

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 RESPONSIVE CLAIM CONSTRUCTION BRIEF

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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>In re: ChromaCode</i> 5:23-cv-04823-EKL, Dkt. 128 (N.D. Cal. July 29, 2025).....	3
<i>Great W. Cas. Co. v. Intell. Ventures II LLC</i> IPR2015-01706, Paper 69 (PTAB Feb. 14, 2020)	8
<i>Hockerson-Halberstadt, Inc. v. Converse Inc.</i> 183 F.3d 1369 (Fed. Cir. 1999)	6, 7, 8
<i>Intex Recreation Corp. v. Bestway (USA), Inc.</i> IPR2019-00454, Paper 34 (PTAB June 22, 2020)	8
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.</i> 868 F.3d 1013 (Fed. Circ. 2017)	5
<i>Phillips v. AWH Corp.</i> 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	5, 8
<i>Siemens Indus. Software Inc. v. Synopsys, Inc.</i> IPR2021-01212, Paper 32 (PTAB Jan. 11, 2023)	6, 7

Pursuant to the Board's October 17, 2025 email, Patent Owner ("PO") submits this responsive claim construction brief regarding "single sample volume." EX3003. Consistent with PO's arguments before the district court, PO is not trying to use its amended infringement contentions to seek a different or narrower construction of "single sample volume." Indeed, both PO and Petitioner agree that "single sample volume" can generally mean either a pre-partitioned sample (*e.g.*, within a tube or bottle) or post-partitioned sample (*i.e.*, a droplet). But the inquiry cannot end there. The scope of claim 1 must be understood as a whole, including its additional limitations requiring "unambiguously detecting the presence or absence" of analytes "wherein the analytes are amplified in the single sample volume." EX1001, claim 1. And, it is the "wherein" clause, which Petitioner largely ignores, that is critical to understanding which of the different flavors of "single sample volume" fall within the claim scope. This is the heart of this dispute.

Critically, as PO has argued all along in this proceeding, a POSITA would understand the "wherein" clause to limit the claim scope, as a whole, to cover *only* the specific flavor of "single sample volume" where the amplification reaction is actually performed: *e.g.*, post-partitioned droplets. For example, in its PO Preliminary Response, PO argued that Larson and Saxonov do not disclose analyzing more than two analytes in a single droplet *after* the sample is partitioned into droplets and amplification is *then* performed in each droplet. See Paper 8 at 50–55, 61; see

also Paper 10 at 3. And in its PO Response, PO argued that “it is clear from PO’s preliminary infringement contentions regarding [the] ‘wherein[’ clause] ... that the single sample volume PO accuses is where amplification occurs: e.g., in a droplet, not in a pre-partitioned volume.” Paper 17 at 26 (citing EX1012 at 27–29); *see also* Paper 10 at 3. Regardless of whether the “single sample volume” is a droplet or a tube or bottle, the “wherein” clause requires that “**the** single sample volume” must be where amplification occurs. And no narrowing construction of “single sample volume” is required to clarify this because the claim language is clear about which flavor of “single sample volume” the claim scope as a whole covers, when **all** claim limitations are applied.

As is typical for Petitioner’s arguments in this proceeding, its opening claim construction brief fabricates conflict where there is none, and adds noise without meaning. Indeed, contrary to Petitioner’s allegations, PO has not requested the Board to construe “single sample volume,” let alone request it here in view of recent activity in parallel litigation. Rather, it is Petitioner who makes that request. And, contrary to Petitioner’s allegations, PO specifically sought to **avoid** putting any “spin” on that recent activity and rather proposed simply apprising the Board of the district court’s Order. EX3003 at 3–4 (“Petitioner has insisted on filing this joint statement with competing positions, and attaching not only the Order, but also a transcript from the district court’s motion hearing that led to the Order, over [PO’s]

objection ... [T]he Board should review and interpret the relevance of the Order without characterization or argument from either party[.]”). Indeed, it is Petitioner that is attempting to spin the events from district court litigation to its favor, namely by continuing to read out claim language (the “wherein” clause) and thus improperly broaden the claims. EX3003 at 2–3; Paper 25. In any event, PO’s amended infringement contentions are merely extrinsic evidence that does not override the clear intrinsic record. Indeed, the district court stated that its order granting-in-part PO’s motion to amend its infringement contentions should *not* have “any impact on proceedings before the PTAB.” EX1046 at 7.

I. BACKGROUND

The present dispute relates to construction of the term “single sample volume” in the ’921 Patent claims and whether such construction is appropriate. In parallel litigation, PO (one of the plaintiffs there) and ChromaCode, Inc. served preliminary infringement contentions (“PICs”) containing two infringement theories relating to the single sample volume. In the first theory, Plaintiffs asserted infringement based on the “single sample volume” being “a droplet,” and in the alternative theory asserted infringement based on the “single sample volume” being the “solution before being partitioned into droplets.” EX1046 at 5; *see also* EX1045 at 4:21–5:3; *In re: ChromaCode*, 5:23-cv-04823-EKL, Dkt. 128 at 4. During claim construction in the litigation, neither party asked the court to construe the terms “single sample

volume” or “wherein the analytes are amplified in the single sample volume.”

