommending that any remedy (that might otherwise issue against Gator Bio) be entirely set aside or severely limited. EX1065, 85. The undersigned is aware of only a handful of instances in the history of the ITC in which the OUII staff have taken such a position. And it would be a rare instance for an IPR to involve such express recognition of the public interests at stake by the independent staff of a sister agency.

To begin, the OUII staff aptly recognized the significant adverse impact that restricting access to Gator Bio’s BLI products would have on the public health and welfare. In particular, the staff recognized 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.” *Id.*, 85. The staff further recognized “Gator Bio’s customers include government agencies, government labs, university labs, hospitals, and large, medium, and small biotech companies.” *Id.*, 86; EX1068, 320:23-321:8 (Tan); 497:21-498:3 (Vander Veen). And Gator Bio’s products, the staff explained, are used (among other things) “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.” EX1065, 85; *see also* EX1068, 393:1-397:25 (Zuk), 499:1-500:13 (Vander Veen).

The OUII staff’s observations are supported by the published literature describing the important applications in which Gator Bio’s BLI products have been used. A few examples are attached as EX1076-EX1080 and summarized below:

- Luo et al. (EX1076): A team at the University of California San Francisco and Zuckerberg San Francisco General Hospital used Gator Bio’s BLI products to develop a test to study COVID-19 antibody avidity maturation and its association with disease severity. *Id.*, e3095; EX1068, 393:20-394:15 (Zuk).
- Titong et al. (EX1077): A team at Ab Studio, a biotech company, used Gator Bio’s BLI products to characterize a panel of antibodies that would bind to the COVID-19 virus in a lead up to preclinical studies. *Id.*, [2]; EX1068, 394:16-395:8 (Zuk).
- Prahl et al. (EX1078): A team at the University of San Francisco and the NIH used Gator Bio’s BLI products to study the transplacental transfer

from pregnant mothers to their babies of COVID-19 antibodies generated by an mRNA vaccine. *Id.*, 8; EX1068, 395:9-396:6 (Zuk).

- Durie et al. (EX1079): A team at the University of Maryland, the University of Georgia, the University of California Riverside, the Centers for Disease Control, and the U.S. Army at Fort Detrick (among others) used Gator Bio's BLI products to characterize the binding of antibodies (from surviving patients) to the Crimean-Congo hemorrhagic fever virus, which has a 40% mortality rate and for which there is no effective vaccine. *Id.*, 9, EX1068, 396:7-21(Zuk).
- Wang et al. (EX1080): A team at Ab Studio, Genor Biopharma, and Fundan University used Gator Bio's BLI products to characterize bi- and tri-specific antibodies to study a platform for computer-aided design of therapeutic antibodies. *Id.*, 217; EX1068, 396:22-397:20 (Zuk).

The OUII staff additionally recognized that "U.S. consumers would suffer harm if they were not permitted to purchase, use, or service Gator Bio BLI instruments and consumables." EX1065, 89. Among other things, the staff noted that "BLI devices must undergo a validation process before it can be used for many applications," particularly in FDA-regulated applications such as gene therapies. *Id.*, 89-10. Because Gator Bio probes are specific to Gator Bio instruments, "if a customer had Gator Bio probes and kits (including universities and government labs), they could not use them with Sartorius instruments and...it would be either very difficult or impossible for customers to switch from a Gator Bio BLI system to

a Sartorius BLI system.” *Id.*, 86; *see also id.*, 90-91; EX1068, 317:1-318:7 (Tan), 414:21-415:8 (Zuk), 1063:17-25 (Forrest), 500:17-502:16 (Vander Veen).

Further, the OUII staff explained that “the market for BLI products is a two-player market with only Sartorius and Gator Bio” and that “the prospect of eliminating Gator Bio (one of two suppliers) in the BLI marketplace would harm competitive conditions in the U.S. economy.” EX1065, 87-88. That prospect is even more concerning given that there are no alternatives for many of Gator Bio’s products, including its industry-first gene-therapy probes and kits, its SA XT and Flex SA probes and kits, and its 32-spectrometer Gator Plus instrument. *See* § II.A. Notably, regarding gene-therapy applications, PO’s own corporate representative and expert have acknowledged that PO does *not* offer any product specifically tailored to the AAV9 virus serotype, any product for determining the ratio of empty-to-full capsids, or any combination of products that provide the same sensitivity or dynamic range as Gator Bio’s products. EX1068, 191:5-12 (Kang), 717:2-4, 717:22-25, 719:16-720:1 (Bailey); *see also id.*, 409:1-7, 418:21-23 (Zuk).

