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18 CHROMACODE, INC. and CALIFORNIA
19 INSTITUTE OF TECHNOLOGY

20 UNITED STATES DISTRICT COURT
21 NORTHERN DISTRICT OF CALIFORNIA

22 IN RE: CHROMACODE LITIGATION

23 Case No. 5:23-cv-04823-EKL
24 (Consolidated)

25 **DECLARATION OF BERNHARD H.
26 WEIGL IN SUPPORT OF
27 CHROMACODE, INC. AND
28 CALIFORNIA INSTITUTE OF
TECHNOLOGY'S CLAIM
CONSTRUCTION BRIEF**

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1 I, Bernhard H. Weigl, declare as follows:

2 **I. INTRODUCTION**

3 1. My name is Bernhard H. Weigl, PhD MSc. I am over eighteen years of age and am
4 otherwise competent to make this declaration. I make this declaration in support of Plaintiffs and
5 Counter-Defendants Chromacode, Inc. and California Institute of Technology's Claim Construction
6 Brief. Unless otherwise indicated, the opinions set forth in this declaration are based on my personal
7 knowledge. Statements made based on information and belief are believed to be true. My opinions
8 expressed herein are based on my education, my personal experience, and on the review of the
9 documents and information described in this declaration. In preparing this declaration, I have
10 considered the documents cited herein and the documents listed in the Materials Considered section
11 of this declaration.

12 2. I am serving as an expert witness regarding claim construction in this matter. I
13 understand that I am a witness who may be used at trial to present evidence. Based on my skills,
14 experience, and education, I expect to offer opinions relating to claim construction and the
15 understanding of certain claim terms from a person of ordinary skill in the art ("POSITA") in view
16 of claim language and intrinsic and extrinsic evidence. These opinions are provided in this
17 declaration.

18 3. In this declaration, I present my opinions as to how a POSITA (see §VI) would have
19 understood certain terms or phrases in the claims of the asserted U.S. Patent No. 12,168,797 ("the
20 '797 Patent"), at the time of its invention. I understand that the '797 Patent claims priority to 2012
21 and provide my opinions from the perspective of a POSITA as of that timeframe. My opinions
22 would not change, however, if the '797 Patent's claims are given a later priority date. I provide
23 technical bases for my opinions as appropriate.

24 4. I am not an attorney. In forming my opinions in this Declaration, I applied the
25 relevant legal principles provided to me by counsel, including as discussed in §VIII.

26 5. This declaration contains statements of my opinions formed to date and the bases and
27 reasons for those opinions. I may offer additional opinions based on further review of materials in
28 this matter, further positions advanced by Bio-Rad Laboratories, Inc. ("Bio-Rad") or any declarant

1 offered by Bio-Rad, and/or as discovery and the case progress. If called upon to testify, I would
2 testify competently to the matters contained herein. As set forth in §IX, I reserve the right to change
3 or add to these opinions.

4 II. ENGAGEMENT

5 6. I have been retained by counsel for the Patent Owner, California Institute of
6 Technology, as an expert witness in the above-captioned proceeding. I have been asked to provide
7 opinions regarding claim construction for certain terms of the '797 Patent as well as related
8 opinions regarding the technology at issue. This declaration includes my opinions, and I may add
9 opinions in the future.

10 7. I am being compensated at the rate of \$375 per hour for my work on this
11 engagement. I am also being reimbursed for reasonable and customary expenses associated with
12 this matter. My compensation is not contingent upon the outcome of this matter or the specifics of
13 my opinions and testimony.

14 III. QUALIFICATIONS

15 8. I am an expert in the field of bioengineering, and particularly in diagnostic assays
16 and technology. This section contains a summary of my educational background, career history,
17 publications, and other relevant qualifications. My full curriculum vitae is attached to this
18 declaration as Appendix A.

19 9. I have over 25 years of experience in the design of diagnostic assays and technology,
20 particularly those involving microfluidic applications. As such, I am familiar with the historical
21 development of the field broadly since the late 1990s. I am also familiar with the historical
22 development of specific technologies within the field during this timeframe, including PCR
23 amplification and systems employing droplet digital PCR amplification and flow cytometry, a
24 technology employed for counting and determining the intensity of droplets.

25 10. I have several patents and papers in this space that are relevant to the technology
26 described herein. I am a named inventor on over 100 U.S. patents and published patent applications
27 relating to diagnostic technology. I am also an author or co-author on over 100 publications,
28 including book chapters and journal publications relating to diagnostic technology. Many of the

1 patents and publications on which I am a named inventor or author relate to microfluidic applications
 2 in diagnostic technology. My work has been published in numerous journals, including *Nature*,
 3 *Science*, *Nature Biotechnology*, *Biomedical Microdevices*, *Sensors and Actuators B*, *Lab on a Chip*,
 4 *Analytical Chemistry*, *Microchimica Acta*, and *Microfluidics*, *BioMEMS*, and *Medical*
 5 *Microsystems*. A full list of these patents and publications is included with my CV. I am a member
 6 of SPIE, ASTMH, AACC, and AAAS, and have served on the editorial board of proceedings and
 7 journals published by SPIE and IEEE. I have also provided manuscript reviews for publications.

8 11. I am currently an Affiliate Professor at the University of Washington's Department
 9 of Bioengineering, in Seattle, Washington, a position I have held since May 2004. During this same
 10 timeframe, from June 2020 to August 2025 I worked as Senior Director of Diagnostics Research
 11 and Development at Global Health Labs, where I oversaw the development of diagnostic
 12 technology, including ultra-sensitive strip-based immunoassays and molecular assays and droplet-
 13 based digital assays. Between April 2015 to June 2020, I served as Principal Investigator for Flow-
 14 Based Diagnostics and then Director of In-Vitro Diagnostics at Intellectual Ventures. Before that,
 15 from 2004 to April 2015, I led the Diagnostics Group and served as a Portfolio Leader for Non-
 16 Communicable Disease Diagnostics, as well as Group Leader for Diagnostics, and Director of the
 17 Center for Point of Care Diagnostics for Global Health at nonprofit PATH (Program for Appropriate
 18 Technology in Health). Between 1995 and 1999, I was a Post-Doctoral Fellow in Professor Paul
 19 Yager's group in the Department of Bioengineering at the University of Washington, and in 1997 a
 20 co-founder and until 2003 Director of Microfluidic Applications for the microfluidics-based point-
 21 of-care diagnostics company Micronics, Inc. of Redmond, Washington (now part of Sony America).
 22 At Micronics, I led the development of the first FDA-approved instrument-free microfluidic test as
 23 well as microfluidic flow cytometry-based hematology assays. I also worked at the microfluidic
 24 engineering firm MicroPlumbers MicroSciences of St. Paul, Minnesota during this time.

25 12. I earned my doctoral and master's degrees in Analytical Chemistry from Karl-
 26 Franzen-Universität Graz, in Graz, Austria. I started my chemistry studies at Leopold-Franzens-
 27 Universität Innsbruck, in Innsbruck Austria, then transferred to Karl-Franzen-Universität where I
 28 earned my Mag. rer. nat. (the equivalent of master of science) and Dr. rer. nat. (the equivalent of a

1 PhD) degrees, both in Analytical Chemistry. Thereafter, I completed my post-doctoral studies at the
2 University of Southampton, UK and the University of Washington in Seattle. I also received a
3 Certificate in Technology Management from the University of Washington in 1998.

4 13. A more detailed listing of my credentials and publications is provided in my CV.

5 14. Based on my experience, I am an expert in the field of diagnostic assays and
6 technology, including in the subject matter described by the asserted patent discussed herein. I have
7 used my years of experience working in the field of diagnostic assays and technology and my
8 understanding of the knowledge, creativity, and experience of a person of ordinary skill in the art in
9 forming the opinions expressed in this declaration. Additionally, for at least the above reasons, and
10 those described in §VI, I consider myself to possess the qualifications to serve as an expert in the
11 field of diagnostic assays and technology, including in the subject matter described by the asserted
12 patent discussed herein, and possessed such qualifications at the time of the '797 Patent's invention.

