

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIO-RAD LABORATORIES, INC.,
Petitioner,

v.

CALIFORNIA INSTITUTE OF TECHNOLOGY,
Patent Owner.

IPR2024-01177
Patent 10,068,051 B2

Before ERICA A. FRANKLIN, GRACE KARAFFA OBERMANN, and
TAWEN CHANG, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Bio-Rad Laboratories, Inc. (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–9 of U.S. Patent No. 10,068,051 B2 (Ex. 1001, “the ’051 patent”). Paper 1 (“Petition” or “Pet.”). California Institute of Technology (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”). With our authorization, Ex. 3001, Petitioner filed a Reply to the Preliminary Response. Paper 7 (“Pet. Reply”). Patent Owner filed a Sur-reply in response. Paper 8 (“PO Sur-reply”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. Upon considering the parties’ arguments and evidence, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we decline to institute an *inter partes* review of the challenged claims.

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 25. Patent Owner identifies itself as the real party-in-interest. Paper 9, 2.

B. Related Matters

Petitioner asserts that the ’051 patent is involved in *ChromaCode, Inc. et al. v. Bio-Rad Laboratories, Inc.*, 5:23-cv-06360 (N.D. Cal.) and co-pending *ChromaCode, Inc. v. Bio-Rad Laboratories, Inc.*, 23-cv-4823 (N.D. Cal. filed September 20, 2023). Pet. 25. Petitioner notes that they are seeking *inter partes* review of U.S. Patent No. 10,770,170 (“the ’170 patent”). *Id.*; see IPR2024-01178, Paper 1 (petition seeking *inter partes* review of the ’170 patent). The ’170 patent issued from a continuation of the application that issued as the ’051 patent. IPR2024-01178, Ex. 1001, code (63).

Patent Owner asserts that the '051 patent, the '170 patent, and U.S. Patent No. 11,827,921 (“the '921 patent”) are involved in *ChromaCode, Inc. et al. v. Bio-Rad Laboratories, Inc.*, 5:23-cv-06360 (N.D. Cal.). Paper 5, 2; Paper 9, 2. Patent Owner also notes that the '921 patent is the subject of IPR2024-01450 (*sic*, IPR2024-01451). Paper 9, 2.

C. The '051 patent

In one aspect, the '051 patent relates to methods for the multiplexed detection of a plurality of analytes in a sample. Ex. 1001, code (57).

The '051 patent describes that “[f]luorescence detection has been a preferred technique for multiplexed assays.” *Id.* at 8:28–29, 8:35–39. A schematic representation of the detection of 6 analytes with four fluorescent colors is shown in Figure 2 below.