As noted, the ALJ in the ITC case ultimately issued a determination of no violation in Gator Bio’s favor, finding that the accused Gator Bio BLI products did not infringe. EX1066, 178. Nonetheless, the ALJ addressed the public interest, and while recognizing many of the same concerns as the OUII staff, the ALJ found that they would be alleviated by several limitations on any remedy at the ITC (if one

were to issue). *Id.*, 159-169. Among other things, the ALJ noted that any remedy at the ITC would not reach (a) Gator Bio's probes and kits, all of which are domestically manufactured and not imported, (*id.*, 161-62); (b) Gator Bio's instruments that had already been imported and deployed (*id.*, 161); (c) Gator Bio's Pivot and Pilot instruments, which PO had represented would not be included in the scope of any ITC remedial order (*id.*, 162-63); or (d) the service and repair of existing Gator Bio instruments, for which the ALJ carved out an exemption (*id.*, 163-64). PO, however, has given no indication that any of those limitations would apply to the remedies it seeks in the pending district court case. To the contrary, PO seeks a sweeping injunction and damages with respect to all Gator Bio BLI products, in an effort to run Gator Bio out of business. EX1062, 49-50.

Further still, when PO sought Commission review of the ALJ's determination of no violation, several leading-edge research groups from across the country submitted letters explaining that not having access to Gator Bio's next-generation BLI products would adversely impact their critical research efforts. EX1081-EX1083. The Commission ultimately did not address the public interest when it affirmed the ALJ's determination of no violation. Nonetheless, the submitted letters underscore the public interests that are at stake in this IPR in light of the pending district court case. For example, a research group affiliated with Harvard Medical School and Massachusetts General Hospital wrote:

We own a GatorPlus instrument that we have used in our research since 2021 and have used BioLayer Interferometry (BLI) for our research for more than 10 years. We have used this technology to support research in mechanisms of pulmonary arterial hypertension (PAH), and in a number of other musculoskeletal and metabolic diseases. Our work using this platform was used to enable drug development programs in pulmonary arterial hypertension, leading to one new therapy recently approved for PAH (sotatercept/Winrevair), and two programs that are currently in Phase 1B and Phase 2 clinical trials. While we have worked in this area of research for more than 20 years, the advent of these technologies, and especially the refinements in the GatorBio platform, have greatly accelerated our progress by allowing us to quantify interactions between protein molecules in a highly accurate and reproducible manner.

We use kits for the GatorBio Plus that utilize standard antibody-coated and streptavidin-coated sensors....The GatorBio platform has been indispensable for our work. We currently do not have access to any platform or technology that would provide the same level of sensitivity, speed, and reproducibility in assaying strength of intermolecular interactions. We have previously tried to use Sartorius experiments for this work but found that these instruments have reduced sensitivity and suffer from excessive noise, precluding their use for quantifying many of the intermolecular interactions that are the focus of our work. We and our collaborators would suffer substantial hardships if we were to lose access to GatorBio reagents and instruments in the future.

EX1081.

Another group affiliated with Florida State University wrote:

[W]e conduct basic research to elucidate the mechanisms of DNA synthesis, DNA lesion bypass, and base excision repair. As a part of our work, we are investigating ways to improve our understanding about how DNA polymerases bind to both normal and damaged DNA, and this research involves using Gator Bio's Gator Plus instrument and Streptavidin (SA) probes to bind biotinylated DNA oligomers. Consistency in our research requires using the same instrument setup across experiments. Without the Gator instrument and SA biosensors, this research would suffer setbacks, including loss of time and resources.

EX1082.

Yet another group at Avantgen, a biotechnology company, wrote:

AvantGen...specializ[es] in the discovery and development of novel antibody drugs, which have great potential for improving public health and welfare. We have developed a proprietary and robust yeast display platform, a natural human antibody database, and a fully human antibody library that is one of the largest in the industry. As part of our work, we use Gator Bio's Gator Plus instrument and probes to study antibody binding kinetics, and this work demands that we use a consistent setup across experiments. If we did not have access to the Gator instrument and probes, our work would suffer substantial setbacks, including lost time and resources to validating other, potentially less effective methods.

