

1 WILSON SONSINI GOODRICH & ROSATI, P.C.
2 AMY H. CANDIDO, SBN 237829
(acandido@wsgr.com)
3 SACHLI BALAZADEH-NAYERI, SBN 341885
(snayeri@wsgr.com)
4 One Market Plaza
Spear Tower, Suite 3300
5 San Francisco, CA 94105-1126
6 Telephone: (415) 947-2000

7 ERIC P. TUTTLE, SBN 248440
(eric.tuttle@wsgr.com)
8 ARIEL C. GREEN ANABA, SBN 304780
(aanaba@wsgr.com)
9 LISA D. ZANG, SBN 294493
(lzang@wsgr.com)
10 953 East Third Street, Suite 100
11 Los Angeles, CA 90013
12 Telephone: (323) 210-2900

13 *Attorneys for Plaintiff and
Counter-Defendant ChromaCode, Inc.*

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN JOSE DIVISION

17
18 CHROMACODE, INC.,
19 Plaintiff and Counter-Defendant,
20 v.
21 BIO-RAD LABORATORIES, INC.,
22 Defendant and Counter-Plaintiff.
23
24

Case No. 5:23-cv-04823-EJD

**PLAINTIFF AND COUNTER-
DEFENDANT CHROMACODE,
INC.'S AMENDED PATENT L.R. 3-
3 DISCLOSURE OF
PRELIMINARY INVALIDITY
CONTENTIONS; PATENT L.R. 3-4
DOCUMENT PRODUCTION**

Hon. Edward J. Davila

1 Pursuant to Patent Local Rule 3-3, the Court’s December 11, 2023 Patent Scheduling
2 Order (Dkt. No. 39), and the Court’s Order to Amend Patent Scheduling Order (Dkt. No. 45),
3 Plaintiff and Counter-Defendant ChromaCode Inc. (“ChromaCode”) makes the following
4 amended disclosure of preliminary invalidity contentions for U.S. Patent No. 9,222,128 (the
5 “’128 Patent”) and U.S. Patent No. 9,921,154 (the “’154 Patent”) (collectively, the “Asserted
6 Patents”). Defendant and Counter-Plaintiff Bio-Rad Laboratories, Inc. (“Bio-Rad”) asserts
7 claims 1-5 and 8-12 of the ’128 Patent and claims 1-4, 6-17, 19-28 of the ’154 Patent
8 (collectively, the “Asserted Claims”).

9 ChromaCode makes the following preliminary invalidity contentions based on
10 information ascertained to date, and reserves the right to modify, supplement, or further amend
11 the disclosures contained herein based on the Court’s claim construction or to reflect information
12 that is ascertained in the future.

13 ChromaCode’s investigation into the facts of this action is ongoing. ChromaCode has not
14 completed its investigation of the facts relating to this case, discovery in this action, or its
15 preparation for trial. This disclosure is without prejudice to ChromaCode’s right to produce
16 evidence of any additional prior art references. Accordingly, ChromaCode reserves its right to
17 supplement or further amend the disclosures made herein as new, additional, or different
18 information is learned and discovered.

19 Further, these disclosures are prepared prior to the Court’s claim construction ruling and
20 disclosure of claim construction positions from Bio-Rad. ChromaCode’s positions on the
21 invalidity of particular claims will depend on how the claims are construed by the Court.
22 ChromaCode reserves the right to supplement or further amend its contentions based on claim
23 construction positions taken by Bio-Rad or any construction adopted by the Court. In the
24 meantime, these contentions are made in the alternative and are not necessarily intended to be
25 internally consistent or consistent with ChromaCode’s claim construction or non-infringement
26 positions. ChromaCode’s contentions herein should not be seen as a suggestion that Bio-Rad’s
27 reading of the patent claims, such as it can be determined, is correct.

