

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

Case No. IPR2024-01451

U.S. Patent No. 11,827,921 B2

PATENT OWNER'S SUR-REPLY CLAIM CONSTRUCTION BRIEF

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Patent Trial and Appeal Board
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PATENT OWNER'S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Kevin Struhl, Ph.D.
2002	<i>Curriculum Vitae</i> of Kevin Struhl, Ph.D.
2003	File history of U.S. Patent No. 11,827,921
2004	U.S. Provisional Application No. 61/507,082
2005	Patent Scheduling Order dated March 8, 2024, Dkt No. 47, <i>ChromaCode, Inc. v. Bio-Rad Laboratories et al.</i> , Case No. 5:23-cv-06360, N.D. Cal.
2006	Petitioner's Amended Invalidity Contentions, <i>ChromaCode, Inc. v. Bio-Rad Laboratories et al.</i> , Case No. 5:23-cv-06360, N.D. Cal.
2007	Comparison of Saxonov and Saxonov Provisional
2008	Appendix M to Bio-Rad's Amended Invalidity Contentions
2009	Appendix I to Bio-Rad's Amended Invalidity Contentions
2010	Docket, <i>ChromaCode, Inc. v. Bio-Rad Laboratories et al.</i> , Case No. 5:23-cv-06360, N.D. Cal.
2011	Plaintiff's Opening Claim Construction Brief, <i>ChromaCode, Inc. v. Bio-Rad Laboratories et al.</i> , Case No. 5:23-cv-06360, N.D. Cal.
2012	Reply Claim Construction Brief, <i>ChromaCode, Inc. v. Bio-Rad Laboratories et al.</i> , Case No. 5:23-cv-06360, N.D. Cal.
2013	Notice Setting Claim Construction Hearing, Dkt. 83, <i>Chromacode Litig.</i> , Case No. 5:23-cv-04823, N.D. Cal.
2014	Joint Case Management Statement, Dkt. 80, <i>Chromacode Litig.</i> , Case No. 5:23-cv-04823, N.D. Cal.
2015	Minute Entry for Case Management Conference held on November 6, 2024, Dkt. 88, <i>Chromacode Litig.</i> , Case No. 5:23-cv-04823, N.D. Cal.
2016	Declaration of Carl Batt, Ph.D. in Support of Patent Owner's Response to Petition for <i>Inter Partes</i> Review, <i>Dropworks, Inc. v. Lawrence Livermore National Security, LLC</i> , IPR2021-00302.
2017	June 4, 2025, Deposition Transcript of Dr. Carl Batt, <i>Bio-Rad Laboratories, Inc. v. California Institute of Technology</i> , IPR2024-01451.
2018	Supplemental Declaration of Kevin Struhl, Ph.D. in Support of the Patent Owner Response.
2019	QX ONE Droplet Digital PCR (ddPCR) System, available at

Exhibit No.	Description
	https://www.bio-rad.com/en-us/life-science/digital-pcr/qx-one-droplet-digital-pcrddpcr-system (accessed June 19, 2025).
2020	QX600 Droplet Digital PCR System, available at https://www.bio-rad.com/en-us/product/qx600-droplet-digital-pcr-system?ID=b07d12ac-0585-fc4c-a586-3ddf20d5c4a0 (accessed June 19, 2025).
2021	Bio-Rad SEC filing, available at https://www.sec.gov/Archives/edgar/data/12208/000119312520315015/d28972dex991.htm (accessed June 19, 2025).
2022	Plaintiffs ChromaCode, Inc. and California Institute of Technology's Opposition to Defendant's Motion to Transfer, Dkt. 29, <i>ChromaCode, Inc. et al. v. Bio-Rad Labs., Inc.</i> , No. 4:23-cv-06360-EKL (N.D. Cal. Nov. 20, 2023).
2023	Bio-Rad SEC filing, available at https://www.sec.gov/Archives/edgar/data/12208/000119312522053527/d901425dex991.htm (accessed June 19, 2025).
2024	Claim Construction Order, Dkt. 125, <i>Chromacode Litig.</i> , Case No. 5:23-cv-04823, N.D. Cal.
2025	October 9, 2025 Cross Examination of Dr. Carl A. Batt.

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<i>Phillips v. AWH Corp.</i> 415 F. 3d 1303 (Fed. Cir. 2005)	1
<i>Siemens Indus. Software Inc. v. Synopsis, Inc.</i> IPR2021-01212, Paper 32 (PTAB Jan. 11, 2023)	2, 3
<u>Other Authorities</u>	
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I. INTRODUCTION

Pursuant to the Board's October 17, 2025 email, Patent Owner ("PO") submits this sur-reply claim construction brief regarding "single sample volume." EX3003.