EX1083.

In short, the extraordinary public interests at stake in this IPR—as expressly recognized by the independent staff of a sister agency and research groups around the country—set it apart from nearly all other IPRs and support institution.

4. The strength of the unpatentability challenge supports institution

a. The petition grounds are strong and seek to correct an error in issuing the '588 patent based on PO's misleading statements

The petition grounds set forth a strong, compelling case of obviousness that the PO fails to meaningfully challenge.

As explained in the petition grounds, by the time of the alleged June 2005 priority, the de facto standard for many laboratory assays was to use microtiter plates, typically comprising 96 wells arranged in an 8x12 array. Pet., 5-6, 26; EX1014, 3:31-48; EX1041. Microtiter plates allowed researchers to perform assays on a smaller scale (using smaller sample/reagent volumes) and also process multiple samples in parallel, thereby increasing speed and throughput. Pet. 5, 26, EX1036, 1; EX1013, 1:12-23. Driven by the microtiter-plate format, persons of ordinary skill in the art (“POSAs”) were motivated to design and use complementary equipment such as 8- and 12-channel pipettes, tip trays that packaged pipette tips in an 8x12 array, and instruments for automating pipetting and assay procedures in this format. Pet. 6-10, 27; EX1039; EX1048-EX1051.

POSAs also successfully designed and used such tip trays to package various sensor probes to facilitate their use with standard microtiter plates as well as automated assaying machines that relied on such plates, as reflected in prior art such as Miles (EX1005). Pet., 10-12, 27-28; Miles, 9:49-54, 10:18-27, Figs. 5-6; EX1016, 3:14-22, Fig. 2. And BLI/RIfS probes having the claimed features likewise were known and disclosed in the prior art such as Yang (EX1006) and WO854 (EX1008), which further taught how to multiplex such probes to assay multiple samples simultaneously. Pet. 12-14; WO854, ¶¶ [0007], [0077]-[0079], Fig. 4, claims 22-23, 26-27; Yang, 431, 436 (describing “parallel” assays); EX1009, 6:28, 8:17-29, 12:54-13:12, Fig. 11. POSAs thus were well motivated to package BLI/RIfS probes in tip trays to facilitate their use with standard microtiter plates and related assay instruments (as was done with other optical probes) so that multiple, simultaneous assays could be easily and efficiently performed on the same plate. Pet. 30

Notably, PO does not (and cannot) suggest that the prior-art combinations or arguments in the petition grounds were previously considered by the Patent Office. As noted, during prosecution, the examiner rejected the claims and allowed them only after PO amended the claims to recite features of BLI probes, including “an optical fiber and a transparent optical element having...first and second reflecting surfaces separated by at least 50 nm.” EX1004, [218], [236]. PO also repeatedly distinguished the cited prior art based on these amendments, for example arguing

that the prior art described dispensing tips instead of optical probes or otherwise did not describe BLI probes having the claimed elements. *Id.*, [218], [236]. And mistakenly relying on PO's assertions, the examiner allowed the claims. *Id.*, [252].

The petition grounds ask the Board to correct the error that occurred during prosecution in allowing the challenged claims based on PO's misleading representations. *See Eunsung*, Paper 14, at 2 (error during prosecution enough to overcome any settled expectations). The Miles reference—which serves as the primary reference in each of the grounds and which was not before the examiner—describes a tip tray for optical probes, contrary to PO's assertions that such trays were not known. Pet. 31-33.⁷ The grounds also identify disclosures in Yang and WO854 of BLI probes having the claimed elements, again contrary to PO's assertions that such BLI probes were not known. Pet. 33-38, 71-73. The grounds further cite admissions by *PO's own expert* that the cited prior art discloses such BLI probes. Pet. 34-38; EX1012, 285:13-286:12, 289:2-24, 291:7-10, 339:17-341:2.

⁷ Rainin (EX1007), relied on in Grounds 2 and 4, also was not before the examiner during prosecution. As established in the petition, Rainin discloses boxed tip trays having a cover and a base to protect the tips. Pet. 7-8, 59-60; Rainin, 4:20-48, 5:1-7, 5:41-45, 5:50-52, Figs. 1, 3, 4, 6.

5. Patent Owner's attacks on the petition grounds are unavailing

PO makes several unfounded arguments that fail to meaningfully challenge the strength of the petition grounds.