1 ChromaCode does not agree with Bio-Rad's application of the Asserted Claims, or that
2 the claims satisfy the requirements of 35 U.S.C. § 112. ChromaCode's contentions herein are
3 not, and should in no way be seen as, admissions or adoptions as to any particular claim scope or
4 construction, or as any admission that any particular element is met in any particular way.
5 ChromaCode objects to any attempt to imply claim construction from the arguments herein.
6 These invalidity contentions are made in a variety of alternatives and do not represent
7 ChromaCode's agreement or view as to the meaning, definiteness, written description support
8 for, or enablement of any claim contained therein.

9 The citations to the prior art provided in ChromaCode's invalidity contentions are
10 intended to be exemplary, not exhaustive. ChromaCode has endeavored to cite to the most
11 relevant portions of the identified prior art. Other portions of the identified prior art may
12 additionally disclose, either expressly or inherently, and/or render obvious one or more elements
13 or limitations of the Asserted Claims. ChromaCode reserves the right to rely on uncited portions
14 of the identified prior art, and the knowledge of one of ordinary skill in the art, to establish the
15 invalidity of the Asserted Claims. Moreover, ChromaCode reserves the right to rely on uncited
16 portions of the identified prior art, all art cited during prosecution of the '128 and/or '154
17 Patents, other prior art, background art, and expert testimony, including to provide context to or
18 aid in understanding the cited portions of the identified prior art. ChromaCode also reserves the
19 right to rely upon treatises, published industry standards, and similar documents to demonstrate
20 the knowledge of one of ordinary skill in the relevant art. Where ChromaCode cites to a
21 particular drawing or figure, the citation encompasses the description of the drawing or figure, as
22 well as any text associated with the drawing or figure. Similarly, where ChromaCode cites to
23 particular text concerning a drawing or figure, the citation encompasses that drawing or figure as
24 well. Also, where ChromaCode cites to any portion of prior art as disclosing a particular
25 limitation, that citation applies with equal force to all similar or identical limitations in each of
26 the Asserted Claims.

27 Furthermore, the obviousness combinations of references provided below under 35
28 U.S.C. § 103 are merely exemplary and not intended to be exhaustive. Additional obviousness

1 combinations of the references identified below are possible, and ChromaCode reserves the right
2 to use obviousness combinations in this litigation. In particular, ChromaCode is currently
3 unaware of the extent to which Bio-Rad may contend that limitations of the claims at issue are
4 not disclosed in the art identified by ChromaCode as anticipatory. To the extent that an issue
5 arises with any such limitation, ChromaCode reserves the right to identify other references which
6 make obvious the addition of the allegedly missing limitation to the disclosed device or method
7 of operation.

8 **I. PATENT LOCAL RULE 3-3(a) DISCLOSURES**

9 As a threshold matter, the Asserted Claims of the '128 and '154 Patents are not entitled to
10 Bio-Rad's claimed priority date of March 18, 2011. *See* Bio-Rad's Amended Patent L.R. 3-1
11 Disclosure of Asserted Claims and Preliminary Infringement Contentions ("Amended
12 Infringement Contentions") at 5. For example, the Asserted Claims each require calculating or
13 determining the "level," "average level," or "respective level" of a target. U.S. Provisional
14 Application No. 61/454,373 (the "'373 Provisional"), which Bio-Rad relies on to claim a March
15 18, 2011 priority date (*see id.*), does not disclose calculating or determining the "level," "average
16 level," or "respective level" of a target. Instead, the '373 Provisional discloses calculating or
17 determining the "concentration" or "average concentration" of a target. *See, e.g.,* '373
18 Provisional at 1-2; European Application No. 12 760 944.4 – 1118, 05/29/20 European Patent
19 Office Communication Under Rule 71(3) EPC at 90-91 ("The present application claims priority
20 to provisional application USP201161454373 filed on 18 March 2011. However, said priority
21 document does not disclose the feature that the '*level calculated accounts for a coincidence of*
22 *different targets in the same individual partitions*' (as in present **claim 1**). Similarly, the priority
23 document does not disclose the feature '*calculating an average level of each target in the*
24 *droplets based on the signals and without determining which of the at least two targets for each*
25 *signal amplified in individual amplification-positive droplets for the signal*' (as in present **claim**
26 **9**). Therefore, at least present **claims 1-6 and 9-10** do not validly claim priority. As a
27 consequence, document D4 is relevant for the present application.") (emphases in original).