13 IV. GENERAL TECHNOLOGY OVERVIEW

14 15. The term “digital PCR”, or digital assay more broadly, was first used in the late
15 1990s. In a conventional assay (also called “bulk assay”, to differentiate from “digital assay”), the
16 concentration of an analyte is usually determined by determining a “bulk” parameter (such as
17 fluorescence intensity) that is correlated with the total number of analyte particles in the sample in
18 an analog fashion – i.e., the more molecules, the higher the signal. *See, e.g.*, Bert Vogelstein &
19 Kenneth W. Kinzler, “Digital PCR,” Proceedings of the National Academy of Sciences of the
20 United States of America, Vol. 96, No. 16 (Aug. 3, 1999) at pp. 9236-41. DOI:
21 10.1074/pnas.96.16.9236.

22 16. In a digital assay, the sample volume is diluted and then partitioned into many
23 smaller volumes such that most of the individual volumes contain only zero or one analyte
24 particle. Then, a signal (again, e.g., fluorescence) is determined in each individual partitioned
25 volume that is correlated to the presence or absence (not originally the concentration) of an
26 analyte. Then, the “positive” partitioned volumes are counted, and the ratio of positive to negative
27 volumes is a measure of the overall concentration of an analyte. Thus, the analyte concentration
28 can be determined digitally (by “counting” of positives vs negatives), as opposed to analog (by

1 “measuring a bulk signal” and comparing it to a calibration graph). The primary advantage of this
2 method is that no calibration is needed, and in general the signal to noise ratio of a presence vs
3 absence measurement is higher than that of an analog signal measurement.

4 17. The method has been applied to PCR. The partitioning can be implemented by the
5 generation of droplets (separated by an immiscible liquid) from a sample volume. The latter
6 method is called digital droplet PCR, invented in the late 2000s. A secondary benefit of this
7 method was found to be the fact that by diluting the sample, inhibitors of PCR reactions are also
8 diluted and not present in some of the droplets, thus simplifying sample preparation.

9 18. Around 2010 scientists developed novel multiplexed digital droplet PCR methods
10 that used various encoding methods. Multiplexing in this context means detecting more than one
11 analytical target (in this case a specific target polynucleotide sequence) present in the sample at
12 the same time. This can refer to multiple target sequences on the same gene (e.g., to determine if
13 there are any variations present in a particular gene, e.g., to see if a cancer marker is present, or if
14 a Covid virus has evolved), or targets on different genes (e.g., to determine the presence of several
15 respiratory viruses such as Flu, Covid, and RSV in a nasal swab at the same time).

16 19. In general, as long as the primers and probes for each of the target sequences that
17 one wants to detect in a single sample are sufficiently different from each other, it is possible to
18 put ten or more different such primers and probes into a single reaction mix, and they will all run
19 largely independently from each other (again, assuming there is an excess of all reaction
20 components compared to the analytical targets).

21 20. However, in order to tell which of the target sequences are actually present and are
22 being amplified, one needs to be able to tell apart the fluorophores that are released by each of the
23 TAQMAN probes that are specific to each target sequence. This had previously been done, to a
24 degree, by using different fluorophores with different emission wavelengths (or “colors”), and
25 detect them each with separate detectors (or “channels”) that are built into the PCR machine.

26 21. In practice, it had previously been known to select up to 6 different colors for the
27 probes, which means that this method would only allow the detection of up to 6 different targets
28 (and in real life, since often more than one sequence is needed to positively identify a target

1 sequence, and usually a “control”, or reference, sequence also needs to be detected, this means that
 2 usually only 3 or 4 useful targets can be detected in a sample using fluorescence based
 3 multiplexing).

4 22. As recognized by the ’797 Patent and its priority applications, there is often a need
 5 to detect more target analytes than the number of color channels used for the detection.

6 **V. THE ’797 PATENT**

7 **A. The Claimed Invention**

8 23. Whereas the claims of the other Caltech Asserted Patents are directed to methods,
 9 assays, and kits, the ’797 Patent’s asserted claims are directed to a system. ’797 Patent, claim 1.
 10 The claimed system includes a sample chamber configured to house a sample and mixtures of
 11 analyte-specific hybridization probes and fluorophores for detecting analytes. *Id.*, claim 1, 9:22–
 12 34. Each of the probes is labeled with a specific fluorophore or combination of fluorophores. *Id.*,
 13 claim 1, 11:25–31, 31:39–48. The system can excite the different fluorophores and measure
 14 electromagnetic signals (i.e., light) emitted at a particular wavelength (i.e., color) and intensity from
 15 each of the excited fluorophore(s). *Id.*, claim 1, 9:22–49, 32:18–40, 35:48–58.

16 24. The system includes a multi-channel detector to detect electromagnetic signals at
 17 corresponding emission wavelengths, each corresponding to a type of fluorophore. ’797 Patent,
 18 claim 1. That is, the claimed detector uses at least four distinct color channels, one for each
 19 fluorophore, each associated with its own wavelength of emitted light. *Id.* (“[T]he multi-channel
 20 detector comprises C channels” and “C=4, 5, or 6.”). The constituent electromagnetic signals (i.e.,
 21 one for each color channel on the detector) are combined into a cumulative signal including a first
 22 component comprising intensity values, and a second component comprising wavelength values.
 23 *Id.*, claim 1, 27:32–49. The intensity values for a given color are both additive and digital. *Id.*,
 24 15:55–58. Furthermore, there is a maximum cumulative intensity value when all analytes associated
 25 with a given color channel are present, i.e., the claimed “maximum cumulative intensity” (F). *Id.*,
 26 claim 1 (“F is a positive integer and is equal to the maximum cumulative intensity ... when all of
 27 the analytes are present[.]”); *see also id.*, 19:46–52, 23:21–24. The F value is limited by the number
 28 of “multiplicity states,” which is the number of distinct intensity values or ranges of intensity values

1 that the detector's precision permits reliable measurement in, for a given color channel. *Id.*, 22:63–
2 23:2, 27:24–26.

3 25. Ranges of intensity values may be organized by bands into normalized, integer
4 intensity values. *See, e.g.*, '797 Patent, 22:62–23:8, 49:5–25. For example, in an example assay
5 performed using the system of the '797 Patent, F, which is the maximum cumulative intensity for
6 any second value (for example maximum fluorescence intensity in any channel) represents a
7 normalized and quantized integer value typically representing a band of signals measured by the
8 analytical system (for example as arbitrary fluorescence units). For each droplet, the multi-channel
9 detector will report arbitrary intensity values in respective channels that correspond to bands of
10 values around respective integer values in the decoding matrix, e.g., around 1, 2, 4, 8, 16, etc. This
11 scales, or normalizes, the arbitrary fluorescence units that are measured to a constituent signal (e.g.,
12 by dividing the arbitrary fluorescence units by a common multiple), and then quantizes the scaled
13 numbers to the closest integer by assigning each scaled droplet intensity to that integer intensity
14 value. This allows any combination of presence or absence of each analyte, in each droplet, to be
15 uniquely and unambiguously determined. *See, e.g.*, '797 Patent, 22:62–23:8, 49:5–25.

16 26. The system further includes a processor controlled analyzer to receive the cumulative
17 signal from the multi-channel detector and then apply a decoding matrix to the cumulative signal to
18 unambiguously detect the presence or absence of each analyte in the sample volume. '797 Patent,
19 claim 1. For each possible combination of analytes present in the sample volume, the decoding
20 matrix enumerates the cumulative intensity value for possible assay results (different possible
21 combinations of analyte(s) which together generate a cumulative signal based on the probes that
22 respectively hybridized to those analytes). *See, e.g., id.*, tables 3–4, 8, 14:11–24 (discussing
23 “enumerating each of the possible cumulative assay results”). The decoding matrix derives from
24 the encoding method employed during the probe labeling process, and the encoding method
25 determines how the electromagnetic signals (i.e. the light) emitted by different possible
26 combinations of fluorescence from probes that hybridized to their respective analyte combine into
27 the cumulative signal measured at the detector. *Id.*, tables 3–4, 8, 14:11–24, 15:55–63. When the
28 analyzer “applies” the decoding matrix, it references the combined cumulative intensity values

1 measured for each color channel to a specific, corresponding combination of analytes, and based on
2 this reference determines that such combination is present in the sample. *E.g.*, '797 Patent, tables 3
3 and 4, 15:64–16:9 (“Table 4 allows the conversion of a cumulative measurement of intensity in four
4 ranges of fluorescent wavelengths ... into the corresponding analytes present in the sample.”), claim
5 1; *see also id.*, table 8.