After completing sufficient discovery, Plaintiffs moved to amend their PICs, including limiting their infringement theory to the single sample volume being a droplet and eliminating the alternative theory based on the single sample volume being subsequently partitioned into droplets. EX1046 at 7. As Plaintiffs argued at the hearing on their motion, PO was “*not* trying to narrow a claim construction in the IPR based on [its] infringement contentions.” EX1045 at 12:21–23 (emphasis added). Rather, “based on what the products do,” the alternative theory was not viable and should be dropped because there is no evidence that in the accused products a “reaction ... occurs in the sample before it’s partitioned into droplets.” EX1045 at 10:17–11:19, 14:14–15:22. The district court granted Plaintiffs’ motion to amend the PICs to “eliminate [their] alternative pre-partition theory of infringement for the single sample volume ..., while retaining the previously-disclosed single droplet theory of infringement,” stating the proposed amendments should not have “any impact on proceedings before the PTAB.” See EX1046 at 7.

II. LEGAL STANDARD

“[C]laim construction must begin with the words of the claims themselves.” *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1373 (Fed. Cir. 2019). Claim language can be dispositive. *Bonutti Skeletal Innovations LLC v. Arthrex, Inc.*, No. 6:13-cv-00620, 2014 U.S. Dist. LEXIS 185178, at *27, 30 (M.D. Fl. Mar. 25, 2014).

Courts then review the specification, which is “always highly relevant to the claim construction analysis.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc).

III. ARGUMENT

A. The Board Does Not Need to Construe “Single Sample Volume”

There is no controversy over the construction of “single sample volume,” and neither party has requested this term be construed either here or in the parallel litigation. To the contrary, PO *agrees* with Petitioner that the '921 Patent's claim term “single sample volume” should be given its plain and ordinary meaning, and accordingly that “single sample volume” should be broadly read as “*not* limited to an individual ‘droplet,’ but rather includes any type or nature of volume, such as a ‘tube or bottle.’” Paper 10 at 3 (quoting Paper 9 at 1, 2); Paper 25, 4–7, 10. And Petitioner's argument that PO, in a “180° turnabout, [now] alleges that this term excludes volumes that are ‘subsequently partitioned into droplets...’” is not true and, in any case, should be rejected because it is a red herring and effectively ignores the “wherein” clause. Paper 25 at 1 (citing Paper 17 at 26). Indeed, PO *agrees* with Petitioner that the term “single sample volume” by itself can include “volumes that are subsequently partitioned into droplets.” Accordingly, there is no need for the Board to construe this term. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Circ. 2017) (The Board “need only construe terms

that are in controversy, and only to the extent necessary to resolve the controversy.” (quotation marks omitted)); Paper 11 at 15–16.

B. The Claim Imposes Other Limitations on “Single Sample Volume”

Whether the single sample volume is a droplet or in a tube or bottle, the “wherein” clause requires that “the analytes are amplified in the single sample volume.” EX1001, claim 1. Neither party asked for this limitation to be construed here or in the parallel litigation. And it is this “wherein” clause that impacts the scope of the claim as a whole, regardless of how the term “single sample volume” is construed. *Siemens Indus. Software Inc. v. Synopsys, Inc.*, IPR2021-01212, Paper 32 at 12 (PTAB Jan. 11, 2023) (“[A]lthough we agree with the construction of the *term*, we must further resolve how that construction affects the reading of the *claim as a whole*.... ‘Proper claim construction, however, demands interpretation of the entire claim in context, not a single element in isolation[.]’”) (quoting *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) (emphasis added)).

The intrinsic record confirms that in embodiments where the “single sample volume” is a droplet or other volume, the amplification reaction takes place in that droplet or other volume. Indeed, the claim language plainly states this through the “wherein” clause’s reference to “*the* single sample volume.” EX1001, claim 1 (emphasis added). And the ’921 Patent specification states that to detect analytes in

a single sample volume, “reagent[s can be] used to generate a signal in the volume,” *Id.*, 30:55–63. The parties do not dispute that the signal from a given volume is generated by performing amplification reactions using reagents within that volume. *See, e.g.*, Paper 1 at 2–4; EX1002 at ¶42; Paper 17 at 4; *accord* EX2018 at ¶32. In nonlimiting examples where the single sample volume is a droplet, the ’921 Patent specification states that its methods can be easily integrated into “[d]igital PCR methods (e.g., DROPLET DIGITAL (BIORAD) ... to significantly expand their throughput by allowing multiplexing in a droplet.” EX1001, 36:58-67. The file history likewise explains how performing amplification in a single sample volume distinguished various prior art references cited by the Examiner. *See* EX1029 at 10–12. And even Petitioner’s expert agrees that “[t]he process is where you take a sample, you separate it into droplets, and then you do preliminary [*sic: polymerase*] chain reaction amplification on those droplets, on that collection of droplets.” EX2025 at 25:8–15.