First, PO incorrectly argues (at 25) that the petition “improperly attempts to shift the burden of claim construction to the Board and PO” and relatedly (at 29) that the petition fails to sufficiently address the requirement of “an optical fiber” in Grounds 3-4 (based on WO854).⁸ As Gator Bio properly explained, it does not believe that any terms need construction to resolve the issues presented. Pet., 18. Indeed, “[t]he Board is required to construe ‘only those terms...that are in controversy, and only to the extent necessary to resolve the controversy.’” *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (citation omitted). And the Board routinely elects not to construe claim terms when it is not necessary to resolve issues in an IPR. *E.g., Apple Inc. v. Masimo Corp.*, IPR2024-00290, Paper 34, at 11 (PTAB June 25, 2025) (“In our Institution Decision, we determined that no terms required express construction....”). In any event, the Board may “instruct[] the parties to set forth any proposed constructions” in their papers after institution. *Id.*

Notably, PO does not identify any real dispute as to the meaning of any claim term, let alone provide any proposed constructions. At most, PO complains (at 26,

⁸ PO does not suggest that these arguments impact Grounds 1-2 (based on Yang).

29) that Grounds 3-4 provide reasons for why WO854 describes a BLI probe comprising an “optical fiber” as claimed or alternatively (if this element is absent from WO854) why this would have been obvious to a POSA.⁹ *See* Pet. 74-75. But the petition’s layering of these arguments in the alternative does not necessarily create a dispute as to the meaning of an “optical fiber” as PO suggests. Such alternative arguments are especially appropriate here given PO’s assertions in the ITC case and in IPR2023-00215 that an optical element of a BLI probe may comprise an optical fiber. *See* Pet. 75 & n.13. Gator Bio and the Board may properly rely on PO’s assertions from these other proceedings when addressing the proposed combinations here. Consolidated Trial Practice Guide, 48 (Nov. 2019).

Even to the extent the meaning of an “optical fiber” is at issue, PO’s arguments only underscore its unfair dealings and the inconsistent positions it has taken when it suits its ends. Indeed, despite complaining here that Gator Bio has not

⁹ Contrary to PO’s assertion (at 31), the petition also provides ample reasons why POSAs would have used a BLI probe comprising an optical fiber. As addressed in the petition, WO describes a BLI probe having a second optical element 66 that is preferably comprised of a “glass or a polymeric material having an index of refraction of between about 1.4 and 1.6.” Pet. 74 (quoting WO854, ¶ [0078]). And were there any uncertainty as to this material, POSAs would have found it obvious to look to known and disclosed BLI probes that comprised an optical fiber. Pet. 75.

shown that WO854 discloses a BLI probe having the claimed optical fiber, PO has asserted in the district court case that Gator Bio's BLI probes infringe the '588 patent, even though PO recently told the court that it does not believe those same probes comprise an optical fiber. *See* § III.A.2.b. Worse still, PO made this assertion to avoid a finding of prosecution disclaimer as to other patents that issued from the same family as WO854. *See supra* note 6. These circumstances warrant instituting IPR so that the Board may apply its expertise to help hold PO to a consistent position.

Second, PO incorrectly argues (at 27) that “[t]he petition lacks sufficient ‘particularity’ to allege a combination of the prior art.” At most, PO points to a statement in the petition that “POSAs would have been motivated to package BLI/RfS probes *such as* those described in Yang (or alternatively WO854, Grounds 3-4) in a tip tray *such as* that described in Miles.” *Id.* (quoting Pet., 26 (emphases modified)). And although PO characterizes the use of “such as” in this statement as an “effort to avoid disclosures from each of the references that are inconsistent with the intended modification,” PO does not identify which disclosures purportedly are inconsistent or how they are being avoided. *Id.* To the contrary, the petition grounds detail the reasons why POSAs would have been motivated to combine Yang's or WO854's BLI/RfS probes with Miles' tip tray. Pet., 26-32. Those reasons may be broadly applicable to other probes and tip trays, especially given the widespread use of probes and tip trays to facilitate assays performed on microtiter plates. But that

underscores (rather than detracts from) the strength of the motivation to combine. The petition grounds also walk through each element of the challenged claims and identify the particular disclosures from the cited prior art on which Gator Bio relies.