6 27. The variables M, C, and F describe certain system parameters and are described by
7 specific mathematic relations. C is defined to be the number of second values (wavelengths/colors)
8 measured on the multi-channel detector, and the value of C, as recited in the '797 Patent claims,
9 must be 4, 5, or 6. '797 Patent, claim 1. F is defined to be the maximum cumulative intensity
10 measured for any second value (color channel on the multi-channel detector), when all analytes are
11 present, and its value, as recited in the '797 Patent claims, must be a positive integer, and F+1 must
12 be a power of 2. *Id.* Finally, M is defined to be the number of analytes unambiguously detected,
13 and its value, as recited in the '797 Patent claims, must satisfy the equation $M=C*\log_2(F+1)$. *Id.*

14 **B. Illustrative Example of the Claimed System**

15 28. By way of example, the specification discloses a system practicing the claimed
16 invention, that, in the disclosed example, uses an “encoding method using one color and one
17 intensity per analyte, but different intensities among analytes.” '797 Patent, 21:47–22:3 (table 8). In
18 this example, the sample chamber is configured to house a sample and analyte-specific reagent
19 mixtures of analyte-specific probes labeled with fluorophores at intensities in accordance with table
20 8, which is reproduced below. '797 Patent, table 8, 14:11–23, 21:47–23:38.

TABLE 8

Example of encoding method using one color and one intensity per analyte, but different intensities among analytes.

Tier	Analyte	B	G	Y	R
1	A	1	0	0	0
	B	2	0	0	0
	C	4	0	0	0
	D	8	0	0	0
2	E	0	1	0	0
	F	0	2	0	0
	G	0	4	0	0
	H	0	8	0	0
3	I	0	0	1	0
	J	0	0	2	0
	K	0	0	4	0
	L	0	0	8	0
4	M	0	0	0	1
	N	0	0	0	2
	O	0	0	0	4
	P	0	0	0	8
		15	15	15	15

'797 Patent, table 8.

29. A POSITA would understand from this disclosure that the multi-channel detector of this illustrative system detects electromagnetic signals on four color channels: blue, green, yellow, and red, i.e., C=4. '797 Patent, table 8, 21:65–67. In the illustrative example of table 8, the precision of the multi-channel detector also supports sufficient state multiplicity to reliably measure up to 15 intensity values, or ranges of intensity values, on each color channel. *Id.*, table 8, 21:65–22:2. In the illustrative example of table 8, analyte-specific probes are labeled with fluorophores at intensity values corresponding to powers of 2, up to an intensity of 8 on a given color channel. *Id.*, table 8, 21:65–67. For the example shown in Table 8, the processor controlled analyzer unambiguously detects the presence or absence of up to 16 analytes by applying a decoding matrix to the cumulative signal. *Id.*, table 8 (showing 16 analytes, A–P, labeled with specific colors and intensities). A POSITA would understand that a decoding matrix associated with this illustrative system may be built by enumerating each possible cumulative intensity value and referencing that value to a possible combination of analytes present in the sample volume. '797 Patent, tables 3–4, 14:11–24.

There are 2^{16} , or 65,536, possible combinations of 16 analytes—far too many to exhaustively list herein the full decoding matrix associated with table 8. Instead, purely for simplicity, a reduced version based only on the analytes that are labeled with blue fluorophore intensities, is provided below:

Example Decoding Matrix for Analytes of Table 8 in Blue Channel		
Possible Cumulative Intensity Value on Blue Channel	Present Analytes (Blue Fluorophore Intensity Label)	Sum of Blue Fluorophore Intensity Labels of Present Analytes
0	None(0)	0
1	A(1)	1
2	B(2)	2
3	A(1), B(2)	1+2 = 3
4	C(4)	4
5	A(1), C(4)	1+4 = 5
6	B(2), C(4)	2+4 = 6
7	A(1), B(2), C(4)	1+2+4 = 7
8	D(8)	8
9	A(1), D(8)	1+8 = 9
10	B(2), D(8)	2+8 = 10
11	A(1), B(2), D(8)	1+2+8 = 11
12	C(4), D(8)	4+8 = 12
13	A(1), C(4), D(8)	1+4+8 = 13
14	B(2), C(4), D(8)	2+4+8 = 14
15	A(1), B(2), C(4), D(8)	1+2+4+8 = 15

30. Because encoding schemes such as described in relation to table 8 are non-degenerate by construction, only one combination of analytes has fluorophore intensity labels that sum to each

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possible cumulative intensity measurement. '797 Patent at 21:56–22:2. For instance, if analyte B (labeled with blue fluorophore intensity of 2) and analyte D (labeled with blue fluorophore intensity of 8) were both present, the emitted blue wavelength electromagnetic signals would additively combine, resulting in a cumulative measured fluorophore intensity in the blue channel of 2+8, or 10. In other words, when the analyzer of the illustrative system receives a cumulative intensity measurement corresponding to a value of 10 on the blue channel, the analyzer “applies the decoding matrix” by referencing the combination of analytes enumerated for a cumulative intensity measurement of 10 on the blue channel (analytes B and C), resulting in a determination that analytes B and C are present in the sample and that the other 14 analytes (A, D–P) are not present. '797 Patent, tables 3–4, table 8, 15:64–16:2. Thus, applying the example decoding matrix above *unambiguously* identifies the presence or absence of any combination of the four analytes (A–D) that are labeled with blue fluorophore intensities. '797 Patent, tables 3–4, table 8, 15:64–16:2. A fuller decoding matrix enumerating all 65,536 possible combinations of the 16 analytes (A–P), when applied by the analyzer to the cumulative signal including all four color channels, would similarly unambiguously identify the 16 analytes (A–P) in any combination of presence or absence.

31. Regarding the claimed mathematical relationship of the system's parameters C, F, and M explained above, C and M for this illustrative system are 4 and 16, respectively. F, which is the maximum cumulative intensity measured for any second value (color channel on the multi-channel detector) when all analytes are present, can be determined by: (1) adding the fluorophore intensity labels of each analyte detected using a given color channel, (2) repeating this calculation for every color channel, and (3) setting F to the highest calculated sum for any color channel. '797 Patent, claim 1 (“F ... is equal to the maximum cumulative intensity of the [intensity value] of the [cumulative] signal, for any [wavelength/color], when all of the analytes are present[.]”). The result of this determination for the blue channel is provided in the bottom row of the reduced decoding matrix above—when all blue fluorophore labeled analytes (A labeled 1, B labeled 2, C labeled 4, and D labeled 8) are present, the sum of their blue fluorophore intensity labels is 1+2+4+8, or 15. '797 Patent, 21:67–22:2. Because the other analytes (E–P) are labeled with intensity values corresponding to powers of 2, but with different color fluorophores, the same calculation for the

1 green, yellow, and red channels will also result in a cumulative intensity measurement of 15 for
2 those channels when all of the associated analytes are present. '797 Patent, 21:67–22:2. F for the
3 illustrative system is thus 15. As a final check, the values of the C, F, and M parameters of the
4 illustrative system are consistent with the claimed mathematical relationship: $C=4$ (C can be 4, 5, or
5 6); $F=15$ (15 is a positive integer, $15+1 = 16$ is a power of 2); $M = 16$ ($M = C \cdot \log_2(F+1)$, and
6 $C \cdot \log_2(F+1) = 4 \cdot \log_2(15+1) = 4 \cdot \log_2(16) = 4 \cdot 4 = 16$). In other words, the system described herein
7 is illustrative of the claimed invention's system and consistent with the way a POSITA would
8 understand it from reading the specification.

9 VI. PERSON OF ORDINARY SKILL IN THE ART ("POSITA")

10 32. In determining the characteristics of a hypothetical POSITA in the field of the
11 asserted patents at the time of the alleged inventions, I considered several things, including various
12 prior art techniques relating to diagnostic assays and related technologies, the types of problems that
13 such techniques gave rise to, and the rapidity with which innovations were made. I also considered
14 the sophistication of the technologies involved, and the educational background and experience of
15 those actively working in the field at the time. I also considered the level of education that would
16 have been necessary to understand the asserted patents. Finally, I placed myself back in the relevant
17 period of time and considered the scientists and engineers that I have worked with and supervised
18 in the field of diagnostic assays and related technologies.