1 Based upon presently known information, pursuant to Patent Local Rule 3-3(a),
2 ChromaCode identifies the following prior art references that anticipate and/or render obvious
3 the Asserted Claims of the '128 and '154 Patents. ChromaCode has identified each prior art
4 patent by its inventor, title, number, country of origin, date of filing, and date of issue. Each
5 prior art publication is identified by its title, date of publication, and, where feasible, author and
6 publisher. To the extent any prior art reference is found not to anticipate any of the Asserted
7 Claims or Bio-Rad contends that the reference is not anticipatory, ChromaCode contends that the
8 reference nevertheless renders all of the Asserted Claims obvious either individually or in
9 combination with other references and/or in view of the general knowledge in the art and/or
10 common sense. Subject to the foregoing, based upon presently known information, the prior art
11 references that anticipate and/or render obvious the Asserted Claims include:

- 12 • U.S. Patent No. 9,074,242 to Jonathan William Larson, Qun Zhong, and
13 Darren Roy Link, issued on July 7, 2015 ("Larson");
- 14 • U.S. Patent Appl. No. 2013/0323716 to Emil Kartalov, Aditya Rajagopal, and
15 Axel Scherer, published on December 5, 2013 ("Kartalov")
- 16 • U.S. Patent No. 10,068,051 to Emil Kartalov, Aditya Rajagopal, and Axel
17 Scherer, issued on September 4, 2018 ("Kartalov 051");
- 18 • U.S. Patent No. 10,770,170 to Emil Kartalov, Aditya Rajagopal, and Axel
19 Scherer, issued on September 8, 2020 ("Kartalov 170");
- 20 • U.S. Patent Application No. 12/170,414, Pub. No. US 2009/0239308 A1
21 (Published Sep. 24, 2009), by Simant Dube, Jian Qin, and Ramesh
22 Ramakrishnan ("Dube Application");
- 23 • Dube S., Qin J., Ramakrishnan R., *Mathematical Analysis of Copy Number*
24 *Variation in a DNA Sample Using Digital PCR on a Nanofluidic Device*,
25 PLoS ONE, vol. 3, no. 8, Aug. 2008, pp. 1 – 9 (2008) ("Dube Paper").

26 ChromaCode reserves the right to update its invalidity contentions after receiving proper
27 infringement contentions from Bio-Rad and to reflect the results of discovery in this matter.

II. PATENT LOCAL RULE 3-3(b) DISCLOSURES

Based upon presently known information, pursuant to Patent Local Rule 3-3(b), below are the grounds on which the Asserted Claims are invalid for failure to meet the requirements of both 35 U.S.C. §§ 102 and 103. The Asserted Claims are neither novel nor non-obvious in the field of multiplexing with digital PCR assays. All aspects of the Asserted Claims were well-known and extensively researched well before the filing of the patent.

A. Anticipation of the Asserted Claims

Based upon presently known information, including the way Bio-Rad appears to be construing and applying the '128 and '154 Patents in this case, ChromaCode contends the Asserted Claims of the '128 and '154 Patents are invalid under 35 U.S.C. § 102 as being anticipated by individual prior art references presented in these contentions. Specifically:

- Larson;
- Kartalov;
- Kartalov 051;
- Kartalov 170.

To be clear, ChromaCode believes that the '128 and '154 Patents do not anticipate or render obvious any claim of the Kartalov patents, even if the '128 and '154 Patents are entitled to their alleged priority date. However, as discussed above, the '128 and '154 Patents are not entitled to their alleged priority date. Bio-Rad's infringement contentions suggest that it believes the '128 and '154 Patents read on the Kartalov invention. If the claims of the '128 and '154 Patents are read as broadly as alleged in Bio-Rad's Infringement Contentions, Kartalov would be anticipating prior art.

B. Obviousness of the Asserted Claims

Based upon presently known information, in addition to the discussion above, and to the extent not anticipated, the Asserted Claims of the '128 and '154 Patents are invalid under 35 U.S.C. § 103 as being obvious to a person having ordinary skill in the art of the relevant technology.