Fig. 2

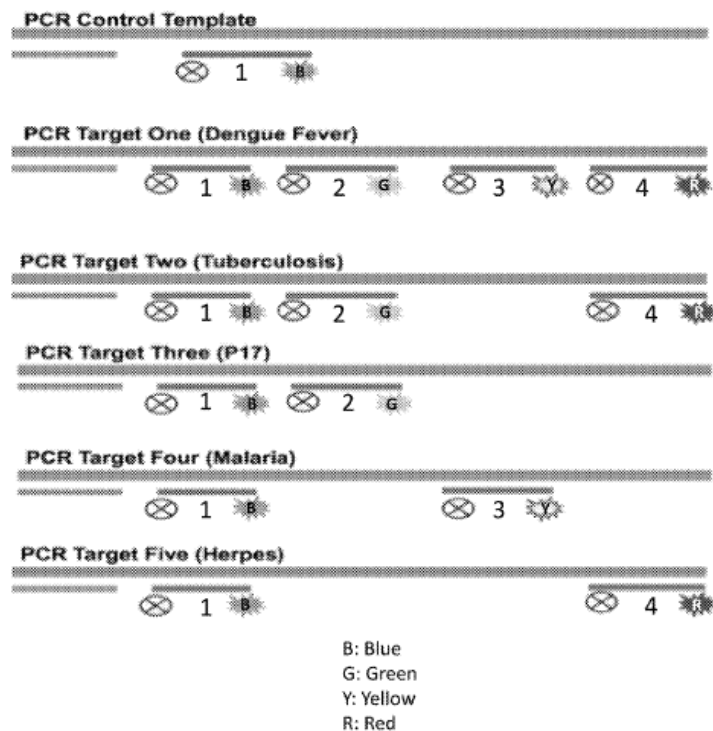


Figure 2 represents the detection of analytes “using hybridization probes attached to a fluorophore (B, G, Y, R; blue, green, yellow, and red, respectively) and a quencher (oval with ‘X’).” *Id.* at 7:62–66. The ’051 patent describes that “[t]he control sequence and the five other sequences” specific for each analyte “are all detected using a probe labeled with a blue fluorophore.” *Id.* at 7:66–8:4. The ’051 patent explains that “standard fluorophores have wide emission spectra. Therefore, in order to avoid spectral overlap (i.e., to preserve spectral resolution) only a relatively small number of colors (e.g., 4 to 6) are typically used simultaneously in multiplexed fluorescent assays.” *Id.* at 8:35–39.

Whenever the number of analytes that can be detected is greater than the number of spectrally resolved fluorescent probes, “fluorescence is generally combined with other techniques, such as aliquoting, spatial arraying, or sequential processing.” *Id.* at 8:45–47. However, “[t]hese additional processing steps are labor-intensive and frequently require relatively expensive and complex optical and mechanical systems,” which “are often impractical to deploy in certain settings, particularly point-of[-]care and low-resource settings.” *Id.* at 8:47–53. Thus, the ’051 patent purports that “there is a significant need for multiplexed encoding and decoding methods that can provide an inexpensive means of multiplexing while avoiding the use of expensive additional processing steps.” *Id.* at 8:53–57.

To address this need, the ’051 patent describes the detection of a number of analytes greater than the number of spectrally resolved fluorescent probes “based on []encoding, analysis, and decoding methods.” *Id.* at 8:60–61. The ’051 patent explains that in some embodiments, “each analyte to be detected is encoded as a value in each of at least two

components of a signal (e.g., intensity and wavelength).” *Id.* at 8:65–67. These components may be “cumulatively measured for the sample” and the “presence or absence of an analyte may then be determined based on the values of each of the at least two components of the signal and the values used to encode the presence of the analyte (i.e., those values in the coding scheme).” *Id.* at 9:36–42.

An example in which seven analytes (A–G), plus control, are encoded using combinations of four fluorophores is shown in Table 3 below.

TABLE 3

Encoding of eight analytes (including control) with four colors and up to four colors per analyte.				
	Blue	Green	Yellow	Red
Ctrl. (p)	1	0	0	0
A	1	0	0	1
B	1	0	1	0
C	1	1	0	0
D	1	0	1	1
E	1	1	0	1
F	1	1	1	0
G	1	1	1	1

Ex. 1001, 14:4–15. The ’051 patent explains that

The presence of the control and analyte G is indicated by a result of 2111. These results express the cumulative intensity of the signal in each color. For example, the result 2111 has a 2X signal intensity in the blue channel, while the result 1000 has only a 1 X signal intensity in the blue channel.

Id. at 14:23–28. “Using Table 3, each of the possible cumulative assay results can be enumerated, in terms of color (blue, green, yellow, red) and intensity (0–8).” *Id.* at 14:19–31. An example of how the method of the ’051

patent may be used to detect combinations of different analytes in a single sample volume is shown in Table 4 below.

TABLE 4-continued

Decoding matrix for encoding method presented in Table 3.				
Cumulative Assay Result				
Blue	Green	Yellow	Red	Analyte(s) Present
7	3	3	3	pABCDEF
8	4	4	4	pABCDEFG

Ex. 1001, 17:1–6. “Table 4 shows a ‘decoding matrix’ generated by enumerating each of the possible cumulative assay results based on the encoding method presented in Table 3 and providing the corresponding decoded result of each assay in terms of the analyte(s) present in the sample.” *Id.* at 14:31–36.

