

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIO-RAD LABORATORIES, INC.,
Petitioner,

v.

CALIFORNIA INSTITUTE OF TECHNOLOGY,
Patent Owner.

IPR2024-01451
U.S. PATENT NO. 11,827,921

**PETITIONER'S PRE-INSTITUTION REPLY AUTHORIZED PURSUANT
TO JANUARY 16, 2025 EMAIL**

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I. PO'S NEW CLAIM INTERPRETATION IS WITHOUT MERIT

Patent Owner (“PO”) contends that Larson does not meet the requirement in the ’921 patent claims’ that multiple targets be amplified in a “single sample volume” because Larson teaches droplets having only a “single analyte” and “expressly teaches excluding” droplets with multiple analytes. *See, e.g.*, POPR at 44. In other words, PO seeks to exclude from the claims systems like Larson’s wherein the “single sample volume” comprises a collection of droplets that each have, for instance, one analyte. This, however, reflects a new narrowing claim construction that is contrary to the intrinsic record and PO’s district court position.

The ’921 claim language requires detecting the presence or absence of “M analytes” in a “single sample volume” and that these analytes be “amplified in the single sample volume.” EX1001 at claim 1. The “single sample volume,” however, is *not* limited to an individual “droplet,” but rather includes any type or nature of volume, such as a “tube or a bottle.” *See id.* at 38:63-65. There is likewise nothing precluding the analytes from being individually compartmentalized or separated within the “single sample volume.” The “single sample volume,” for instance, can be a combination of droplets each having one analyte, but this is not required. The open-ended claims are not limited to this effect one way or the other, so long as the “single sample volume” (which can be a bottle or tube) is subject to amplification.

This latter point is critical because the specification contemplates *both*

embodiments where the sample volume is separated and those where it is not. The specification explicitly teaches, for instance, that “the invention could be used with separation...if desired.” *Id.* at 36:5-6. Likewise, the specification states that “[n]o separation is necessary.” *Id.* at 36:2-3. PO’s attempt to exclude from the claims the embodiments where the “single sample volume” is separated should be rejected because a “claim construction that excludes a preferred embodiment is rarely, if ever correct and would require highly persuasive evidentiary support.” *Kaufman v. Microsoft Corp.*, 34 F.4th 1360, 1372 (Fed. Cir. 2022). The prosecution history is in accord. There, PO amended the claims to **remove** a requirement that the sample volume **not** be separated and instead substituted broader language requiring only that the amplification be in a “single sample volume.” *See* EX1029 at 2. Thus, the inventors of the ’921 patent contemplated **requiring** no separation of the “single sample volume,” but decided against it. Finally, claims of patents in the same family that are at issue in co-pending IPRs further undermine PO’s interpretation. Claim 1 of U.S. Patent No. 10,068,051 recites that the analytes be detected “without...physical separation.” *See* IPR2024-01177, EX1001. Similarly, claim 1 of U.S. Patent No. 10,770,170 recites the use of “droplets.” *See* IPR2024-01178, EX1001. Thus, when the patentees wanted to exclude “separation” from the claims or limit them to “droplets,” they did so. But, in the ’921 patent, they did neither.

Ultimately, the clearest proof that the claims do not exclude embodiments

where the “sample volume” is further separated is PO’s own district court position. As Petitioner explained, in district court, PO contends that Petitioner infringes through an approach wherein “the detection is performed in a single sample volume that is *subsequently* partitioned into multiple droplets.” Petition at 30 (quoting EX1012 at 20). While PO encourages the Board to now disregard its prior admission,¹ it never would have originally advanced this infringement theory if it truly believed the claims were as narrow as it now contends. In fact, as proven above, such a construction is contrary to the intrinsic record.

II. SAXONOV IS PRIOR ART

PO contends that institution should be denied because the Petition does not show that certain material from Saxonov was “carried over” from the ’013 provisional. *See* POPR at 37-42. Yet, all but a handful of paragraphs—addressed below—the ’013 provisional and Saxonov are *identical*, as PO’s own expert and evidence shows. *See* EX2001 ¶¶ 88-89; EX2007. The “carried over” “requirement is often established if the relied-upon disclosures in the reference patent application

¹ PO downplays its contentions as “preliminary” and subject to change. *See* POPR at 28. Nonsense. PO’s contentions are final and subject to amendment only upon a showing of good cause. *See* N.D. Cal. Patent L.R. 3-6.

appear in substantially the same form in the provisional application.” *Illumina, Inc. v. Ravgen, Inc.*, IPR2021-01271, Paper 12 at 45 (P.T.A.B. Jan. 26, 2022). That is the case here. PO’s contentions that ¶¶ 18, 78-79, and Figures 9 and 10 of Saxonov are not “carried over” are without merit. *See* POPR at 37-42.

All of PO’s arguments about this material boil down to the contention that the ’013 provisional does not disclose the analysis of three or more targets in a single droplet. *See, e.g., id.* at 40-41. As shown below, however, PO effectively admits that the ’013 provisional does indeed disclose this.

The Petition explains how the provisional teaches an approach wherein targets are detected based on combinations of colors and that one can distinguish droplet types that indeed have more than one target. *See* Petition at 13 (citing ’013 provisional at 9:14-15); *id.* at 59 n.4 (citing ’013 provisional 9:8-10). Page 60 of the Petition goes on to cite ¶ 20 of Saxonov, which teaches that using two colors for three targets will “generate eight clusters or populations of data, but they would be separated in a two-dimensional intensity space *and so in principle more easily resolvable.*” EX1004 ¶ 20. Saxonov discloses this again—both textually and in a table—in ¶ 41, which is discussed in pages 18-19 of the Petition. This disclosure of multiple targets per droplets and eight different populations of data based on the use of multiple colors is the exact substance of Figure 10 of Saxonov and its accompanying text, as detailed in the Petition. *See* Petition at 59-60.

Importantly, in its preliminary response, PO acknowledges the disclosure ¶¶ 20 and 41 of Saxonov, detailing, for instance, how Saxonov ¶ 41 broadly teaches that the number of distinct droplet populations is given by 2^N , “where N is the number of targets” and depicting Saxonov’s tabular representation of this. See POPR at 22-23. Likewise, PO acknowledges Saxonov’s teaching in ¶ 20 that the eight different populations of droplets “would be separated in a two-dimensional intensity space.” *Id.* at 56-57. PO’s half-hearted assertion that this disclosure is not enabled, *id.*, is, if anything, an admission that PO has no good response to it. The critical point, though, is that it is undisputed that the ’013 provisional includes *identically* the content in ¶¶ 20 and 41 of Saxonov. PO’s own exhibits and expert testimony confirm this. See EX2001 ¶¶ 88-89; EX2007. This ends any dispute about whether the disputed content is carried over from the ’013 provisional. It plainly is.

III. *FINTIV* CONSIDERATIONS DO NOT DISFAVOR INSTITUTION

Since the filing of the Petition, the district court case has made minimal progress. The parties disagree on how the case ought to be handled, *see* EX2014, and the Court has not set any deadlines outside of the close of fact discovery, let alone a trial date. See EX2015. There has been a *Markman* hearing and supplemental claim construction briefing, but there is no *Markman* Order. The parties have made only modest document productions, and not a single deposition has been scheduled. Thus, *Fintiv* considerations do not weigh against institution.

Dated: January 28, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PETITIONER'S PRE-INSTITUTION REPLY AUTHORIZED PURSUANT TO JANUARY 16, 2025 EMAIL** as being served on January 28, 2025, via email pursuant to 37 C.F.R. § 42.6(e) to counsel for Patent Owner at the address below:

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