19 33. In my opinion, a POSITA would have possessed at least the following: a Ph.D. in
20 molecular biology, genetics, biochemistry, chemistry, or a related discipline, with at least a year of
21 experience in quantitative and/or dPCR and fluorescence-based analyte detection. A person with
22 less education but more relevant practical experience, or more education and less experience, may
23 also meet this standard.

24 34. In the 2012–2013 timeframe, and in view of the types of problems encountered in
25 the art and prior art solutions to those problems, a POSITA for the technology claimed in the '797
26 Patent would have known how and had the skills necessary to design a diagnostic assay, and to
27 operate systems necessary for performing such diagnostic assays. This would include, but is not
28 limited to, the knowledge and skills relating to PCR amplification procedures, droplet digital PCR

1 testing, flow based droplet detection such as performed in ddPCR analyzers, and various other
2 techniques and prior art systems known at the time.

3 35. I believe that I am at least a POSITA and, furthermore, I have supervised those who
4 POSITAs in my work in the field. Moreover, I qualified as at least POSITA as of at least 2012.
5 Accordingly, I believe that I am qualified to opine from the perspective of a POSITA regarding the
6 meaning of terms in the claims of the '797 Patent.

7 VII. CLAIM TERMS FOR CONSTRUCTION

8 A. "F" (claims 1, 5)

9 Claim Term(s)	Plaintiffs' Proposed Construction	Bio-Rad's Proposed Construction
10 "F"	11 No construction of "F" is required for the asserted claims because the claims expressly recite that "F is a positive integer and is equal to the maximum cumulative intensity of the first component of the signal, for any second value, when all of the analytes are present, ... wherein F+1 is a positive integer and F+1 is a power of 2." 12 To the extent a construction is required, this term should be construed to mean "F, a value that scales with a constituent signal."	13 Indefinite.

14 36. No construction for the term "F" is needed because the claim language already
15 defines F using clear language, reciting that "F is a positive integer and is equal to the maximum
16 cumulative intensity of the first component of the signal, for any second value, when all of the
17 analytes are present, ... wherein F+1 is a positive integer and F+1 is a power of 2." Thus, under the
18 plain and ordinary meaning in view of the patent specification, a POSITA would have understood
19 that F is the value resulting from: (1) adding the fluorophore intensity labels of each analyte detected
20 using a given color channel ("F ... is equal to ... the ... *cumulative* intensity of the first component
21

of the signal, when all of the analytes are present...”), (2) repeating this calculation for every color channel (“... for any second value (i.e., wavelength)...”), and (3) setting F to the highest calculated sum for any color channel (“F ... is equal to the *maximum* cumulative intensity...”). ’797 Patent, claim 1 (emphasis added).

37. For example, as shown in table 8, when analytes A–D are present in a droplet, the blue fluorophore intensity labels for analytes A–D sum to 15: A is labeled 1, B is labeled 2, C is labeled 4, D is labeled 8, and 1+2+4+8 is 15. ’797 Patent, table 8, 21:65–22:2. 15 is thus the cumulative intensity value associated with the presence of all analytes labeled with blue fluorophore intensity values (i.e. A–D). *Id.* The cumulative intensity value for all other color channels can be shown to be the same for analytes labeled with green, yellow, or red fluorophore intensity values (E–H present = 15 cumulative green intensity, I–L present = 15 cumulative yellow intensity, M–P present = 15 cumulative red intensity), the *maximum* cumulative intensity (F) associated with the encoding scheme employed in the table 8 embodiment is 15. *Id.*; *see also* §V above. The ’797 Patent specification supports this understanding.

38. As stated earlier, the intensity and cumulative intensity values stated above may be arrived at by scaling and quantizing the arbitrary fluorescence units that are measured by a detector instrument as described in Paragraph 25.

39. To the extent a construction is required, “F” should be construed to mean “F, a value that scales with a constituent signal.”

40. The intrinsic evidence and understanding of a POSITA fully support this construction. For example, the ’797 Patent further teaches that “the cumulative signal scales with the constituent signals of the same color.” ’797 Patent, 28:15–28. The patent explains that “the presence of each analyte results in a particular intensity ... in each of the four colors.... The combination of these constituent signals leads to a cumulative signal that may be measured by measuring an intensity at each wavelength or range of wavelengths.” ’797 Patent, 27:44–55; *see also id.*, table 8, 21:65–22:2. Accordingly, F, which is the maximum cumulative intensity value for any color channel of the cumulative signal, measured when all analytes are present, scales with the

1 sum of the fluorophore color and intensity labels assigned to all individual analytes identified using
2 a given color channel.

3 41. When using this construction, the remaining language in the claim regarding F is
4 retained. That is, the claim would read “F, a value that scales with a constituent signal, is a positive
5 integer and is equal to the maximum cumulative intensity of the first component of the signal, for
6 any second value, when all of the analytes are present,” “wherein F+1 is a positive integer and
7 wherein F+1 is a power of 2,” etc.

8 42. Accordingly, the meaning of “F” is clear and the claims viewed in light of the
9 specification and prosecution history inform those skilled in the art about the scope of this term with
10 reasonable certainty.

11 **B. “analyte-specific hybridization probes” (claims 1, 10)**

12 Claim Term(s)	Plaintiffs’ Proposed Construction	Bio-Rad’s Proposed Construction
13 “analyte-specific hybridization probes”	14 Plain and ordinary meaning. 15 If a more specific interpretation of the plain and ordinary meaning is required, 16 this term should be construed as “a probe that binds to a portion of an analyte having a 17 specific sequence, with the sequence generally also characterizing the analyte.”	18 “a reagent capable of generating a signal in the presence of particular analyte and that hybridizes to the analyte”

20 43. This term should be given its plain and ordinary meaning.

21 44. First, the ’797 Patent teaches that an “analyte” “may be any suitable analyte, such as
22 a polynucleotide, a protein, a small molecule, a lipid, a carbohydrate, or mixtures thereof.” ’797
23 Patent, 9:13–15.

24 45. And the ’797 Patent teaches that “[t]he term ‘probe,’ as used herein, generally refers
25 to a reagent capable of generating a signal in the presence of a particular analyte.” ’797 Patent,
26 11:19–21. According to the ’797 Patent, “[a] probe generally has at least two portions: a portion
27 capable of specifically recognizing an analyte, or a portion thereof, and a portion capable of
28

1 generating a signal in the presence of an analyte, or a portion thereof.” *Id.* at 11:21–24; *see also id.*
2 at 31:39–48 (Probes, or hybridization probes, or reagents, generate signals in the presence of an
3 analyte, and generally have an analyte-specific portion and a signal-generating portion.) According
4 to the specification, “[a]ny suitable probe may be used with the methods presented in this disclosure,
5 so long as the probe generates a quantifiable signal in the presence of an analyte.” *Id.* at 11:31–33.
6 “For example, the analyte-specific portion of a probe may be coupled to an enzyme that, in the
7 presence of an analyte, converts an uncharged substrate into a charged product, thereby increasing
8 the electrical conductivity in the medium over time.” *Id.* at 11:33–38. “[D]ifferent analytes may be
9 encoded by coupling the analyte-specific portion of the probe (e.g., hybridization probe or antibody)
10 to an enzyme at different ratios.” *Id.* at 11:38–41. In other words, a given probe may be
11 complementary to a sequence in an analyte. ’797 Patent, 10:39–42.

12 46. The specification specifically enumerates so-called “TAQMAN” probes, which also
13 may be referred to as “hydrolysis probes” and are well understood by POSITAs and include a
14 polynucleotide sequence, a fluorophore, and a quencher. *See, e.g.*, ’797 Patent, 9:22–34, 10:31–55,
15 54:9–24. When the quencher and fluorophore are in proximity, bound to each other by the
16 polynucleotides sequence, the quencher quenches the fluorescence emitted by the fluorophore upon
17 excitation by a light source. ’797 Patent, at 10:36–39. The polynucleotide sequence of the
18 TAQMAN probe hybridizes to a polynucleotide sequence of an analyte it is desired to detect: “The
19 sequence of the ... probe is designed to be complementary to a polynucleotide sequence present in
20 an analyte, and therefore capable of hybridizing to the polynucleotide sequence present in the
21 analyte.” ’797 Patent, 10:39–42. Then, when a polymerase is used to generate a copy of the
22 sequence in the analyte to which the TAQMAN probe is hybridized, the quencher and the
23 fluorophore are released from each other, resulting in a detectable signal, as “[t]he proximity
24 between the fluorophore and the quencher is broken and the signal from the fluorophore is no longer
25 quenched.” *Id.* at 10:45–52. “Thus, the amount of fluorescence detected is a function of the amount
26 of analyte present. If no analyte is present, the probe will not hybridize to an analyte, and the
27 fluorophore and quencher will remain in close proximity. Little or no signal will be produced.” *Id.*
28

1 at 10:50–55. The '797 Patent's relevant description of probes is consistent with the understanding
2 of a POSITA.

