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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

SARTORIUS BIOANALYTICAL
INSTRUMENTS, INC.,

Plaintiff,

v.

GATOR BIO, INC. and HONG TAN,

Defendants.

Case No. 5:22-cv-01417-EJD

**DEFENDANTS' NOTICE OF MOTION
AND MOTION TO DISMISS SECOND
AMENDED COMPLAINT;
MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT**

Judge: Hon. Edward J. Davila
Date: April 17, 2025
Time: 9:00 a.m.
Courtroom: 4 - 5th Floor

GATOR-1063
Gator Bio v. Sartorius Bioanalytical Instruments
IPR2025-00633

1 in a change in the optical thickness, and hence the interference signal. *Id.* at 7:50-63, Fig. 8.

2 The '887 patent includes two independent claims, claim 1 being directed to the
3 "Immobilized Substate" format and claim 8 being directed to the "Substrate Capture" format. *See*
4 *id.* at claims 1, 8. In the ITC action, Sartorius initially asserted claim 1 (among others) but ultimately
5 withdrew all claims except claim 8, which the ALJ and the Commission determined was not
6 infringed. Dkt. 52-1 at 2-3, 81-86; Dkt. 52-2 at 2-3. 32-36, 46. Here, Sartorius asserts claim 1:

7 1. A method for assaying enzyme activity, comprising:

8 providing an optical element coupled to a light source via **a mechanical**
9 **coupling that engages the optical element with an optical fiber** and
provides an air gap between the optical element and the fiber,

10 **the optical element including** (a) a proximal reflecting surface and a distal
11 reflecting surface separated by at least 50 nm, and (b) **a layer of enzyme**
12 **substrate molecules** positioned so that interference between a reflected
beam from the proximal reflecting surface and a reflected beam from the
distal reflecting surface varies as an enzyme reacts with the substrate, and
wherein the reflected beams are coupled into the optical fiber;

13 **exposing the optical element to an enzyme;** and
14 detecting a change in the interference between the reflected beams, wherein
15 the change is indicative of enzyme activity.

16 SAC Ex. B ('887 patent) at claim 1 (emphasis added). Relevant here, claim 1 requires using a BLI
17 probe ("optical element") that includes "a layer of enzyme substrate molecules" and "exposing [it]
18 to an enzyme." *Id.* Claim 1 also requires "a mechanical coupling that engages the optical element
19 with an optical fiber," similar to claims 13 and 18 of the '585 patent. *Id.*

20 **D. Inter Partes Review of the '585 Patent (IPR2023-00215)**

21 In November 2022, Gator Bio filed an IPR petition challenging all claims of the '585 patent.
22 Ex. 3. As discussed above, the '585 and '547 patents share the same specification, which also is
23 incorporated by reference into the '887 patent's specification.

24 In its IPR petition, Gator Bio asserted that the '585 patent's claims are invalid as obvious
25 based on the Sun prior-art reference (Ex. 6) among others.⁷ Ex. 3 at 1, 4. As discussed above and
26 as Sartorius' expert acknowledged, Sun describes a BLI/RIfS probe having an optical-fiber portion

27 _____
28 ⁷ In the '585 IPR, Gator Bio and Sartorius made similar arguments as to another prior-art reference (Yang), but for brevity, only the Sun reference is addressed here.

that is coated on its distal end with an interference layer (referred to in Sun as a “siliconization film”), and the probe is connected at its proximal end to the Y-shaped fiber of a spectrophotometer instrument via a “standard SMA connector” (noted in Figure 3 as an “SMA splice bushing”).