Moreover, given the proposed combinations and reasons for combining, it should be hardly surprising that the petition grounds cite extensively to the disclosures of the BLI probes in Yang or WO854 for elements [1B]-[1C], which recite elements of a BLI probe, and cite extensively to the disclosure of a trip tray in Miles for elements [1D]-[1G], which recite elements of a tip tray. That does not reflect a “piece-meal attack of the claims” as PO suggests (at 29) but rather a proper obviousness analysis that combines the teachings of multiple references.

PO’s assertions (at 28) further ignore that POSAs need not have “physically combined” or “bodily incorporated” the precise design of Miles’ probes into the BLI/RIfS probes of Yang or WO854. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (collecting cases). Miles describes optical probes having a proximal collar that serves to attach the probes to an assay machine and to retain the probes in the tip tray openings. Pet. 30, 51. But as the petition properly explains, the bodily incorporation of that precise proximal collar into Yang’s or WO854’s BLI probes is not necessary: “POSAs would have recognized that Miles’ teachings may be applied to BLI/RIfS probes by providing some structure on the proximal ends of the probes that allows them to attach to a

corresponding assaying apparatus and that is...appropriately sized to prevent the probes from falling through the tray openings.” Pet., 30-31; *see also id.*, 51-52.

a. The petition does not rely on expert testimony to backfill claim limitations

PO’s argument (at 32) that the extent of the petition’s reliance on expert testimony supports discretionary denial is similarly unavailing. Obviousness analyses necessarily must be undertaken from the perspective of a POSA at the time of the alleged invention, and the Board has long recognized the useful role of expert testimony in explaining complex technologies and how POSAs would have understood them. Consolidated Trial Practice Guide, 34-35.

PO faults Gator Bio for submitting a 110-page declaration by Dr. Laird Forrest and citing it 150 times in the petition supposedly to backfill claim elements. Request, 32. But notably, PO does not identify any authority suggesting that a declaration of that length or the number of citations weighs in favor of discretionary denial. Nor does PO identify any specific examples of alleged backfill. To the contrary, the petition grounds provide specific citations to the prior art for each claim element and further extensively cite the prior art in addressing the motivations to combine. *See Advanced Micro Devices Inc. v. Realtek Semiconductor Corp.*, IPR2023-00789, Paper 9, at 39 (PTAB Oct. 26, 2023) (rejecting PO’s assertion that petitioner improperly relied on expert testimony to gap fill where petition provided “sufficient evidence and argument” with citations to prior art).

PO also criticizes (at 33) Dr. Forrest’s reliance on two exhibits (EX1057 and EX1059) that PO says are not properly supported as prior art. EX1059 is the 2004 product catalog of Metrotek, a company that sold optical-fiber equipment and connectors, and EX1057 is an article by the Fiber Optics Association (“FOA”) describing various optical-fiber connectors from a historical perspective. Dr. Forrest cites these exhibits in a footnote as background to explain the SMA connectors described in Yang and to note the myriad other known optical-fiber connectors. EX1002, ¶61 n.101. PO identifies no authority for denying institution based on a challenge to the prior-art status of such background references. Notably, Dr. Forrest cites other supporting exhibits in the same footnote, including the testimony of PO’s own expert describing such SMA connectors. *Id.* (citing EX1012, 285:4-12, 297:12-18). PO also ignores that EX1059 has a 2004 copyright date and that its own expert previously identified and relied on EX1057 as evidence of the types of optical-fiber connectors known and available to POSAs in the 2003 timeframe—*two years before* the alleged priority date here. EX1085, vii, 69-70 (¶167) (referencing Ex. 25, “FOA Fiber Optic Connector Identifier”). If relevant and necessary, any dispute relating to the prior-art status of these exhibits may be addressed after institution.

b. The other issues PO raises do not warrant denial

Repackaging its assignor-estoppel argument, PO argues (at 24-25) that “[c]onfidence in the value of” the patent system will be lost if IPR is instituted. As

addressed in § III.A.1, PO ignores that assignor estoppel does not apply to IPRs and further ignores the underlying factual issues and the numerous other compelling considerations that make it unsuitable to address here.