Accordingly, the intrinsic evidence confirms what the “wherein” clause requires—analytes must be amplified in the “single sample volume.” While the “wherein” clause does not alter the broader *meaning* of “single sample volume,” it nonetheless restricts what *types* of “single sample volumes” the claim as a whole encompasses—namely, volumes where the amplification occurs (droplet, tube, or bottle). *Siemens*, IPR2021-01212, Paper 32 at 12; *Hockerson*, 183 F.3d at 1374.

C. Bio-Rad's Continued Elevation of PO's Preliminary Infringement Contentions over the Intrinsic Evidence Should Be Rejected

Grounds 1 and 2 rely on the PICs from the parallel litigation, and Grounds 3 and 4 point back to Grounds 1 and 2. *See* Paper 1 at 22–51, 51–67. Dr. Batt's opinions ostensibly supporting these grounds likewise rely on the PICs, although he admittedly did not know (and thus did not apply) the proper legal standard for interpreting claims in view of PICs. *Id.*; EX2017, 47:8–49:11. But the PICs are, at most, non-binding *extrinsic* evidence with respect to how claims should be construed in an IPR. *Great W. Cas. Co. v. Intell. Ventures II LLC*, IPR2015-01706, Paper 69 at 13 (PTAB Feb. 14, 2020); *Intex Recreation Corp. v. Bestway (USA), Inc.*, IPR2019-00454, Paper 34 at 11 (PTAB June 22, 2020). Extrinsic evidence “of what a party [allegedly] subjectively thought was a proper construction is of limited value.” *Great W.*, Paper 69 at 13. Accordingly, the Board should decline Petitioner's persistent invitation to circumvent *Phillips* by elevating the PICs above the intrinsic record (e.g., the “wherein” clause), and reject Dr. Batt's testimony doing the same. *Id.* (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005)).

And to the extent Petitioner now tries to pull in intrinsic evidence to bolster its case (Paper 25 at 4–8), this also fails. For example, in attempting to show the breadth of “single sample volume,” Petitioner alleges that 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.”

Thus, the inventors of the '921 patent contemplated requiring no separation of the 'single sample volume,' but decided against it.

Paper 25 at 7 (quoting EX1029 at 2).

This is another red herring. Contrary to Petitioner's misleading assertion, the prior claim language clearly did *not* recite that the "sample volume not be separated." See EX1029 at 2. And PO's remarks accompanying the amendment clarified precisely what "separation" *does* mean in the '921 Patent specification and claims: "[I]mportantly, the methods and compositions provided herein may be used to detect multiple analytes by obtaining a cumulative measurement on a single solution. *No separation is necessary. The invention does not require the use of beads or a solid phase.*" *Id.* at 6–7 (quoting '921 Patent pre-grant publication at [0155]) (emphasis original); see also EX1025 at 6–7. Thus, contrary to Petitioner's assertions, the term "separation" in the '921 Patent claims, specification, and prosecution history clearly relates to the "use of beads or a solid phase," *not* to forming droplets through a purported "separation" process. And in any event, PO agrees "single sample volume" is broad, but again, this has minimal impact on the claim scope as a whole given the "wherein" clause.

D. Bio-Rad's Waiver Arguments Should Be Rejected Because they Are Contrary to the Record

Petitioner's waiver argument should be rejected because a closer look at the record confirms PO never agreed the claims do not require amplification to occur in

the single sample volume. For example, in the parallel litigation, PO's counsel confirmed that "nothing has changed from how we're arguing in the IPR and nothing will change how we've been arguing in the IPR." EX1045 at 56:14–21. As explained above, it has always been PO's position in this IPR that amplification must occur in the single sample volume. Similarly, PO's counsel confirmed that "we're not trying to narrow a claim construction in the IPR based on our infringement contentions." *Id.* at 12:21–23. Indeed, as explained above, it is not the infringement contentions but the intrinsic record that requires amplification to occur in the single sample volume. Thus, Petitioner's waiver argument is without merit.

IV. CONCLUSION

For these reasons, no construction of the term "single sample volume" is required. However, the Board should consider the "wherein" clause when analyzing the scope of the challenged claims. As explained above, 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 Bio-Rad's interpretation to the contrary, which wholly ignores the claim language and intrinsic record.

Respectfully submitted,

Dated: October 31, 2025

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