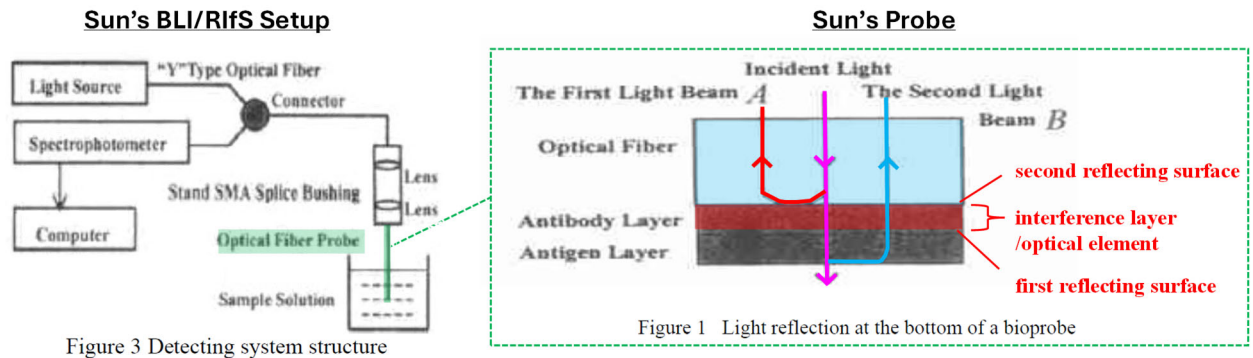


Figure 3 Detecting system structure

Figure 1 Light reflection at the bottom of a bioprobe

Ex. 6 at 657-58, Figs. 1, 3 (annotated); Ex. 3 at 49-51; Ex. 1 at 1131:4-1134:13.

The main dispute in the IPR was whether Sun (among other citer prior art) disclosed “an optical element removably attached to the tip of [an] optical fiber,” as recited in claim 1 of the ’585 patent, and “a mechanical coupling that engages [the] optical element with [the] optical fiber,” as recited in claims 13 and 18. SAC Ex. C (’585 patent) at claims 1, 13, 18.

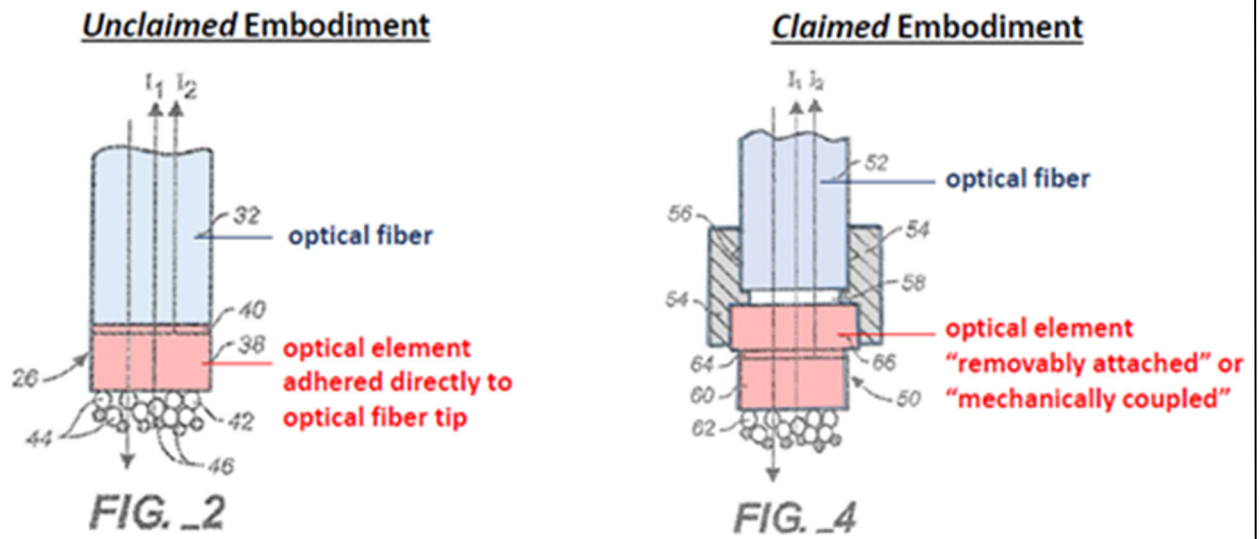
Gator Bio asserted that the optical-fiber portion of the Sun’s probe comprises an “optical element” that is removably attached or mechanically coupled via the SMA connector to the distal end or tip of the Y-shaped optical fiber. Ex. 3 at 49-50, 57-58, 71-72; *see also id.* at 32-35, 45-46.