1 For example, to the extent Bio-Rad contends that the following limitations are not
2 disclosed in Larson, Kartalov, Kartalov 051, and/or Kartalov 170:

- 3 • “calculating an average level of each target in the partitions based on the R
4 signals, wherein the level calculated accounts for a coincidence of all possible
5 combinations of the more than R targets in the same individual partitions”
6 (’128 Patent, claim 1) (emphasis added)
- 7 • “wherein the step of calculating an average level includes a step of
8 determining a total number of amplification-positive partitions for each type
9 of the more than R targets” (’128 Patent, claim 9) (emphasis added)
- 10 • “calculating levels of at least three of the targets based on light detected from
11 only two fluorophores, wherein the levels calculated account for a coincidence
12 of all possible combinations of the at least three targets in the same individual
13 partitions” (’128 Patent, claim 12) (emphasis added)
- 14 • “determining a respective level of each of the R targets from the data, wherein
15 each level is specific for a single target of the R targets, and wherein the level
16 determined for at least one of the R targets is based in part on a partition count
17 for a partition population positive for two of the R targets” (’154 Patent,
18 claims 1, 11, 18, 19) (emphasis added)
- 19 • “wherein the step of identifying includes a step of resolving each partition
20 population that is positive for exactly two of the R targets from each partition
21 population that is positive for only one of the R targets” (’154 Patent, claims
22 10, 11, 26) (emphasis added)

23 Those limitations would have been obvious to one of ordinary skill in the art at the time.

24 The statistical literature is replete with discussion of methods for inferring levels of
25 characteristics in a population when observations of samples do not uniquely identify the
26 characteristic due to convolution or degeneracy. This type of problem is referred to generally as
27 indeterminacy, under-determinacy, non-uniqueness, degeneracy, non-identifiability, ill-posed
28 problems, inverse problems, deconvolution, and latent variable problems, among other names.

1 In general, they all address the scenario where the states of interest are being observed indirectly,
2 and more than one state of nature gives rise to the same observed data, so the measurements do
3 not directly distinguish between those states. There is an enormous literature on how to estimate
4 parameters in such problems. One of the most widely-known and used methods is the
5 Expectation Maximization algorithm. See '154 Patent, 15:7-10.

6 The Expectation Maximization algorithm was popularized as a method to solve such
7 problems by a well-known article in 1977.¹ Numerous textbooks and overview articles discuss
8 and explain it.² In the decades since it has been widely used across a great many fields,³
9 including specifically in computational/molecular biology and molecular genomics/genetics,⁴
10 and in connection with PCR.⁵

11
12 ¹ Dempster, A.P., Laird, N.M., Rubin, D.B., *Maximum Likelihood from Incomplete Data via the*
13 *EM Algorithm*, Journal of the Royal Statistical Society, Series B. vol. 39 no.1, 1–38 (1977).

14 ² See, e.g., McLachlan G.J. & Krishnan T., *The EM Algorithm and Extensions* (1st ed. 1997, 2nd
15 ed. 2008); Hogg, R., McKean, J., & Craig, A., *Introduction to Mathematical Statistics* (6th ed.
16 2004); Gupta, M.R. & Chen, Y., *Theory and Use of the EM Algorithm, Foundations and Trends*
17 *in Signal Processing*, vol. 4 no.3, 223–296 (2010); *EM and Related Algorithms*, Statistica Sinica,
vol. 5, no. 1 (1995), 1-107; McLachlan, G.J., Krishnan, T. & Ng, S.K., *The EM Algorithm*,
Papers, No. 2004,24, Humboldt-Universität zu Berlin, Center for Applied Statistics and
Economics (CASE), Berlin (2004).

18 ³ See, e.g., Moon, T.K., *The Expectation-Maximization Algorithm*, *IEEE Signal Processing*
19 *Magazine* (1996), 47-60; Meng, X.L. & van Dyk, D., *The EM algorithm – an old folk-song sung*
20 *to a fast new tune*, J. Royal Statist. Soc. B. vol. 59 no. 3, 512–514 (1997); Meng, X. L. &
21 Pedlow, S., EM: a bibliographic review with missing articles, *The Proceedings of the Statistical*
22 *Computing Section of the American Statistical Association*, Proc. Statist. Comput. Sect. Am.
23 Statist. Ass., 24-27 (1992).

