

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.

IPR2024-01178
U.S. PATENT NO. 10,770,170

PETITIONER'S PRE-INSTITUTION REPLY AUTHORIZED PURSUANT TO
NOVEMBER 11, 2024 EMAIL

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I. SAXONOV IS PRIOR ART

Patent Owner (“PO”) contends that institution should be denied because the Petition does not show that the cited material from Saxonov was “carried forward” from the ’013 provisional. *See* Paper 6 at 35-39. Yet, outside of a handful of paragraphs—addressed in detail below—the ’013 provisional and Saxonov are *identical*, as PO’s own expert and evidence shows. *See* EX2001 ¶¶ 46-47; EX2007. As this tribunal has held, the “carried forward” “requirement is often established if the relied upon disclosures in the reference patent application appear in substantially the same form in the provisional application.” *Illumina, Inc. v. Ravgen*, IPR2021-01271, Paper 12 at 45 (PTAB Jan. 26, 2022). That is the case here.

Petitioner nonetheless complains that the Petition lacks citations to the provisional for certain claim elements. *See* Paper 6 at 34-36. These complaints are without merit. For the “forming a mixture” element, for instance, the Petition cites seven paragraphs and a figure in Saxonov that are undisputedly among the material that is identically present in the provisional. Petition at 32-33 (citing Saxonov ¶¶ 49, 50, 63-67 and Fig. 5). The Petition also cites ¶¶ 157-62 of Dr. Batt’s declaration, which specifically cites the passages in the provisional corresponding to ¶¶ 63-67 and Fig. 5 of Saxonov. *See* EX1002 ¶ 161 (citing 4:1-7, 17:20-19:9, Fig. 5). Likewise, for the “partitioning” claim element, the Petition cites seven paragraphs and a figure from Saxonov that are undisputedly identically present in the

provisional. *See* Petition at 36 (citing ¶ 25-30 and Fig. 1); EX2007; EX2001 ¶¶ 46-47. Moreover, the Petition includes copious citations confirming that the provisional teaches partitioning to form droplets. *See* Petition at 13-15. As to the “determining” claim element, the support for this element cross-references Section X.A.8 for support, which cites to 10 different passages in the ’013 provisional. *See* Petition at 43 (citing Section X.A.8); *id.* at 41. Finally, the “wherein” clause is a negative limitation reciting the ***absence*** of immobilization or mass spectrometry. As Dr. Batt explains, the assays in Saxonov do not use immobilization or mass spectrometry. EX1002 ¶¶ 193-95. The Petition confirms that the ’013 provisional describes and supports the very same types of assays as in Saxonov. *See* Petition at 12-14.

To the extent PO contends any material from Saxonov cited in the Petition is not actually present verbatim in the ’013 provisional, this material is limited to Figures 9-10 and ¶¶ 17-18, 37, 76-79. *See* Paper No. 6 at 38-41; EX2001 ¶ 48. Yet, the Petition rarely cites this material, and, when it does, it also cites other disclosure that is in ***both*** Saxonov and the ’013 Provisional and that is sufficient to support the invalidity ground on its own. None of the disputed material is truly essential. And, even if it were, the Petition confirms that it was carried forward from the provisional, as documented below. Any suggestion otherwise would be an improper “formulistic approach divorced from the merits.” *See, e.g., Mastercard, Inc. v. OV Loop, Inc.*, IPR2023-1289, Paper 15 at 18-19 (PTAB March 20, 2024).