3 47. The types of fluorophores attached to probes may be the same, or different, for
4 respective analytes that the probes specifically recognize, such that when the probes hybridize to
5 those analytes and then are degraded during PCR to release the fluorophore from the quencher, the
6 fluorophores produce the same or different colors. '797 Patent, 17:5–26, tables 5 and 8.

7 48. Turning now to different types of analyte-specific hybridization probes that can be
8 used with the example of table 8 described above (as well as other examples in the '797 patent),
9 tables 9-14 contain example probe sequences that are complementary to, and thus hybridize to, one
10 or more target sequences within the analytes listed in that table, and which contain respective
11 fluorophores and quenchers. '797 Patent, 40:21-58, Tables 9-14. For example, the probe listed in
12 the last row of table 9 is complementary to a portion of the HIV-1 polyprotease sequence, contains
13 a FAM fluorophore, and a Black Hole Quencher (BHQ). '797 Patent, 40:21-58, Table 9. As another
14 example, two probes are listed in the bottom two rows of table 10 which are complementary to
15 different portions of the HIV p17 sequence and which respectively contain the FAM fluorophore
16 and a BHQ or the Cy3 fluorophore and BHQ. '797 Patent, 40:21-58, table 10. A wide variety of
17 examples of TAQMAN probes (which may also be referred to as “hydrolysis probes”) are described
18 throughout the '797 Patent specification that are specific to sequences in other analytes. See, e.g.,
19 '797 Patent specification at table 15, tables 18-24, table S1-S27, and SEQ. ID. NOS. 4, 7, 8, 12, 13,
20 17, 18, 22, 23, 25, 28, 29, 31, 32. Accordingly, as a POSITA would understand from the '797 Patent
21 specification, each of these and other probes disclosed in the '797 Patent is analyte-specific. '797
22 Patent at 11:21–24; *see also id.* at 31:39–48.

23 49. Given the above, this term should be given its plain and ordinary meaning. If a more
24 specific interpretation of the plain and ordinary meaning is required, this term should be construed
25 as “a probe that binds to a portion of an analyte having a specific sequence, with the sequence
26 generally also characterizing the analyte.” '797 Patent, 32:23–27.

27 50. In comparison, Bio-Rad's proposed construction is imprecise and inaccurate and
28 contrary to the understanding of a POSITA because it characterizes the probe as being “capable of

generating a signal in the presence of a particular analyte.” A POSITA would consider such characterization to be incomplete, and inconsistent with the way TAQMAN probes work and with how they are described in the specification. TAQMAN probes are the primary type of probes described throughout the ’797 Patent specification. Rather than “being capable of generating a signal in the presence of a particular analyte,” a POSITA would understand that a TAQMAN probe is only capable of generating a signal after (1) the probe hybridizes to a sequence in the analyte, (2) a polymerase copies that sequence which degrades the probe and releases the probe’s quencher from the probe’s fluorophore, and (3) the fluorophore is excited.

51. Accordingly, this term should be given its plain and ordinary meaning, or Plaintiffs’ construction should be adopted.

C. “associating, for each analyte, a first value in a first component of the cumulative signal...” (claim 1)

Claim Term(s)	Plaintiffs’ Proposed Construction	Bio-Rad’s Proposed Construction
“associating, for each analyte, a first value in a first component of the cumulative signal [and a second value in a second component of the cumulative signal, wherein each first value is an intensity or a range of intensities and each second value is a wavelength or a range of wavelengths]”	Plain and ordinary meaning. To the extent a construction is necessary, the Court should construe the entire term of “associating, for each analyte, a first value in a first component of the cumulative signal and a second value in a second component of the cumulative signal, wherein each first value is an intensity or a range of intensities and each second value is a wavelength or a range of wavelengths” to mean “assigning each analyte to an intensity value of the cumulative signal and a wavelength value of the cumulative signal, wherein each intensity value is an intensity or range of intensities and each wavelength value is a	“associating each analyte with one value in a series of values for a first component of the cumulative signal that follow the progression 1, 2, 4, 8, 16, and so on.”

	wavelength or a range of wavelengths.”	
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52. First, this term does not require construction and should be interpreted according to its plain and ordinary meaning. According to the straightforward claim language, a POSITA would readily understand that an intensity or range of intensities and a wavelength (color) or range of wavelengths are associated with each analyte.

53. Second, if the Court is inclined to construe this term, the full term of “associating, for each analyte, a first value in a first component of the cumulative signal and a second value in a second component of the cumulative signal, wherein each first value is an intensity or a range of intensities and each second value is a wavelength or a range of wavelengths” should be construed, as opposed to the partial term Bio-Rad proposes. Bio-Rad’s construction of the truncated portion of the term should be rejected because, contrary to the clear claim language, it does not account for the analyte being associated with a color channel (wavelength value) in addition to an intensity value (first component). ’797 Patent, claim 1. Associating each analyte with both color and intensity according to the plain and ordinary meaning and Plaintiffs’ construction is—unlike Bio-Rad’s construction—fully consistent with the plain claim language and the intrinsic evidence, as demonstrated below. *Id.*

54. Regarding the ’797 Patent specification, the invention’s encoding solution encodes analytes using color and intensity. ’797 Patent, 8:66–9:21, 19:65–21:45. For example, table 8 discloses an encoding method for 16 analytes (A–P) where a color value and an intensity value is assigned to each analyte. “Table 8 ... illustrat[es] four tiers of encoding based on four color and intensities 1, 2, 4, and 8.” ’797 Patent, 21:65–67. As table 8 shows, each analyte A–P is labeled with a fluorophore color selected from blue, green, yellow, and red and, within the selected color channel, an intensity selected from the values 0, 1, 2, 4, and 8. ’797 Patent, table 8, 22:40–43. As explained above in §V, the coding scheme shown in table 8 uses both color and intensity to generate a unique signal for every possible combination of presence or absence of each of the 16 analytes (of which there are 2^{16} , or 65,536 possible combinations), and readily allows for the identification and detection of each such combination. As the specification explains, “the presence of each analyte

1 results in a particular intensity ... in each of the four colors.... The combination of these constituent
2 signals leads to a cumulative signal that may be measured by measuring an intensity at each
3 wavelength or range of wavelengths. The corresponding coding scheme or decoding matrix may
4 then be used to convert the cumulative measurement into a determination of the presence or absence
5 of an analyte.” ’797 Patent, 27:44–55. Regarding using both intensity and color to encode analytes,
6 the patent teaches “assigning” intensity values to analytes within a given color channel. ’797 Patent,
7 9:2–6, 21:49–55, 50:14–24, 54:26–27.

8 55. Accordingly, in contrast to Bio-Rad’s construction, each analyte is associated with
9 and assigned both an intensity value, which encompasses an intensity or range of intensities, and a
10 wavelength (color) value, which encompasses a wavelength or a range of wavelengths. Consistent
11 with this, if the Court decides to construe this term, the full term should be construed, and it should
12 be construed to mean “assigning each analyte to an intensity value of the cumulative signal and a
13 wavelength value of the cumulative signal, wherein each intensity value is an intensity or range of
14 intensities and each wavelength value is a wavelength or a range of wavelengths.”