PO also argues (at 24) that denial is warranted because the '588 patent will expire a few months before a final written decision. But that is entirely PO's doing: PO strategically chose to delay identifying or asserting the '588 patent for *nearly three years* while the parties litigated PO's claims that *the same accused products* infringed PO's other patents. *See* § III.A.2.a. PO's dilatory litigation tactics and gamesmanship should be *discouraged*, not rewarded with a denial here. Indeed, had PO asserted the '588 patent when it sued Gator Bio in 2022, Gator Bio would have filed this IPR long ago, and the Board already would have resolved it with years remaining on the '588 patent's statutory term. Moreover, the '588 patent's approaching expiration has not stopped PO from asserting it as PO continues to seek both an injunction and past damages to put Gator Bio, a startup company, out of business. EX1062. 49-50. If anything, given the extraordinary public interests at stake, the fact that PO seeks to use a near-expired patent of dubious validity to prevent the public from accessing critical, next-generation BLI products compellingly *supports* institution.

B. The *Fintiv* Factors Do Not Warrant Discretionary Denial, and to the Contrary, Fully Support Institution

As almost an afterthought, PO asserts that the factors articulated in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”), also support discretionary denial. PO is mistaken.

1. Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

Factor 1 weighs against denial or at worst is neutral. Although neither party has yet moved for a stay of the district court case, Gator Bio already has informed the court of this IPR (EX1060) and intends to seek a stay if IPR is instituted. As the Acting Director recently recognized, “there is good reason to believe that a stay will be granted” under those circumstances. *Twitch Interactive, Inc. v. Razdog Holdings LLC*, IPR2025-00307, Paper 28, at 2-3 (PTAB May 16, 2025) (cleaned up). “Over the past twelve years, judges in the [N.D. Cal.] district have granted or partially granted 76% of all post-institution motions to stay pending *inter partes* review.” *Id.* (cleaned up); *see also* EX1072. Judge Davila also has granted or partially granted six out of seven (85%) such motions dating back to 2014. EX1073.¹⁰

¹⁰ The one stay motion Judge Davila denied was brought under starkly different circumstances where the parties had already completed “claim construction, fact discovery, expert discovery, and dispositive motions.” *NetFuel, Inc. v. Cisco Sys. Inc.*, No. 18-CV-02352, 2020 WL 836714, at *2 (N.D. Cal. Feb. 20, 2020).

PO notes (at 34) that it continues to assert other non-challenged patents from the ITC case in the district court case. But unlike those other patents, the '588 patent was not litigated in the ITC case because PO strategically chose to wait to assert it. Thus, even if the district court does not stay the case entirely, it is likely that it would stay the case at least as to the '588 patent. *See Speir Techs. Ltd. v. Apple, Inc.*, No. 23-CV-00095, 2023 WL 2714931, at *2 (N.D. Cal. Mar. 30, 2023) (Davila, J.) (granting stay as to all patents after IPR instituted as to just one of four patents).

2. Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

Factor 2 weighs heavily against denial. The district court case is still in its early pleading stage because it was stayed pending the ITC case. EX1061. Gator Bio has filed a motion to dismiss the three patents PO previously unsuccessfully asserted in the ITC case. *Id.*, Dkt. 67. That motion is pending, and it may be weeks or months before the district court rules. Until then, the court is not expected to hold a scheduling conference or otherwise enter a case schedule. Even then, the median time to trial in this district is 31.8 months (EX1070), and before Judge Davila, it is even longer at 49.9 months (EX1071), suggesting that any trial on the '588 patent would not occur until long after a final written decision here.

PO asserts (at 34) that the median time to trial in the district for cases filed in the past five years has been 20.8 months. That statistic is based on small sample size of seven trials and ignores that the one patent trial over which Judge Davila presided

during that period was *54.4 months* out. EX1084. But even accepting PO's statistic, because Gator Bio has not even answered the complaint, a trial on the '588 patent is unlikely to occur until after a final written decision here.

Nor should the Board give credence to PO's speculation that the district court might grant a request for an expedited schedule. PO has made no such request and offers no basis to suggest that such a request would be granted, especially given that the parties have not previously litigated the '588 patent as a result of PO's strategic choice not to assert it in the ITC action.