In response, Sartorius pointed to the ’585 patent’s specification and asserted that the “optical element” is a separate component that cannot merely be a “continuation of the optical fiber”:

The specification makes it clear that the claimed “optical element” is not merely a continuation of the optical fiber, but is instead a separate component of the optical assembly. The optical element, unlike the optical fiber, has first and second reflecting surfaces and a layer of analyte binding molecules. The optical element, unlike the optical fiber, is removably attached to the distal end of the optical fiber.

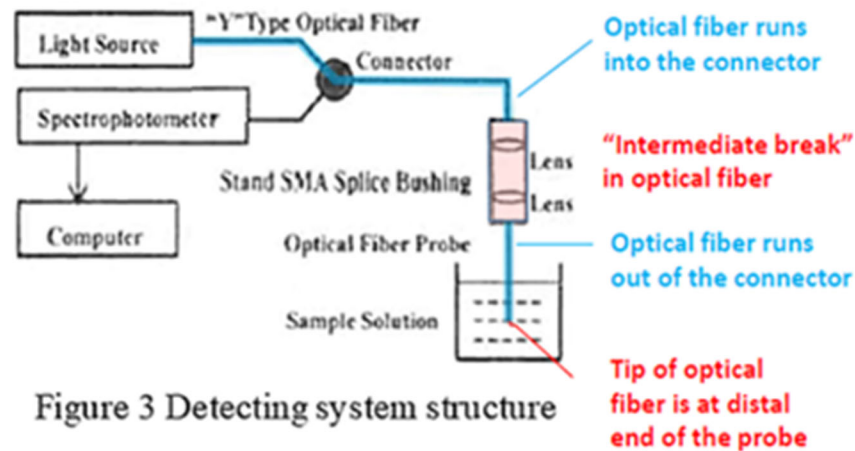
Ex. 4 at 46 (emphasis added, internal citations omitted). As illustrated in the demonstrative below, Sartorius represented that an arrangement where the “optical element” is merely a continuation of the “optical fiber” corresponds to an “*unclaimed*” embodiment shown in the ’585 patent’s Figure 2. Ex. 4 at 50, 54. And Sartorius distinguished such an arrangement from what it identified as the claimed embodiment shown in Figures 4 and 5, where the optical element is removably attached or

mechanically coupled to the optical fiber via flexible gripping arms (54). *Id.* at 43-45.



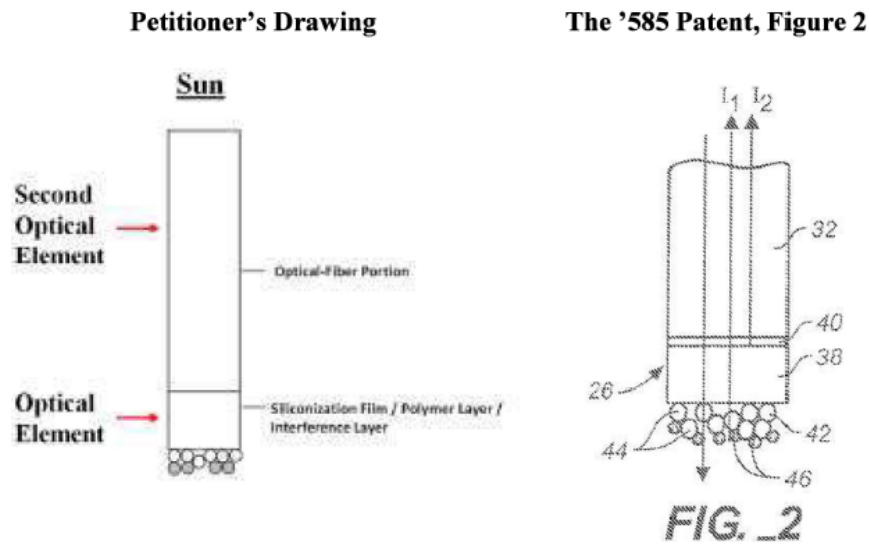
SAC Ex. C ('585 patent) at Figs. 2, 4 (annotated).