24 ⁴ See, e.g., Do , C.B. & Batzoglou, S., *What is the expectation maximization algorithm?*, *Nature*
25 *Biotechnology*, vol. 26, no. 8 (2008); Ceppellini, R.M., Siniscalco, M. & Smith, C.A.B., *The*
26 *estimation of gene frequencies in a random-mating population*, Ann. Hum. Genet. vol. 20 no. 2,
27 97–115 (1955); Bickel, P.J. et al., *An overview of recent developments in genomics and*
28 *associated statistical methods*, Phil. Trans. R. Soc. A, vol. 367, no. 1906, 4313-4337 (2009);
Clote, P. & Backofen, R., *Computational Molecular Biology: An Introduction* (1st ed. 2000);
Qin, J., Jones, R.C. and Ramakrishnan, R. *Studying copy number variations using a nanofluidic*
platform, Nucleic Acids Research, vol. 36, no. 18 (2008).

⁵ Pak, S.I. & Kim, D., *Evaluation of Diagnostic Performance of a Polymerase Chain Reaction*
for Detection of Canine Dirofilaria immitis, J. Vet. Clin. vol. 24 no.2, 77-81 (2007);
Chattopadhyay, P. et al., *Global survey of haplotype frequencies and linkage disequilibrium at*
the RET locus, European Journal of Human Genetics 11, 760-769 (2003); White III, R.A. et al.,

Several references in particular discuss use of statistical methods to solve this type of problem in an area closely related to the Larson reference, the Kartalov reference, the Kartalov 051 reference, the Kartalov 170 reference, the '128 Patent, and the '154 Patent:

- Dube Application;
- Dube Paper.

To the extent not fully disclosed in Larson, Kartalov, Kartalov 051, and/or Kartalov 170, the asserted claims of the '128 Patent and the '154 would have been rendered obvious to one of ordinary skill in the art by the combination of Larson, Kartalov, Kartalov 051, and/or Kartalov 170 with each and any of the above references, including the Dube Application and Dube Paper.

Moreover, multiplexing with digital PCR assays was already well-documented by the time of the filing of the '128 and '154 Patents.

Thus, in the event Larson, Kartalov, Kartalov 051, and/or Kartalov 170 do not anticipate an Asserted Claim, the references, alone or in combination with one or more other references and/or with the knowledge of a person having ordinary skill in the relevant art renders such Asserted Claim obvious. At most, the claimed inventions of the '128 and '154 Patents were nothing more than the obvious combination of familiar elements, yielding entirely predictable results.

If and to the extent Bio-Rad challenges the correspondence of any of these references to particular elements of the Asserted Claims of the '128 and '154 Patents, ChromaCode reserves the right to supplement these invalidity contentions to identify additional obviousness combinations of prior art references and motivation to combine particular references with one

Digital PCR provides sensitive and absolute calibration for high throughput sequencing, BMC Genomics 10:116 (2009); Reuman, E.C. et al., *A classification model for G-to-A hypermutation in hepatitis B virus ultra-deep pyrosequencing reads*, Bioinformatics, vol. 26, no. 23 (2010), 2929–2932; Xing, Y. et al., *An expectation-maximization algorithm for probabilistic reconstructions of full-length isoforms from splice graphs*, Nucleic Acids Res., vol. 34, no. 10 (2006), 3150–3160; Hinoda Y. et al., *Association of functional polymorphisms of matrix metalloproteinase (MMP)-1 and MMP-3 genes with colorectal cancer*, Int. J. Cancer, vol.102, no. 5, 526–529 (2002); Lalam, N., *A quantitative approach for polymerase chain reactions based on a hidden Markov model*, J. Math. Biol. vol. 59, no. 4, 517–533 (2009).

1 another. ChromaCode may rely upon a subset of those references, depending upon the Court's
2 claim construction and further investigation.