15 56. Bio-Rad’s proposed construction requires that each analyte be associated with one
16 integer intensity value among a progression of integer intensity values. However, the ’797 Patent
17 specification describes embodiments where analytes are associated with intensity values by
18 comparing experimental results with “bands” that may cover ranges of intensities. ’797 Patent,
19 48:62–49:20 (“The intensity value for each color in reactions 11-14 was measure in arbitrary
20 fluorescence units (AFU), plotted on the chromatogram, and then assigned to a band based on two
21 criteria. First, if an experimental result was within a band, then the result was assigned to the
22 multiplicity of the band....”); *see also id.* at claim 1 (“each first value is an intensity or range of
23 intensities...”). Accordingly, to the extent Bio-Rad’s construction seeks to limit the scope of the
24 claims to exclude associating analytes with bands, or ranges of intensities, and cover only
25 associating each analyte with one specific intensity value, this is not supported by the claim
26 language, the ’797 Patent specification, or the understanding of a POSITA.

27 57. Thus, the term in its entirety should be given its plain and ordinary meaning, or
28 Plaintiffs’ construction should be adopted.

VIII. LEGAL STANDARDS

58. In forming my opinions in this Declaration, I applied the following legal principles.

59. I understand that, to determine how a POSITA would have understood a claim term, one should look to sources available at the time of the alleged invention that show what a POSITA would have understood the disputed claim language to mean. It is my understanding that this may include what is called “intrinsic” evidence as well as “extrinsic” evidence.

60. I understand that, in construing a claim term, one should primarily rely on intrinsic patent evidence, which includes the words of the claims themselves, the remainder of the patent specification, and the prosecution history. I understand that extrinsic evidence, which is evidence external to the patent and the prosecution history, may also be useful in interpreting patent claims when the intrinsic evidence itself is insufficient. I understand that extrinsic evidence may include principles, concepts, terms, and other resources available to a POSITA at the time of the invention.

61. I understand that words or terms should be given their ordinary and accepted meaning unless it appears that the inventors were using them to mean something else or something more specific. I understand that to determine whether a term has special meaning, the claims, the patent specification, and the prosecution history are particularly important, and may show that the inventor gave a term a particular definition or intentionally disclaimed, disavowed, or surrendered some aspect of the term or claim’s scope.

62. I understand that the claims of a patent define the scope of the rights conferred by the patent. I understand that, because the claims point out and distinctly claim the subject matter which the inventors regard as their invention, claim construction analysis must begin with and is focused on the claim language itself. I understand that the context and how the term is used within the claim as well as other claims of the patent can inform the meaning of a claim term.

63. I understand that a claim term should be construed not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the entire specification. I understand that because the specification is a primary basis for construing the claims, a correct construction must align with the specification.

64. I understand that the prosecution history of the patent as well as art incorporated by reference or otherwise cited during the prosecution history are also relevant in construing claim terms. For instance, art cited by or incorporated by reference may indicate how the inventor and others of skill in the art at the time of the invention understood certain terms and concepts. Additionally, the prosecution history may show that the inventors disclaimed or disavowed claim scope, or further explained the meaning of a claim term.

65. With regard to extrinsic evidence, I understand that all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises, can also be considered. However, I understand that extrinsic evidence is considered to be less reliable than intrinsic evidence, and for that reason is generally given less weight than intrinsic evidence.

66. I understand that a claim is indefinite if a POSITA would not have understood what is claimed even after the claim is read in light of the specification. Specifically, a claim is indefinite if a POSITA would not understand the scope of the claim with reasonable certainty.

IX. RESERVATION OF RIGHTS

67. My opinions are based upon the information that I have considered to date. I reserve the right to supplement my opinions in the future to respond to any arguments raised by Bio-Rad and/or any declarants offered by Bio-Rad and to take into account new information that becomes available to me.

68. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on 10/29/2025, at Seattle, Washington.


Bernhard H. Weigl

Materials Considered

Number	Description
1	U.S. Patent No. 12,168,797 (“the ’797 Patent”)
2	File history for the ’797 Patent

APPENDIX A

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Education

KARL-FRANZEN-UNIVERSITÄT GRAZ
M.Sc (Mag. rer. nat.) and Ph.D. (Dr. rer. nat.)

LEOPOLD-FRANZENS-UNIVERSITÄT INNSBRUCK
Undergrad Studies Chemistry

Employment

AFFILIATE PROFESSOR, DEPARTMENT OF BIOENGINEERING
University of Washington May 2004 – Present · 21 years

GLOBAL HEALTH LABS
5 years 2 months

SENIOR DIRECTOR, DIAGNOSTICS RESEARCH AND
DEVELOPMENT
June 2020 – August 2025 ·
Bellevue, WA

INTELLECTUAL VENTURES
5 years 3 months

DIRECTOR, CENTER FOR IN-VITRO DIAGNOSTICS
Apr 2018 – June 2020 · 2 year 3 months
Bellevue, WA

PRINCIPAL INVESTIGATOR, FLOW BASED DIAGNOSTICS
Apr 2015 – April 2018 · 3 years
Bellevue ,WA

PATH
11 years

PORTFOLIO LEADER, DIAGNOSTICS FOR NON-
COMMUNICABLE DISEASES
Jan 2011 – Apr 2015 · 4 years 4 months

GROUP LEADER DIAGNOSTICS AND DIRECTOR, CENTER
FOR POINT OF CARE DIAGNOSTICS FOR GLOBAL HEALTH
2004 – 2011 · 7 years
Seattle

SENIOR PARTNER - MICROPLUMBERS MICROSCIENCES
2004 – 2011 · 7 years

DIRECTOR MICROFLUIDIC APPLICATIONS MICRONICS
1997 – 2001 · 4 years

SENIOR RESEARCH FELLOW
University of Washington Department of Bioengineering
1995 – 1997 · 2 years

Book Chapters

Gonzalo Domingo, Kenneth R. Hawkins, Roger B. Peck, Bernhard H. Weigl: *Chapter II.5.17. Diagnostic Applications of Biomaterials*. Biomaterials Science. An Introduction to Materials in Medicine, Third Edition edited by Buddy Ratner, Alan Hoffman, Frederick Schoen, Jack Lemons, 12/2013: chapter Chapter II.5.17 Diagnostic Applications of Biomaterials: pages 1087-1106; Academic Press., ISBN: 978-0-12-374626-9, DOI:10.1016/B978-0-08-087780-8.00106-6

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Patents

US Patents and Published Patent Applications

Patent number	Title	Inventor name	Publication date
US-12097499-B2	Determining a bulk concentration of a target in a sample using a digital assay with compartments having nonuniform volumes	Huynh; Toan et al.	9/24/2024
US-11726078-B2	Device for rapid detection of tuberculosis-lipoarabinomannan (TB-LAM) with enhanced sensitivity	Misner; Matthew Jeremiah et al.	8/15/2023
US-20230149932-A1	DETERMINING A BULK CONCENTRATION OF A TARGET IN A SAMPLE USING A DIGITAL ASSAY WITH COMPARTMENTS HAVING NONUNIFORM VOLUMES	Huynh; Toan et al.	5/18/2023

US-20230062787-A1	SYSTEMS AND METHODS FOR PARTICLE MULTIPLEXING IN DROPLETS	Byrnes; Samantha A. et al.	3/2/2023
US-11577247-B2	Determining a bulk concentration of a target in a sample using a digital assay with compartments having nonuniform volumes	Huynh; Toan et al.	2/14/2023
US-11512356-B2	Systems and methods for particle multiplexing in droplets	Byrnes; Samantha A. et al.	11/29/2022
US-20220193661-A1	DETERMINING A BULK CONCENTRATION OF A TARGET IN A SAMPLE USING A DIGITAL ASSAY WITH COMPARTMENTS HAVING NONUNIFORM VOLUMES	Huynh; Toan et al.	6/23/2022
US-11318467-B2	Assay structures for multi-step biochemical assays	Anderson; Caitlin E. et al.	5/3/2022
US-11305284-B2	Determining a bulk concentration of a target in a sample using a digital assay with compartments having nonuniform volumes	Huynh; Toan et al.	4/19/2022
US-20210370290-A1	Assay Structures for Multi-Step Biochemical Assays	Anderson; Caitlin E. et al.	12/2/2021
US-20210055282-A1	DEVICE FOR RAPID DETECTION OF TUBERCULOSIS-LIPOARABINOMANNAN (TB-LAM) WITH ENHANCED SENSITIVITY	Misner; Matthew Jeremiah et al.	2/25/2021
US-10830760-B2	Device for rapid detection of tuberculosis-lipoarabinomannan (TB-LAM) with enhanced sensitivity	Misner; Matthew Jeremiah et al.	11/10/2020
US-20200164364-A1	DETERMINING A BULK CONCENTRATION OF A TARGET IN A SAMPLE USING A DIGITAL ASSAY WITH COMPARTMENTS HAVING NONUNIFORM VOLUMES	Huynh; Toan et al.	5/28/2020
US-20200149092-A1	Systems and Methods for Particle Multiplexing in Droplets	Byrnes; Samantha A. et al.	5/14/2020