Turning to Sun, Sartorius argued that Sun's setup corresponds to the unclaimed Figure 2 embodiment. Ex. 4 at 51-54. As illustrated in the demonstrative below, Sartorius argued that the SMA connection between the Y-shaped optical fiber and the optical-fiber portion of the probe in Sun's setup is merely an "intermediate break" in one long optical fiber (highlighted in blue).



Ex. 6 at Fig. 3 (annotated); Ex. 4 at 50 ("intermediate break"), 51-54 (applying reasoning to Sun).

Pointing to the coating on the end of Sun's probe as the "optical element," Sartorius asserted that the optical element in this arrangement is not removably attached or mechanically coupled at the SMA connection but instead is "adhered directly" to the tip of this one long optical fiber (i.e., the distal end of the optical-fiber probe) like the unclaimed Figure 2 embodiment.



Ex. 4 at 54. Sartorius succinctly framed this distinction using a fiber-in-fiber-out rule, explaining that in Sun's setup, the "[o]ptical fiber runs into the SMA connector, and out again," rather than the SMA connector being a point of removable attachment or mechanical coupling between an "optical fiber" and an "optical element." *Id.* at 53.

Sartorius applied this fiber-in-fiber-out rule to both claim 1, which includes the "removably attached" limitation, and claims 13 and 18, which include the "mechanical coupling" limitation:

Because **claims 1, 13, and 18 all unambiguously require a coupling between an optical fiber and an optical element**, Petitioner is forced to contend that the portion of optical fiber running out the distal end of the SMA connector is, in fact, no longer optical fiber, but is instead the claimed "optical element" to which the optical fiber is coupled. This makes little sense; applicants understood the difference between the various optical components in their assembly, and the unique terms that identified them.

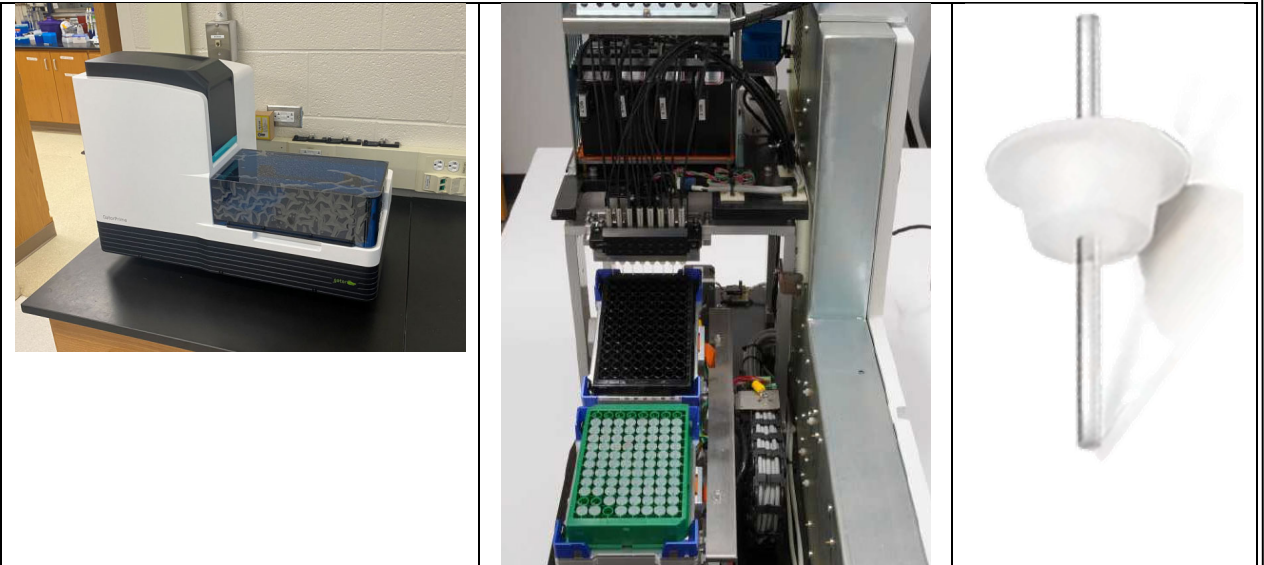
Ex. 4 at 49 (emphasis added); *see also id.* at 53-54 (applying reasoning to Sun).