Figure 10 and ¶¶ 18, 76-79 all pertain to Example 4 of Saxonov, where three targets are detected using just two colors, a scenario that yields eight distinct populations of droplets. All of this is present in passages from the '013 provisional that are specifically called out in the Petition in connection with one or more of Figure 10 or ¶¶ 18, 76-79. The Petition, for instance, cites the '013 provisional at *inter alia* Fig. 5 and 2:15-3:3, which describe detecting “two or more targets in a single partition,” including by using only a single color channel. *See* Petition at 41. Likewise, the overview of Saxonov in the Petition specifically calls out the extensive disclosure in the '013 provisional of using differing intensity of the same color to distinguish different targets. *See id.* at 12. As to the eight populations of droplets described in Figures 10 and ¶ 78, the '013 provisional at 5:19-6:3 discloses precisely this, teaching assays that can be “extended” and explaining that such an assay for three targets generates “eight clusters or populations of data, separated by intensity,” just as in Figure 10. *See* Petition at 41. *See* EX1007 at 5:19-6:3. This part of the provisional is cited three times in the overview of Saxonov, *see* Petition at 12-13, and three additional times in connection with citations to one or more of Fig. 10 and ¶¶ 76-79. *See* Petition at 29, 41. Dr. Batt further explains that Saxonov ¶ 41 includes three tables, one of which lays out how three targets will yield eight distinct “Populations” of droplets. *See* EX1002 ¶¶ 145-54. In essence, this table is Figure 10 of Saxonov in tabular form. It appears verbatim in the '013 provisional at 9:4-

10:3 and is cited in the Petition at page 41. The Petition thus cites extensive support in the '013 provisional for Figure 10 and ¶¶ 18, 76-79 of Saxonov.

As to Figure 9 and ¶¶ 17, 77 of Saxonov, the Petition cites this for the concept that every probe will correspond to a target and multiple targets can be in a droplet. *See* Petition at 29, 32-33, 41. Again, there is support from the '013 provisional. For example, Page 32 of the Petition cites ¶ 161 of Dr. Batt's declaration, which, in turn, cites the '013 provisional at 13:14-17. This passage refers to multiple "targets" and their "corresponding probes." *See* EX1007 at 13:14-17; *see also* Petition at 29 (citing '013 provisional at 5:19-6:3 and 10:18-11:3, which describes a three-target scenario with eight droplet "populations"); *id.* at 41 (citing '013 provisional at *inter alia* 2:15-3:3 and 4:17-20, which describes detecting "two or more targets within each partition" and "two or more targets" in the "same channel"); *id.* at 13 (citing provisional at 9:4-15, 7:11, 7:17, 8:11, 8:19, 9:4-8, and 7:35, which supports multiple colors per target and "amplifying two or more targets in droplets.").

Finally, Saxonov ¶ 37, which is cited only once in the Petition, is referred to merely for routine disclosure about detecting fluorophores in color channels. *See* Petition at 38. The Petition cites disclosure in the '013 provisional that teaches the exact same thing. *See id.* at 40 (citing *inter alia* '013 provisional at 17:4-19:9 and 5:19-6:3, which describes optical channels for detecting fluorophore intensity data).

II. PO'S SHIFTING PORTRAYAL OF THE CLAIMS

PO contends that Saxonov and the '170 claims are different “in kind” because the former does not determine what analytes are present in individual droplets that have multiple analytes. *See* Paper 6 at 42-45. This mischaracterizes the claims and is inconsistent with PO’s district court position. Indeed, rather than referring to targets in a single “droplet,” the claims refer to a “sample” that is partitioned into a “*plurality* of droplets.” This “plurality” is then measured to determine what targets are present not in each droplet, but rather the original “said sample,” as recited in step (e). *See* EX1001 at claim 1. In its district court contentions, PO is clear that a “sample” is not limited to a “droplet,” but rather encompasses any mixture of “DNA or RNA with primers, probes, dye, and Bio-Rad ddPCR supermixes,” and can be provided “via a well plate.” *See* EX1012 at 12-15. PO’s new characterization of the claims as requiring determination on a per droplet basis should be rejected.

III. *FINTIV* CONSIDERATIONS DO NOT DISFAVOR INSTITUTION

Since filing of the Petition, the parallel district court case has only slowed further. It has been reassigned to a new judge and the schedule was vacated, including claim construction deadlines. The parties disagree on how the case ought to be handled, *see* EX2080, and the Court has not set a full schedule, let alone a trial date. *See* EX1039. There’s been no *Markman* hearing. The parties have made only modest document productions, and not a single deposition has been scheduled. On these facts, *Fintiv* considerations do not weigh against institution.

Dated: November 25, 2024

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 NOVEMBER 11, 2024 EMAIL** as being served on November 25, 2024, via email pursuant to 37 C.F.R. § 42.6(e) to counsel for Patent Owner at the address below:

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