The ’051 patent describes that a result may be degenerate “because it can indicate more than one possibility in terms of the presence or absence of an analyte.” *Id.* at 17:64–67 (noting that the “result 5233 is degenerate because it can be decoded as either pADFG or pBDEG.”) (*see id.* at Table 4, 15:39)). The ’051 patent explains that the problem of degenerate samples may be resolved by reducing or eliminating degeneracy from the coding scheme, “thereby increasing the confidence with which an analyte is detected.” *Id.* at 18:16–18. The ’051 patent describes different solutions for degeneracy, such as encoding individual analyte states using intensity levels separated by integer $\log_2$ intensity values (1, 2, 4, 8, 16, etc.) so that every possible combination of analytes has a unique cumulative intensity. *Id.* at 23:33–25:19.

D. Challenged Claims

Petitioner challenges claims 1–9 in the '051 patent. Claim 1, the independent claim, is illustrative and set forth below.

1. A method of detecting the presence or absence of at least seven polynucleotide analytes, in any combination of presence or absence, in a single sample solution volume, the method comprising:

- a) providing a sample solution volume comprising or potentially comprising, at least one of at least seven polynucleotide analytes, and comprising at least seven hybridization probes, each hybridization probe corresponding to one of the at least seven polynucleotide analytes, wherein each hybridization probe comprises at least one fluorophore selected from four fluorophores, and wherein each hybridization probe, when excited and when contacted with its corresponding polynucleotide analyte, generates a cumulative intensity signal, further wherein each generated cumulative intensity signal comprises at least one signal generated by excitement of at least one of the four fluorophores;
- b) contacting said sample solution volume with the plurality of hybridization probes and exciting the hybridization probes to generate the cumulative intensity signal(s) if one or more of the at least seven polynucleotide analytes is present in the sample volume; and
- c) measuring the cumulative intensity signal(s), thereby generating a cumulative signal measurement, wherein the cumulative signal measurement non-degenerately indicates the presence or absence of the at least seven polynucleotide analytes, in any combination of presence or absence,

wherein said method non-degenerately detects the presence or absence of the at least seven polynucleotide analytes in said single sample solution volume, in any combination of presence or absence, without requiring any step of immobilization of said polynucleotide analytes, physical

separation of said polynucleotide analytes, or mass spectrometry.

Ex. 1001, 69:8–70:11.

E. Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §¹	Reference(s)
1–4	103(a)	Saxonov ²
5, 6	103(a)	Saxonov, Silverbrook ³
7	103(a)	Saxonov, Maltezos ⁴
8, 9	103(a)	Saxonov, Maltezos, Oh ⁵
1–4	103(a)	Saxonov, Kramer, ⁶ and/or Larson ⁷
5, 6	103(a)	Saxonov, Kramer, and/or Larson, Silverbrook
7	103(a)	Saxonov, Kramer, and/or Larson, Maltezos
8, 9	103(a)	Saxonov, Kramer, and/or

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013.

Because the application from which the ’051 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of §103 applies.

² Saxonov, U.S. Patent App. Pub. 2013/0040841 A1, published February 14, 2013 (“Saxonov,” Ex. 1004).

³ Silverbrook, U.S. Patent App. Pub. 2011/0312704 A1, published December 22, 2011 (“Silverbrook,” Ex. 1009).

⁴ Maltezos, U.S. Patent App. Pub. 2008/0003649 A1, published January 3, 2008 (“Maltezos,” Ex. 1010).

⁵ Oh, U.S. Patent App. Pub. 2010/0311070 A1, published December 9, 2010 (“Oh,” Ex. 1011).

⁶ Kramer, U.S. Patent App. Pub. 2008/0124705 A1, published May 29, 2008 (“Kramer,” Ex. 1008).