3 ChromaCode also reserves the right to update its invalidity contentions after receiving
4 proper infringement contentions from Bio-Rad and to reflect the results of discovery in this
5 matter.

6 **III. PATENT LOCAL RULE 3-3(c) DISCLOSURES**

7 Based upon presently known information, pursuant to Patent Local Rule 3-3(c),
8 ChromaCode attaches claim charts for the '128 and '154 Patents as Appendices 1-12.⁶ The
9 claim charts identify the prior art that anticipates and/or in combination with other identified
10 prior art and/or the knowledge of a person having ordinary skill in the relevant art renders
11 obvious the Asserted Claims, and where, in each item of prior art, each element of each Asserted
12 Claim is found. These charts are provided for illustrative purposes only and may not set forth
13 every place in every reference where a claim element is disclosed. In instances where
14 ChromaCode cites to a particular figure in a prior art reference, the citation should be understood
15 to encompass the caption and description of the figure, and any text relating to the figure in
16 addition to the figure itself. Conversely, where a cited portion of text refers to a figure, the
17 citation should be understood to include the figure as well.

18 ChromaCode reserves the right to update its invalidity contentions after receiving proper
19 infringement contentions from Bio-Rad and to reflect the results of discovery in this matter.

20 **IV. PATENT LOCAL RULE 3-3(d) DISCLOSURES**

21 Based upon presently known information, pursuant to Patent Local Rule 3-3(d), below
22 are the grounds on which the Asserted Claims of the '128 and '154 Patents are invalid for failure
23 to meet the requirements of 35 U.S.C. §§ 101 and 112.

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27 ⁶ To be clear, ChromaCode believes that the '128 and '154 Patents and the Kartalov publication and patents cover
28 distinct inventions, and disagrees with Bio-Rad's infringement contentions. ChromaCode has prepared charts for
the Kartalov publication and patents on the assumption that the claim terms in the '128 and '154 Patents are
construed as broadly as Bio-Rad's infringement contentions suggest.

1 **A. 35 U.S.C. § 101**

2 At least the Asserted Claims (claims 1-5 and 8-12 of the '128 Patent and claims 1-4, 6-
3 17, and 19-28 of the '154 Patent) are invalid for failure to meet the requirements set forth in 35
4 U.S.C. § 101. Under 35 U.S.C. § 101, a patent may generally be granted for “any new and
5 useful process, machine, manufacture, or composition of matter” or any improvement thereof.
6 Because the '128 and '154 Patents are directed to an abstract idea, one or more of the Asserted
7 Claims are invalid for failing to claim patent-eligible subject matter, which, as the Supreme
8 Court confirmed in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, does not extend to abstract ideas.
9 573 U.S. 208, 216 (2014) (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569
10 U.S. 576, 589 (2013)).

11 Each of the Asserted Claims appears to be directed to an abstract idea, for example the
12 abstract idea of using statistics to estimate characteristics of interest in a population using
13 samples from that population, when the individual observations of the samples do not necessarily
14 uniquely identify each characteristic, as applied to digital PCR assays. The character of the
15 claims as a whole, in light of the claims, specification, and claimed advancement of the prior art,
16 is to use statistics to estimate population characteristics from observations of samples that only
17 indirectly and degenerately measure the characteristic, in the context of digital PCR.

18 The elements of the Asserted Claims do not provide an inventive concept. The use of
19 statistics to estimate population characteristics from samples, when the observations of the
20 characteristics are confounded in the samples, was well-known. The Asserted Claims simply
21 claim using these well-known processes of statistical estimation in the context of digital PCR.
22 The function performed at each step was well-known, routine, and conventional in the prior art,
23 as explained more fully elsewhere in these disclosures. The elements fail to add significantly
24 more to the abstract idea. *See Alice*, 573 U.S. at 217-18.

25 **B. 35 U.S.C. § 112**

26 The Asserted Claims of the '128 and '154 Patents are invalid under 35 U.S.C. § 112
27 because they are indefinite. The Asserted Claims lack a written description and enabling
28

1 disclosure commensurate with the alleged scope of the claims and are unduly vague and
2 indefinite.