3. Factor 3: investment in the parallel proceeding by the court and the parties

Factor 3 weighs against denial. PO alleges (at 35) that there has been "significant investment" in the ITC case. But again, because PO strategically chose not to assert the '588 patent in the ITC case, the reality is that the '588 patent has not been litigated, and the district court case is still at the early pleading stage. As it relates to the '588 patent, some fact discovery relating to Gator Bio's BLI products may carry over from the ITC case, but the parties are largely starting from scratch. Gator Bio has not even answered the complaint, and the parties have a long way to go before they exchange contentions, conduct fact and expert discovery, engage in the claim-construction process, brief dispositive motions, and prepare for trial. *See Microsoft Corp. v. XI Discovery, Inc.*, IPR2025-00253, Paper 13, at 2 (PTAB June

25, 2025) (“[T]here has not been meaningful investment in the district court proceeding, as infringement and invalidity contentions have not been served.”).

4. Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Factor 4 weighs heavily against denial. Gator Bio has stipulated that it will not raise any prior-art invalidity arguments under 35 U.S.C. §§ 102 and 103 in the district court case—whether based on patents, printed publications, products, or systems—if the Board institutes IPR here. EX1060. Gator Bio’s stipulation goes far beyond *Sotera* stipulations that only forego grounds based on patents and printed publications that a petitioner raised or reasonably could have raised during an IPR. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, at 18-19 (PTAB Dec. 1, 2020) (precedential as to § II.A). Although not dispositive, Gator Bio’s stipulation largely minimizes “concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions,” and thus “weighs strongly in favor of not exercising discretion to deny institution.” *Id.* at 19. The Acting Director recently referred a series of IPRs to merits review noting that a similarly “broad stipulation” “counsel[ed] against discretionary denial.” *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00217, Paper 9, at 2 (PTAB June 13, 2025). Recent Board panels have even found that *Sotera* stipulations, which forego less than what Gator Bio has done here, strongly favor institution. *E.g., SAP Am., Inc. v. Cyandia, Inc.*, IPR2024-01433, Paper 13, at 12 (PTAB Apr. 7, 2025)

(“In light of the stipulation and nature of the asserted ground...this [factor] strongly favors institution.”); *Samsung Elecs. Co. v. Headwater Rsch. LLC*, IPR2024-01407, Paper 9, at 6-14 (PTAB Mar. 20, 2025).

PO acknowledges (at 35) that “there is no substantial overlap of the issues raised in the petition and the parallel proceeding” but nonetheless asserts that this factor is neutral, presupposing that assignor estoppel would preclude Gator Bio from raising the petition grounds at the district court. As explained above, however, PO’s assertion of assignor estoppel is undermined and complicated by factual issues and post-assignment developments such as PO’s misleading statements to the Patent Office during prosecution and its inconsistent positions, PO’s own unfair dealings in litigation, and other considerations. *See* § III.A.1.

5. Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Factor 5 weighs against denial or at worst is neutral. Contrary to PO’s assertion, *Fintiv* did not hold that Factor 5 favors denial whenever the petitioner is also the defendant in a parallel proceeding. Rather, *Fintiv* simply noted that “if a petitioner is unrelated,” the Board has weighed that “fact against exercising discretion.” *Fintiv*, Paper 11, at 13-14. Where, as here, a final written decision “is likely to issue before the district court trial,” the Board has “weigh[ed] this factor against exercising discretion.” *BMW of N. Am., LLC v. Mich. Motor Techs. LLC*, IPR2023-01234, Paper 11, at 14-15 (PTAB Jan. 26, 2024) (collecting cases).

6. Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Factor 6 weighs heavily against denial. As addressed above, compelling considerations including extraordinary public interests (*see* § III.A.3), PO's unfair dealings and inconsistent positions (*see* § III.A.2), and the strength of the petition grounds (*see* § III.A.4.a) set this IPR apart from others and support institution.

At most, PO refers back (at 35) to its undeveloped arguments attacking the petition. As explained above, those arguments lack merit and fail to meaningfully challenge the strength of the petition grounds. *See* § III.A.5.

IV. Conclusion

Considering all factors holistically, PO's request should be denied.

Date: July 14, 2025

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24 and the Interim Process for PTAB Workload Management, the undersigned hereby certifies that the word count for the foregoing OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL totals 11,516 and is within the word-count limit of 14,000 words.

This word count was calculated by using the built-in word-count tool in Microsoft Word, the software used to prepare the document.

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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2025, true and correct copies of the foregoing
OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY
DENIAL and EXHIBITS 1061-1086 and accompanying exhibits were served via
electronic mail upon the counsel of record for Patent Owner at the following
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