US-10634591-B2	Device for concentration of biological sample prior to immunoassay	Connelly; John Thomas et al.	4/28/2020
US-10549273-B2	Flow assay with at least one electrically-actuated fluid flow control valve and related methods	Gasperino; David et al.	2/4/2020
US-20190383807-A1	METHODS AND SYSTEMS FOR CONCENTRATION OF SAMPLES FOR LATERAL FLOW ASSAYS	Connelly; John Thomas et al.	12/19/2019
US-20190187126-A1	DEVICE FOR RAPID DETECTION OF TUBERCULOSIS-LIPOARABINOMANNAN (TB-LAM) WITH ENHANCED SENSITIVITY	MISNER; Matthew Jeremiah et al.	6/20/2019
US-20190126265-A1	METHOD OF DIVERTING THE FIRST FRACTION OF SAMPLE AWAY FROM A LATERAL FLOW ASSAY	Weigl; Bernhard Hans et al.	5/2/2019
US-20180348218-A1	SEROLOGY ASSAY FOR RECENT MALARIA INFECTION	Cate; David Michael et al.	12/6/2018
US-20180259434-A1	DEVICE FOR CONCENTRATION OF BIOLOGICAL SAMPLE PRIOR TO IMMUNOASSAY	Connelly; John Thomas et al.	9/13/2018
US-20170212109-A1	FLOW ASSAY WITH AT LEAST ONE ELECTRICALLY-ACTUATED FLUID FLOW CONTROL VALVE AND RELATED METHODS	Gasperino; David et al.	7/27/2017
US-8945910-B2	Method and apparatus for an improved sample capture device	Marsot; Travis et al.	2/3/2015
US-20140370581-A1	MICROFLUIDIC DEVICES FOR FLUID MANIPULATION AND ANALYSIS	Saltsman; Patrick et al.	12/18/2014
US-20140154786-A1	Chemical Temperature Control	Labarre; Paul Donald et al.	6/5/2014
US-8697009-B2	Microfluidic devices for fluid manipulation and analysis	Saltsman; Patrick et al.	4/15/2014
US-20140010736-A1	MICROFLUIDIC DEVICES FOR FLUID MANIPULATION AND ANALYSIS	Saltsman; Patrick et al.	1/9/2014
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US-8431387-B2	Chemical temperature control	LaBarre; Paul Donald et al.	4/30/2013
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US-20120259186-A1	Method and apparatus for an improved sample capture device	Marsot; Travis et al.	10/11/2012
US-8282576-B2	Method and apparatus for an improved sample capture device	Marsot; Travis et al.	10/9/2012
US-20120115212-A1	Assay Tube	WEIGL; Bernhard et al.	5/10/2012
US-20120064612-A1	MICROFLUIDIC DEVICES FOR FLUID MANIPULATION AND ANALYSIS	Saltsman; Patrick et al.	3/15/2012
US-20110117668-A1	SELF-POWERED SMART DIAGNOSTIC DEVICES	Stayton; Patrick S. et al.	5/19/2011
US-20100173395-A1	MICROFLUIDIC DEVICES FOR FLUID MANIPULATION AND ANALYSIS	Saltsman; Patrick et al.	7/8/2010
US-7648835-B2	System and method for heating, cooling and heat cycling on microfluidic device	Breidford; Wayne L. et al.	1/19/2010
US-20090204025-A1	Method and apparatus for an improved sample capture device	Marsot; Travis et al.	8/13/2009
US-7544506-B2	System and method for heating, cooling and heat cycling on microfluidic device	Breidford; Wayne et al.	6/9/2009
US-20090081771-A1	SYSTEM AND METHOD FOR HEATING, COOLING AND HEAT CYCLING ON MICROFLUIDIC DEVICE	Breidford; Wayne L. et al.	3/26/2009
US-20090036665-A1	Disposable Sample Processing Unit	Domingo; Gonzalo et al.	2/5/2009
US-20090029867-A1	DNA purification and analysis on nanoengineered surfaces	Reed; Michael W. et al.	1/29/2009
US-20090022624-A1	MICROFLUIDIC DEVICES FOR FLUID MANIPULATION AND ANALYSIS	Saltsman; Patrick et al.	1/22/2009
US-20090004732-A1	Chemical Temperature Control	LaBarre; Paul Donald et al.	1/1/2009

US-7419638-B2	Microfluidic devices for fluid manipulation and analysis	Saltsman; Patrick et al.	9/2/2008
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US-7271007-B2	Microscale diffusion immunoassay	Weigl; Bernhard H et al.	9/18/2007
US-7223371-B2	Microfluidic channel network device	Hayenga; Jon W. et al.	5/29/2007
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US-20060073599-A1	Microfabricated diffusion-based chemical sensor	Weigl; Bernhard H. et al.	4/6/2006
US-7011791-B2	Microfluidic devices for rotational manipulation of the fluidic interface between multiple flow streams	Weigl; Bernhard H. et al.	3/14/2006
US-20050205816-A1	Pneumatic valve interface for use in microfluidic structures	Hayenga, Jon W. et al.	9/22/2005
US-20050201903-A1	Microfluidic device for concentrating particles in a concentrating solution	Weigl, Bernhard H. et al.	9/15/2005
US-20050129582-A1	System and method for heating, cooling and heat cycling on microfluidic device	Breidford, Wayne et al.	6/16/2005
US-20050106066-A1	Microfluidic devices for fluid manipulation and analysis	Saltsman, Patrick et al.	5/19/2005
US-20050045479-A1	Pumpless microfluidics	Weigl, Bernhard H. et al.	3/3/2005
US-20050013732-A1	Method and system for microfluidic manipulation, amplification and analysis of fluids, for example, bacteria assays and antiglobulin testing	Battrell, C. Frederick et al.	1/20/2005
US-20040229378-A1	Well-plate microfluidics	Schulte, Thomas H. et al.	11/18/2004
US-6743399-B1	Pumpless microfluidics	Weigl; Bernhard H. et al.	6/1/2004

US-6742661-B1	Well-plate microfluidics	Schulte; Thomas et al.	6/1/2004
US-20040094479-A9	WELL-PLATE MICROFLUIDICS	Schulte, Thomas et al.	5/20/2004
US-6674525-B2	Split focusing cytometer	Bardell; Ronald et al.	1/6/2004
US-20030175990-A1	Microfluidic channel network device	Hayenga, Jon W. et al.	9/18/2003
US-20030175980-A1	Ribbon flow cytometry and cell sorting	Hayenga, Jon W. et al.	9/18/2003
US-20030124619-A1	Microscale diffusion immunoassay	Weigl, Bernhard H. et al.	7/3/2003
US-6582963-B1	Simultaneous analyte determination and reference balancing in reference T-sensor devices	Weigl; Bernhard H. et al.	6/24/2003
US-6557427-B2	Capillaries for fluid movement within microfluidic channels	Weigl; Bernhard H. et al.	5/6/2003
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US-6541213-B1	Microscale diffusion immunoassay	Weigl; Bernhard H. et al.	4/1/2003
US-20030034306-A1	Well-plate microfluidics	Schulte, Thomas et al.	2/20/2003
US-6488896-B2	Microfluidic analysis cartridge	Weigl; Bernhard H. et al.	12/3/2002
US-20020172622-A1	Microfluidic device for concentrating particles in a concentrating solution	Weigl, Bernhard H. et al.	11/21/2002
US-20020159920-A1	Multiple redundant microfluidic structures cross reference to related applications	Weigl, Bernhard H.	10/31/2002
US-20020160518-A1	Microfluidic sedimentation	Hayenga, Jon W. et al.	10/31/2002
US-20020148992-A1	Pneumatic valve interface for use in microfluidic structures	Hayenga, Jon W. et al.	10/17/2002