3 Each of the '128 and '154 Patents, read in light of its respective specification and
4 prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the
5 scope of its respective inventions. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898,
6 901 (2014). The '128 and '154 Patents do not enable one of skill in the art to practice the full
7 scope of the inventions claimed without undue experimentation. Nor do the '128 and '154
8 Patents enable one of skill in the art to practice the scope of the inventions set forth in Bio-Rad's
9 infringement contentions.

10 In particular, at least the following claim terms of the '128 and '154 Patents are indefinite
11 because a person skilled in the art could not determine the bounds of the claim limitations:

12 1. '128 Patent, claim 1:

13 (a) “accounts for a coincidence of all possible combinations”;

14 (b) “wherein the more than R targets include three targets”;

15 2. '128 Patent, claim 9:

16 (a) “determining a total number of amplification-positive partitions for each
17 type”;

18 3. '128 Patent, claim 12:

19 (b) “account for a coincidence of all possible combinations”;

20 4. '128 Patent, claims 1, 9, 10, 12:

21 (c) “partitions” / “in [] partitions” / “from the partitions” / “among the
22 partitions”;

23 5. '154 Patent, claims 1, 11, 19:

24 (d) “specific for a single target”;

25 6. '154 Patent, claims 1, 11, 19:

26 (a) “based in part on a partition count for a partition population positive for
27 two of the R targets”;

28 7. '154 Patent, claims 10, 11, 26:

1 (b) “resolving”;

2 8. ’154 Patent, claims 1, 6, 7, 8, 9, 10, 11, 15, 16, 17, 19, 23, 24, 25, 26, 27, 28:

3 (a) “partition[s]” / “in the partitions” / “partition count” / “partition
4 population[s]”; “from each partition population”

5 The specification of the ’128 Patent does not enable a person of ordinary skill in the art to
6 “calculat[e] an average level of each target in the partitions based on the R signals, wherein the
7 level calculated accounts for a coincidence of all possible combinations of the more than R
8 targets in the same individual partitions” (claim 1) (emphasis added), and further “wherein the
9 average levels of the three targets are calculated based on light detected from only two
10 fluorophores associated with probes that bind to amplicons of the three targets during
11 amplification” (claim 1) (emphasis added); or “determin[e] a total number of amplification-
12 positive partitions for each type of the more than R targets” (claim 9) (emphasis added); or
13 “calculat[e] levels of at least three of the targets based on light detected from only two
14 fluorophores, wherein the levels calculated account for a coincidence of all possible
15 combinations of the at least three targets in the same individual partitions” (claim 12) (emphasis
16 added). The specification of the ’128 Patent does not enable the full scope of “calculating” a
17 “level” as Bio-Rad apparently construes that term; one of ordinary skill would not know from the
18 specification how to apply the method beyond determining concentrations—e.g., to determine
19 the total number of partitions positive for a target. The specification of the ’128 Patent certainly
20 does not disclose a method of calculating the level of each target that is in general capable of
21 accurately accounting for a coincidence of all possible combinations, or accurately determining a
22 total number of partitions of each type, and in particular that is capable of accurately and
23 unambiguously distinguishing between all targets or combinations of targets (as opposed to
24 statistically inferring possible or likely scenarios), and one of ordinary skill would not have
25 known how to do this.

26 The specification of the ’154 Patent does not enable a person of ordinary skill in the art to
27 “determin[e] a respective level of each of the R targets from the data, wherein each level is
28 specific for a single target of the R targets, and wherein the level determined for at least one of

1 the R targets is based in part on a partition count for a partition population positive for two of the
2 R targets” (claim 1, 11, 19) (emphasis added); or “resolv[e] each partition population that is
3 positive for exactly two of the R targets from each partition population that is positive for only
4 one of the R targets” (claims 10, 11, 26) (emphasis added). The specification of the ’154 Patent
5 does not enable the full scope of “determining” a “level” as Bio-Rad apparently construes that
6 term; one of ordinary skill would not know from the specification how to apply the method
7 beyond determining concentrations. The specification of the ’154 Patent certainly does not
8 disclose a method of “determining a respective level of each of the R targets from the data” that
9 is in general capable of accurately determining a specific level for each target, or accurately
10 counting the partition population positive for two targets, or accurately resolving partitions
11 positive for exactly two targets from partitions positive for only one target, and in particular that
12 is capable of accurately and unambiguously distinguishing between all targets or combinations of
13 targets (as opposed to statistically inferring possible or likely scenarios), and one of ordinary
14 skill would not have known how to do this.