⁷ Larson, U.S. Patent App. Pub. 2011/0250597 A1, published October 13, 2011 (“Larson,” Ex. 1017).

Claims Challenged	35 U.S.C. § ¹	Reference(s)
		Larson, Maltezos, Oh

Petitioner also relies upon the Declaration of Carl A. Batt, Ph.D. (Ex. 1002). Patent Owner relies on the Declaration of Kevin Struhl, Ph.D. (Ex. 2001).

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art at the time of the invention (also referred to as “POSA”) “would have had a Ph.D. in molecular biology, genetics, biochemistry, or a related discipline, with at least a year of experience in quantitative and/or digital PCR and fluorescence-based analyte detection” or “someone with greater relevant experience sufficient to compensate for having less relevant formal education.” Pet. 10 (citing Ex. 1002 ¶¶ 70–72). Petitioner also asserts that a POSA would have understood the following technologies and techniques:

- Multiplex PCR and its application in detecting and measuring polynucleotide analytes.
- The design and use of fluorescent-labeled oligonucleotides, including use of quenchers, and use in conjunction with multiplex PCR.
- The quantitative detection and measurement of polynucleotide analytes using fluorescent-labeled oligonucleotides in multiplex applications.

- Techniques for labeling probes and detecting multiple targets using fewer differently colored fluorophores than polynucleotide targets.
- Quantitative PCR (qPCR) and digital PCR (dPCR) and their application in detecting and measuring polynucleotide analytes, including in multiplex applications.

Pet. 10 (citing Ex. 1002 ¶ 73).

At this stage in the proceeding, Patent Owner does not dispute Petitioner’s definition of the person of ordinary skill in the art. Prelim. Resp. 26.

Because Petitioner’s uncontested definition of one of ordinary skill in the art is reasonable and consistent with the ’051 patent and the cited art, we adopt Petitioner’s definition for purposes of this Decision.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 100(b) (2019). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner has identified certain claim terms for which it has proposed constructions in a parallel proceeding. Pet. 27–29. Petitioner notes that it has

applied those constructions in the Petition. *Id.* at 29. Petitioner also asserts that “[o]ther terms, as used herein, are consistent with Patent Owner’s arguments and positions in the parallel proceeding,” without identifying those terms. *Id.* at 28. Patent Owner requests that the Board adopt Patent Owner’s proposed constructions from the parallel proceeding for certain claim terms. PO Prelim. Resp. 26–27. Neither party provides a discussion for their proposed constructions. In any event, for purposes of this Decision, we determine there is no need to expressly construe any claim term, as the parties appear to agree to the ordinary and customary meaning of the identified terms.

C. Obviousness over Saxonov

Petitioner asserts that independent claim 1 and its dependent claims 2–4 would have been obvious over Saxonov. Pet. 29–49. Patent Owner disagrees. Prelim. Resp. 44–56.

1. Saxonov

Saxonov, titled “Digital Assays with Multiplexed Detection of Two or More Targets in the Same Optical Channel,” relates to “performing a digital assay on a potentially greater number of targets through multiplexed detection of signals from reporters for two or more distinct targets in a common or shared channel.” Ex. 1004, code (54), ¶ 19. Saxonov was filed July 12, 2012, and claims the benefit of provisional application Nos. 61/507,082 and 61/510,013, filed July 12, 2011, and July 20, 2011, respectively. *Id.*, codes (22), (60).

Saxonov explains that digital assays

generally rely on the ability to detect the presence or activity of individual copies of an analyte in a sample. In an exemplary digital assay, a sample is separated into a set of partitions, generally of equal volume, with each containing, on average, less

than about one copy of the analyte. If the copies of the analyte are distributed randomly among the partitions, some partitions should contain no copies, others only one copy, and, if the number of partitions is large enough, still others should contain two copies, three copies, and even higher numbers of copies. The probability of finding exactly 0, 1, 2, 3, or more copies in a partition, based on a given average concentration of analyte in the partitions, is described by a Poisson distribution.