The PTAB, in turn, relied on Sartorius' representations to deny IPR institution, finding that "[Sartorius] unambiguously admits that Figure 2 illustrates an 'unclaimed embodiment' of the invention" and "advances significant information that details how and why the disclosures in ... Sun, upon which Petitioner relies to make out the removable attachment limitation of the challenged claims, correspond to the unclaimed embodiment." Ex. 5 at 4, 21.

E. Accused Products

Sartorius accuses Gator Bio's "Gator Bioanalysis System line of devices," which include instruments, such as the GatorPrime and GatorPlus instruments, and consumable optical-fiber

probes and kits containing such probes that are useable with such instruments. SAC ¶¶ 49-55. Shown below is an example of GatorPrime instrument (left), a GatorPrime instrument with its housing removed and shown loaded with probes (middle), and an individual probe (right).



SAC ¶¶ 51, 52 (image cropped); SAC Ex. E at 4 (image cropped and rotated). Each probe comprises a segment of optical fiber that is coated on its distal end with an optical layer and surface chemistry that allows it to interact with analyte in a sample. SAC ¶¶ 151, 154 156 (alleging that Gator probes are an optical sensing assembly comprising an optical fiber and a transparent element with reflecting surfaces and a layer of analyte-binding molecules); *see also* Ex. 2 at 14; Dkt. 52-1 at 11.

F. Alleged Direct Infringement

Claim 1 of the '585 patent requires an “optical element” that is “removably attached to the tip of [an] optical fiber.” SAC Ex. C ('585 patent) at claim 1. Similarly, claim 21 (via claim 1) of the '547 patent and claim 1 of the '887 patent require a mechanical coupling that engages [an] optical element with [an optical] fiber.” SAC Ex. A ('547 patent) at claim 1; SAC Ex. B ('887 patent) at claim 1. As discussed above, Sartorius asserted in the '585 IPR that this language does not cover a fiber-in-fiber-out design. Here, in its SAC, Sartorius alleges only “[u]pon information and belief, [that] the GatorPrime has an optical element removably attached to the tip of the optical fiber.” SAC ¶ 134. And Sartorius points to a photo (below) of a GatorPrime instrument loaded with probes and alleges that a “registration plate and sensor housing” in the instrument “form a mechanical coupling” (annotated here as a red box). SAC ¶ 64. Going from top to bottom, the photo

1 **V. ARGUMENT**

2 **A. The Court Should Dismiss Sartorius’ Direct Infringement Claims Under 35**
 3 **U.S.C. § 271(a) as to the ’585, ’547, and ’887 Patents**

4 **1. Sartorius disclaimed a fiber-in-fiber-out arrangement in the ’585 IPR,**
 5 **precluding any infringement of the ’585 patent**