15 To the extent Bio-Rad contends that the Asserted Claims of the ’128 and ’154 Patents
16 apply to non-digital PCR methods (e.g., quantitative PCR), the specifications of the ’128 and
17 ’154 Patents do not enable a person of ordinary skill in the art to apply those methods outside of
18 digital PCR. Similarly, the specifications of the ’128 and ’154 Patents do not contain a written
19 description that would cover non-digital PCR methods; only digital PCR methods are described.

20 ChromaCode reserves the right to supplement and/or further amend these invalidity
21 contentions based on 35 U.S.C. § 112 when Bio-Rad clarifies its infringement position, as
22 discovery progresses, and in view of claim construction positions taken by Bio-Rad and the
23 Court’s claim construction.

24 Because expert disclosures are not yet due, including those in connection with claim
25 construction, ChromaCode reserves the right to raise any additional issues from the perspective
26 of one skilled in the art at the appropriate time in the case.

27 ChromaCode reserves the right to update its invalidity contentions after receiving proper
28 infringement contentions from Bio-Rad and to reflect the results of discovery in this matter.

1 **V. PATENT LOCAL RULE 3-4 DOCUMENT PRODUCTION**

2 Based on the foregoing and on presently known information, and as will be further
3 specified as discovery proceeds, ChromaCode provides the following documents as indicated
4 below:

- 5 • **Patent Local Rule 3-4(a)** (“Source code, specifications, schematics, flow charts,
6 artwork, formulas, or other documentation sufficient to show the operation of any
7 aspects or elements of an Accused Instrumentality identified by the patent
8 claimant in its Patent L.R. 3-1(c) chart”): CHROMA_00000001-
9 CHROMA_00000066; CHROMA_00000291 - CHROMA_00000426.
- 10 • **Patent Local Rule 3-4(b)** (“A copy or sample of the prior art identified pursuant
11 to Patent L.R. 3-3(a) which does not appear in the file history of the patent(s) at
12 issue. To the extent any such item is not in English, an English translation of the
13 portion(s) relied upon shall be produced”): CHROMA_00000163-
14 CHROMA_00000290; CHROMA_00000427- CHROMA_00000565.
- 15 • **Patent Local Rule 3-4(c)** (“All agreements that may be related to the accused
16 instrumentality or may be comparable to a license that would result from a
17 hypothetical reasonable royalty negotiation”): CHROMA_00000067-
18 CHROMA_00000158; CHROMA_00000575 - CHROMA_00000598.⁷ In
19 producing documents responsive to this category, ChromaCode does not admit or
20 take the position that any agreement is comparable to a license that would result
21 from a hypothetical reasonable royalty negotiation but reserves the right to use
22 said agreements in connection with a reasonable royalty analysis.
- 23 • **Patent Local Rule 3-4(d)** (“Documents sufficient to show the sales, revenue,
24 cost, and profits for accused instrumentalities identified pursuant to Patent L.R. 3-
25 1(b) for any period of alleged infringement”): CHROMA_00000159-
26 CHROMA_00000162; CHROMA_00000566 - CHROMA_00000574.

27
28 ⁷ ChromaCode has withheld production of one document for which it is in the process of resolving third-party notice and confidentiality obligations, and intends to produce that document pursuant to Patent Local Rule 3-4(c) once those issues are resolved.

*Attorneys for Plaintiff and Counter-Defendant
ChromaCode, Inc.*

CERTIFICATE OF SERVICE

I, Kazuko Shintani, certify that I served the foregoing document on counsel of record for
Bio-Rad, via email on February 29, 2024.

/s/ Kazuko Shintani
Kazuko Shintani