US-20020149766-A1	Split focusing cytometer	Bardell, Ronald et al.	10/17/2002
US-20020150502-A1	Surface tension reduction channel	Weigl, Bernhard H.	10/17/2002
US-6454945-B1	Microfabricated devices and methods	Weigl; Bernhard H. et al.	9/24/2002
US-20020114739-A1	Microfluidic cartridge with integrated electronics	Weigl, Bernhard H. et al.	8/22/2002
US-20020090644-A1	Microscale diffusion immunoassay	Weigl, Bernhard H. et al.	7/11/2002
US-6409832-B2	Protein crystallization in microfluidic structures	Weigl; Bernhard H. et al.	6/25/2002
US-6408884-B1	Magnetically actuated fluid handling devices for microfluidic applications	Kamholz; Andrew et al.	6/25/2002
US-20020076350-A1	Microfluidic devices for rotational manipulation of the fluidic interface between multiple flow streams	Weigl, Bernhard H. et al.	6/20/2002
US-20020052049-A1	Microfluidic separation device	Weigl, Bernhard H. et al.	5/2/2002
US-20020048535-A1	Rotation device for sequential microfluidic reaction	Weigl, Bernhard H. et al.	4/25/2002
US-20020041827-A1	Devices for Analyzing the Presence and Concentration of Multiple Analytes Using a Diffusion-based Chemical Sensor	Yager , Paul et al.	4/11/2002
US-20020025279-A1	Capillaries for fluid movement within microfluidic channels	Weigl, Bernhard H. et al.	2/28/2002
US-20020015959-A1	Fluid mixing in microfluidic structures	Bardell, Ronald L. et al.	2/7/2002
US-20020006670-A1	Simultaneous particle separation and chemical reaction	Wu, Caicai et al.	1/17/2002
US-20020003001-A1	Surface tension valves for microfluidic applications	Weigl, Bernhard H. et al.	1/10/2002
US-20010055546-A1	Method and apparatus for controlling fluid flow rate in a microfluidic circuit	Weigl, Bernhard H.	12/27/2001

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US-20010048637-A1	Microfluidic system and method	Weigl, Bernhard H. et al.	12/6/2001
US-20010046453-A1	Microfluidic analysis cartridge	Weigl, Bernhard H. et al.	11/29/2001
US-20010046701-A1	Nucleic acid amplification and detection using microfluidic diffusion based structures	Schulte, Thomas H. et al.	11/29/2001
US-20010027745-A1	Protein crystallization in microfluidic structures	Weigl, Bernhard H. et al.	10/11/2001
US-6297061-B1	Simultaneous particle separation and chemical reaction	Wu; Caicai et al.	10/2/2001
US-6221677-B1	Simultaneous particle separation and chemical reaction	Wu; Caicai et al.	4/24/2001
US-6171865-B1	Simultaneous analyte determination and reference balancing in reference T-sensor devices	Weigl; Bernhard H. et al.	1/9/2001
US-6159739-A	Device and method for 3-dimensional alignment of particles in microfabricated flow channels	Weigl; Bernhard et al.	12/12/2000
US-6136272-A	Device for rapidly joining and splitting fluid layers	Weigl; Bernhard et al.	10/24/2000
US-6134950-A	Method for determining concentration of a laminar sample stream	Forster; Fred K. et al.	10/24/2000
US-6091502-A	Device and method for performing spectral measurements in flow cells with spatial resolution	Weigl; Bernhard H. et al.	7/18/2000
US-5974867-A	Method for determining concentration of a laminar sample stream	Forster; Fred K. et al.	11/2/1999
US-5972710-A	Microfabricated diffusion-based chemical sensor	Weigl; Bernhard H. et al.	10/26/1999
US-5948684-A	Simultaneous analyte determination and reference balancing in reference T-sensor devices	Weigl; Bernhard H. et al.	9/7/1999

US-5747349-A	Fluorescent reporter beads for fluid analysis	van den Engh; Ger et al.	5/5/1998
US-5716852-A	Microfabricated diffusion-based chemical sensor	Yager; Paul et al.	2/10/1998

IP Consulting - Expert Witness Patent Cases

WSGR: Wilson Sonsini Goodrich & Rosati (Michael Rosati, Jad Mills)

1. **Nanocollect:** NanoCollect Biomedical, Inc. v. Cytonome/ST, LLC, IPR2020-00551, filed on 12-02-2020, Proceedings Before the U.S. Patent and Trademark Office Regarding Cytonome Patents. Engagement to provide assistance to WSGR, on behalf of NanoCollect Biomedical, Inc. (referred to in this letter as “NanoCollect”); cell sorting; Declaration filed 2/12/2020; Deposition 11/13/2020.
2. **Dropworks:** Engagement assist WSGR, on behalf of DropWorks Inc., in connection with DropWorks Inc. v. Bio-Rad Patent Laboratories, Inc. Litigation for Patent Nos.: 9,127,310 and 8,304,193; Digital PCR. Declaration filed 11/18/2020.
3. **Drawbridge:** Drawbridge Health Inc. vs Seventh Sense Biosystems Inc.: consulting regarding Patent No. 8,821,412, blood collection; IPR petition drafting. Start of engagement 05/15/2018
4. **Chromacode:** ChromaCode, Inc. v. Bio-Rad Laboratories, Inc., Case No. 5:23-cv04823 (N.D. Cal.), and ChromaCode, Inc. and California Institute of Technology v. Bio-Rad Laboratories, Inc., Case No. 5:23-cv-06360 (N.D. Cal.). Matters related to signal encoding and decoding in multiplexed digital assays.

Covington & Burling:

5. **BioTeke and others;** Consulting and Certain Flocked Swabs, Products Containing Flocked Swabs, And Methods of Using Same; Inv. No.337-TA-1279, as well as potential matters, including all appeals and during any litigation, ITC matter or IPR arising out of or relating to same in all venues. Patent(s): Include, but are not limited to 10327741, 9011358, 9173779 Client(s): BioTeke Corporation (Wuxi) Co., Ltd.; Fosun Pharma USA Inc.; Jiangsu Changfeng Medical Industry Co., Ltd.; Miraclean Technology Co., Ltd.; NEST Scientific Inc.; NEST Scientific USA; Wuxi NEST Biotechnology Co., Ltd. Law Firm(s): Covington & Burling; court: ITC Court Inv. No. 337-TA-1279; case went to trial. I served as a witness and was cross- examined; *Copan flocked swabs*. Opening Expert Report 3/18/2022; Rebuttal Report 4/1/2022; Deposition 4/18/2022; Hearing Testimony 7/1/2022.

Carlson Caspers:

6. Consulting services to Carlson, Caspers, Vandenburg, & Lindquist (“Carlson Caspers”) on behalf of Qiagen North American Holdings, Inc., **Qiagen GmbH, and NeuMoDx Molecular**, Inc., (a wholly owned subsidiary of QIAGEN N.V.)(collectively “QIAGEN”) with respect to the lawsuit Becton, Dickinson and Company (who acquired Handylab) et al v. NeuMoDx Molecular, Inc., Case 1:19-cv-01126-LPS (D.

Del. Aug. 9, 2019), involving U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; 8,709,787; 10,494,663; 10,364,456; 10,443,088; 10,604,788; 10,625,261; 10,625,262; and 10,632,466; *Molecular assays on cartridges*. Case was settled

Sidley:

7. Sidley: On behalf of **ABS Global**. Inguran, LLC d/b/a STgenetics and Cytonome/ST LLC v. ABS Global, Inc. and Genus plc, No. 20-cv-00349-wmc (W.D. Wis. Apr. 15, 2020); *3 dimensional focusing in flow cytometers*, declaration and responses submitted. Expert Reports 10/23/2023 and 12/13/2023.

Sheppard, Mullin:

8. **Chromacode**: taken over from WSGR. ChromaCode, Inc. v. Bio-Rad Laboratories, Inc., Case No. 5:23-cv04823 (N.D. Cal.), and ChromaCode, Inc. and California Institute of Technology v. Bio-Rad Laboratories, Inc., Case No. 5:23-cv-06360 (N.D. Cal.). Matters related to signal encoding and decoding in multiplexed digital assays. Ongoing.

Cooley LLP:

9. **Cytek** vs Beckman Coulter, *Infringement of US patents 11,703,443 and 10,330,582*. Ongoing.