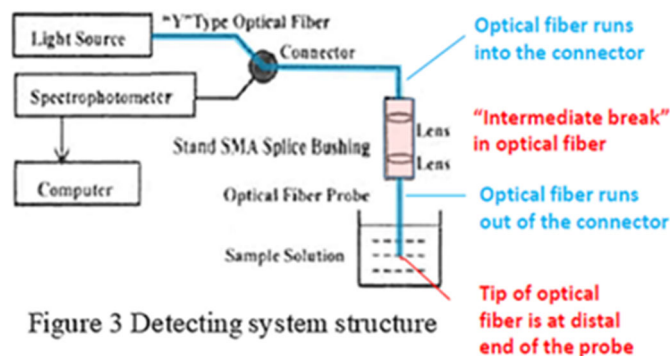
6 Asserted claim 1 of the ’585 patent requires “an optical element removably attached to the
 7 tip of [an] optical fiber.” SAC Ex. C (’585 patent) at claim 1. Sartorius represented to the PTAB in
 8 the ’585 IPR that this “removably attached” limitation does *not* cover a fiber-in-fiber-out design in
 9 which a coupling mechanism is used to connect two optical fibers, with optical fiber running into
 10 and out of the coupling. Because the accused products—as the SAC shows on its face and as even
 11 Sartorius’ expert has acknowledged—apply a fiber-in-fiber-out design, the doctrine of prosecution
 12 disclaimer forecloses any infringement of the ’585 patent as a matter of law.

13 Prosecution disclaimer “preclud[es] patentees from recapturing through claim interpretation
 14 specific meanings disclaimed during prosecution,” including “during an IPR proceeding, whether
 15 before or after an institution decision.” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359,
 16 1362 (Fed. Cir. 2017) (citation omitted). When a patentee makes “clear and unmistakable”
 17 statements disavowing claim scope in an IPR, prosecution disclaimer “narrows the meaning of the
 18 claim consistent with the scope of the claim surrendered.” *Id.* at 1359 (citation omitted). And courts
 19 have consistently applied prosecution disclaimer at the pleading stage to dismiss infringement
 20 claims. *Grecia*, 605 F. Supp. 3d at 914-15; *Seoul Semiconductor*, 2023 WL 7106480, at *4-5;
 21 *Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443, 449-50 (D. Del. 2021).

22 *Grecia* is instructive. The claim at issue there was directed to a digital rights management
 23 (DRM) scheme and required “a relationship or correspondence between [a] ‘membership
 24 verification token’ and ... ‘encrypted digital media.’” *Grecia*, 605 F. Supp. 3d at 908, 914. In
 25 asserting infringement, the patentee alleged that a user’s payment account number was the
 26 “membership verification token.” *Id.* at 914. Taking judicial notice of the record of a related IPR,
 27 the court found that the patentee had “expressly disavowed any position that payment account
 28 information could constitute ‘a membership verification token ... corresponding to the encrypted
 digital media.’” *Id.* (citation omitted). The court then applied prosecution disclaimer to dismiss the

patentee's infringement claim with prejudice, finding that the patentee's allegations contradicted its "statements concerning the invention's scope during IPR and, therefore, fail[ed] to 'articulate why it is plausible that the accused product infringes the patent claim.'" *Id.* at 915 (citation omitted).

This Court should similarly take judicial notice of the '585 IPR record and find that Sartorius disavowed any position that "an optical element removably attached to the tip of [an] optical fiber" covers a fiber-in-fiber-out design. To convince the PTAB to deny IPR institution, Sartorius represented that the Sun prior-art reference (among others) does not disclose the claimed removable attachment and instead corresponds to the "*unclaimed* embodiment" shown in Figure 2 of the '585 patent. Ex. 4 at 51-54. As discussed above (*see* § III.D) and illustrated below, Sun describes a coated optical-fiber probe that is attached via an SMA connector to the distal end of a Y-shaped optical fiber, but Sartorius argued that the SMA connector (highlighted in red) merely reflects an "intermediate break" in one long optical fiber (highlighted in blue).