The Board need not construe the term "single sample volume" because there is no controversy over its construction and the term should be given its plain and ordinary meaning. The claimed "single sample volume" includes a droplet or any other type of volume, such as a tube or bottle. Nonetheless, claim 1's concluding "wherein" clause limits to the claim scope by requiring that "the analytes are amplified in the single volume." Accordingly, the claims, as a whole, exclude the embodiment of "single sample volume" that is *subsequently* partitioned into droplets in which amplification is then performed. As PO explained in its responsive brief (Paper 29), this understanding is confirmed by not only the claim language itself, but also the intrinsic record. By contrast, Petitioner's interpretation of the claim—that the single sample volume includes volumes *subsequently* partitioned into droplets for amplification—contradicts the claim language and intrinsic record, and improperly elevates purported extrinsic evidence over the intrinsic record in violation of *Phillips v. AWH Corp.*, 415 F. 3d 1303 (Fed. Cir. 2005) (en banc).

Accordingly, the Board should reject Bio-Rad's arguments and interpret "single sample volume" according to its plain and ordinary meaning, where amplification occurs within the single sample volume (*i.e.*, a droplet).

II. ARGUMENT

A. PO's Claim Interpretation Has Not Changed

The scope of the *claimed* “single sample volume” must be interpreted in view of the claim as a whole. As PO has asserted all along, the “wherein” clause requires that amplification occurs in the “single sample volume.” When viewed in isolation, however, *i.e.*, without considering the “wherein” clause, the lone *term* “single sample volume” can include volumes that are subsequently partitioned into droplets. While Petitioner characterizes these two points as being inconsistent, they merely reflect the principle that “[p]roper claim construction[.]..demands interpretation of the entire claim in context, not a single element in isolation[.]” *Siemens Indus. Software Inc. v. Synopsis, Inc.*, IPR2021-01212, Paper 32 at 12 (PTAB Jan. 11, 2023) (quoting *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999)) (quotation marks omitted).

Thus, to be clear, PO has not “abandoned” its consistent interpretation of the claims: amplification must occur in the single sample volume, whether a droplet, tube, or bottle. *See* Paper 30 at 1. And Petitioner has not pointed to any “evidence in the claim language, specification, [or] file history” suggesting that amplification occurs in a single sample volume that is *subsequently* partitioned into droplets. *Id.* Because there is none.

Accordingly, no construction of “single sample volume” is required, so long as the claims as a whole are interpreted to require amplification in the single sample volume. *Siemens*, IPR2021-01212, Paper 32 at 12.

B. Separation Does Not Affect the Proper Claim Interpretation

Petitioner's argument regarding “separation” is that the specification and claims cover detection with or without partitioning the single sample volume. Paper 30 at 2. As PO explained in its responsive brief, Petitioner's interpretation of “separation” in the file history is incorrect (Paper 29 at 9) so Petitioner now instead points to the specification's use of “separation” and Dr. Batt's regurgitation of the same. Paper 30 at 2 (citing EX1043, ¶¶14-15). But ultimately, even though “single sample volume” on its own is a broad term, the discussion of separation “has minimal impact on the claim scope as a whole given the ‘wherein’ clause.” Paper 29 at 9. Petitioner's argument completely ignores this point.

C. Petitioner Does Not Address How the “Wherein” Clause Affects Claim Scope

Rather than address PO's explanation of the “wherein” clause and the requirement it imposes on the claimed “single sample volume”—that amplification must occur in the “single sample volume”—Petitioner merely argues Larson discloses this feature. Paper 30 at 3. This argument exceeds the scope of what the Board authorized in this briefing, and Larson's teachings do not bear on how “single sample volume” should be construed. Moreover, PO has explained in detail in its

Response and Sur-Reply why Larson fails to anticipate the claims or render them obvious.

Petitioner continues to argue that Larson discloses detecting multiple analytes in a purported single sample volume that is subsequently partitioned into droplets. Paper 30 at 3. But this completely ignores the “wherein” clause. When properly accounting for the “wherein” clause, Larson clearly does *not* teach (and indeed teaches away from) analyzing droplets having more than one analyte *in the volume where amplification occurs*. And indeed, although Petitioner disputes such teachings in Larson here, Petitioner took the exact *opposite* position when arguing the validity U.S. Patent No. 9,127,310, which is a continuation of Larson and shares the same specification. There, Petitioner represented to the Board that “the teachings of the ’310 Patent[] state that[] in order to successfully perform multiplex PCR, not only *must each droplet contain only one DNA template* but it should preferentially be single stranded.” *Dropworks, Inc. v. Bio-Rad Labs., Inc.*, IPR2021-00212, Paper 6 at 36 (PTAB Mar. 8, 2021) (emphasis added). And, quoting U.S. Patent No. 9,127,310, Petitioner argued that “[h]aving only one haploid genome (i.e., one allele) per droplet gives droplet PCR advantages over standard singleplex or multiplex PCR in tubes or microwells” and that this distinguished the prior art. *Id.*

Accordingly, Petitioner's new arguments regarding Larson are not only irrelevant and improper, they are wrong and contrary to Petitioner's representations to the Board in other matters. Thus, the Board should reject them.

III. CONCLUSION

As explained above and in PO's responsive brief, the claim scope as a whole requires that the analytes are amplified in the single sample volume, ultimately precluding the claims from covering amplification in a sample and then subsequently partitioning the sample into droplets. The Board should reject Petitioner's interpretation to the contrary.

Respectfully submitted,

Dated: November 14, 2025

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