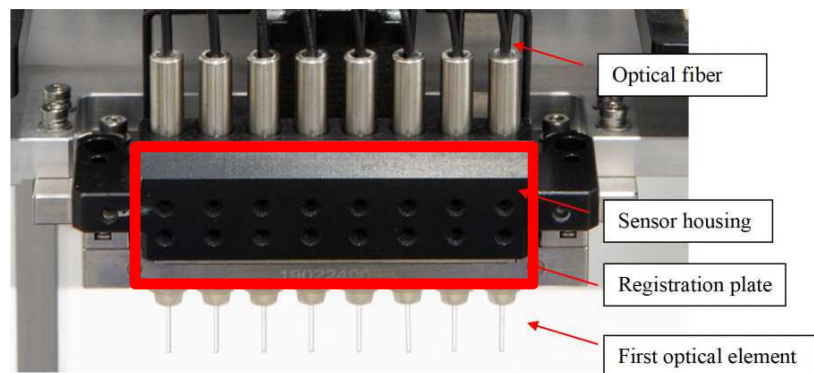


Ex. 6 at 658, Fig. 3 (annotated); *see also id.* at 657, Fig. 1 (describing coating on Sun's probe); Ex. 4 at 50 (referencing SMA connection as "intermediate break"), 52-53 (applying reasoning to Sun). Pointing to the coating on the end of Sun's probe as the "optical element," Sartorius asserted that "the optical element is not removably attached to the tip of the optical fiber" at the SMA connection but instead "adhered directly" to the tip of this one long optical fiber, just like the unclaimed Figure 2 embodiment. Ex. 4 at 51, 54. As Sartorius put it, "[o]ptical fiber runs into the SMA connector, and out again," rather than the SMA connector being a point of removable attachment between an "optical fiber" and an "optical element." *Id.* at 53.

Lest there be any doubt that Sartorius' statements during the '585 IPR amount to a "clear and unmistakable" disclaimer, *Aylus*, 856 F.3d at 1359, the PTAB confirmed it. In adopting

Sartorius’ position and denying IPR institution, the PTAB expressly recognized that Sartorius “*unambiguously admits* that Figure 2 illustrates an ‘*unclaimed embodiment*’ of the invention” and “advances significant information that details how and why *the disclosures in ... Sun, upon which Petitioner relies to make out the removable attachment limitation, correspond to the unclaimed embodiment.*” Ex. 5 at 4, 21 (emphasis added). Sartorius thus cannot be heard to argue here that a fiber-in-fiber-out design is a removable attachment as claimed.

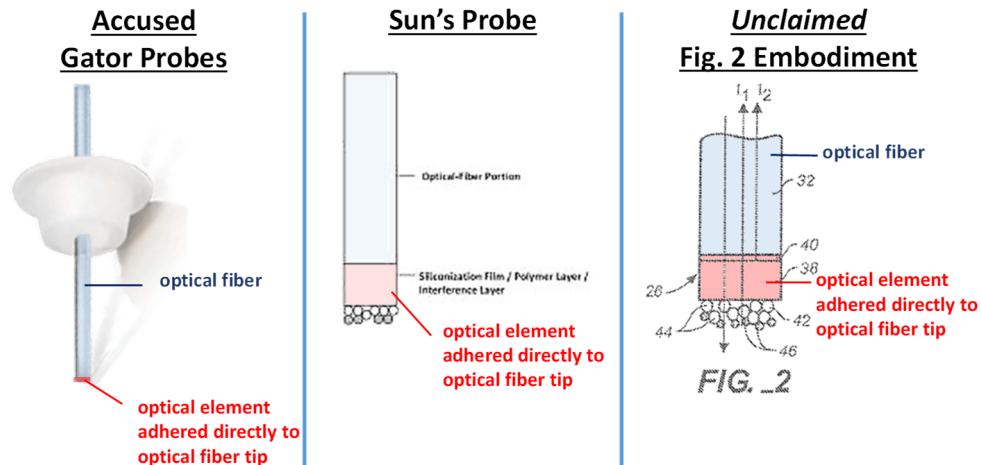
If Sartorius is properly held to this disclaimer, its infringement assertion as to the ’585 patent must be dismissed because the SAC confirms that the accused products apply the disclaimed fiber-in-fiber-out design. The SAC alleges “[u]pon information and belief,” without any factual basis, that the accused products include “an optical element removably attached to the tip of the optical fiber.” SAC ¶ 134. Elsewhere, with reference to a photo (below) showing the interface between a GatorPrime instrument and the accused fiber probes, the SAC points a “registration plate and sensor housing” in the instrument as a “mechanical coupling” (annotated here as a red box).



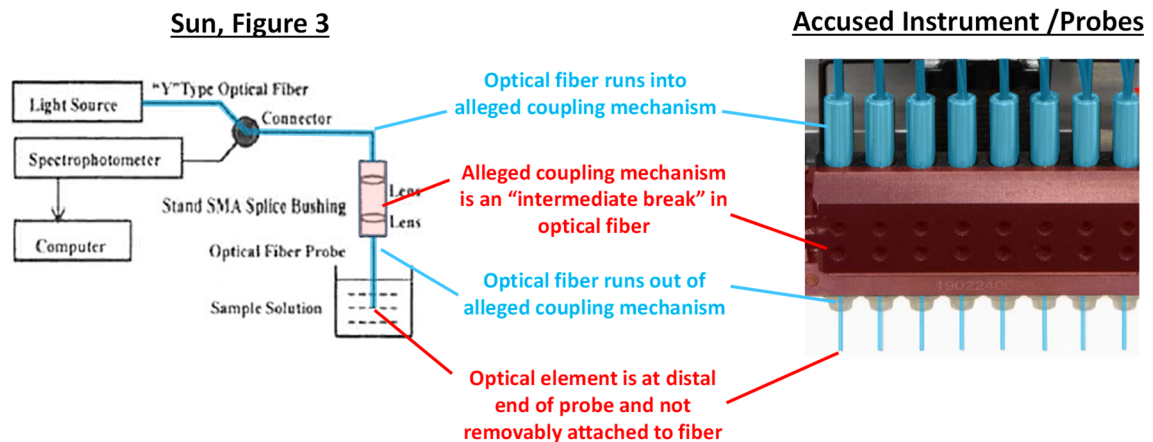
SAC ¶ 64 (annotated). Going from top to bottom, the photo confirms that optical fiber runs into the coupling and the optical fiber of the Gator fiber probes runs out of it. Although the SAC itself confirms this fiber-in-fiber-out design, the Court also may take judicial notice of Sartorius’ expert Dr. Bailey’s testimony from the ITC evidentiary hearing, where he admitted in reference to a similar photo (Ex. 2 at 20) that the accused products apply a fiber-in-fiber-out design, explaining that the “fiber bundles are inserted into ... the mechanical coupling” and “then coming out of the mechanical coupling . . . are the Gator fiber probes.” Ex. 1 at 666:16-667:2.⁹

⁹ See *Realtek*, 732 F. Supp. 3d at 1111 (judicial notice of ITC record). Even if not treated as fact, this testimony underscores the failure to plausibly allege the “removably attached” limitation.

The demonstratives below put this in the context of what Sartorius told the PTAB. The accused probes each comprises an optical fiber with a coating (optical element) adhered directly to its distal end or tip—just like Sun’s probe and the ’585 patent’s unclaimed Figure 2 embodiment.



SAC ¶ 69 (annotated version of probe shown in Fig. 13); Ex. 4 at 54 (annotated versions of diagram of Sun’s probe and ’585 patent’s Figure 2 referenced by Sartorius). When the accused probes and instruments are used together, optical fiber runs into and out of the mechanical coupling (highlighted in red), forming one long optical fiber (highlighted in blue) with an “intermediate break” at the coupling point, while the optical element (the coating on each probe) is directly adhered to the distal end or tip of this one long fiber—again just like the unclaimed design in Sun.



Ex. 6 at 658, Fig. 3 (annotated); SAC ¶ 64 (image of GatorPrime cropped and annotated).

As in *Grecia*, this Court should dismiss Sartorius’ infringement assertion as to the ’585 patent because its allegations contradict its statements “concerning the invention’s scope during IPR and, therefore, fail to ‘articulate why it is plausible that the accused product infringes the