Id. ¶ 3. Saxonov explains that “[d]igital assays frequently rely on amplification of a nucleic acid target in partitions to enable detection of a single copy of an analyte,” and such “[a]mplification may be conducted via the polymerase chain reaction (PCR).” *Id.* ¶ 5. Saxonov states that “[a]mplification of the target can be detected optically from a fluorescent probe included in the reaction,” and “the probe can include a dye that provides a fluorescence signal indicating whether or not the target has been amplified.” *Id.*

According to Saxonov, “[a] new approach is needed to increase the multiplex levels of digital assays,” because increasing multiplex levels of digital assays currently require “instruments with more optical channels, to detect emission from more dyes, [which] are more expensive than those with fewer channels.” *Id.* ¶¶ 6, 7. Moreover, Saxonov explains that “increasing the number of distinguishable dyes is expensive and becomes impractical beyond a certain number.” *Id.*

To that end, Saxonov describes using a “common or shared channel (‘the same optical channel’)” to detect signals from “reporters for two or more distinct targets.” *Id.* ¶ 19. Saxonov explains that “[t]he reporters may include the same fluorophore, such as FAM or VIC, or different fluorophores with similar spectral characteristics, so that light from two or more reporters may be collected simultaneously in the same optical

channel.” *Id.* According to Saxonov, “[t]he assays may be constructed so that data for each target are distinguishable, for example, by choosing assays for each target that have sufficiently distinct endpoints (or time courses).” *Id.* This allows a determination of the contents of each sample or sample partition, i.e., “those with no targets, those with a first assay (assay 1) target, those with a second assay (assay2) target, and those with both, in a two-target assay.” *Id.*

Saxonov explains that “[t]he assays may be extended in various ways,” for example, “to involve analysis of more than two targets in the same channel.” *Id.* ¶ 20. In this regard, Saxonov exemplifies an assay for three targets that may generate eight clusters or populations of data, separated by intensity. *Id.* Saxonov explains that “some targets may be analyzed in one channel (e.g., a FAM channel), and one or more other targets may be analyzed in one or more other channels (e.g., a VIC channel).” *Id.* In this example, “[t]he targets, two in a first channel and one in a second channel, would again generate eight clusters or populations of data, but they would be separated in a two-dimensional intensity space and so in principle more easily resolvable.” *Id.*

The sample used in Saxonov’s system may be separated into partitions. *Id.* ¶ 28. “One or more signals may be created that are representative of light detected from the partitions.” *Id.* ¶ 36. Saxonov explains that “[t]he signal may represent an aspect of light, such as the intensity of the light, detected in the same optical channel from reporters for two or more distinct targets.” *Id.* Additionally, the signals “may include data collected in one or more different channels (e.g., in different wavelength ranges (color regimes) from reporters for the same and/or different targets).” *Id.*

Saxonov explains that “[t]he signal detected from each partition, and the partition itself, may be classified as being positive or negative for each of the reactions/targets contributing to the signal.” *Id.* ¶ 41. According to Saxonov, “[t]he data including all permutations of positives will generally fall into 2^N populations or clusters, here N is the number of targets, assuming that each population is distinguishable.” *Id.* The tables in Saxonov showing “[e]xemplary results for one, two, and three target systems in which data are collected in a single channel” are set forth below:

	Target A	Intensity
Population 2	+	Highest
Population 1	–	Lowest

	Target A	Target B	Intensity
Population 4	+	+	Highest
Population 3	+	–	Intermediate
Population 2	–	+	Intermediate
Population 1	–	–	Lowest

	Target A	Target B	Target C	Intensity
Population 8	+	+	+	Highest
Population 7	+	+	–	Intermediate
Population 6	+	–	+	Intermediate
Population 5	–	+	+	Intermediate
Population 4	+	–	–	Intermediate
Population 3	–	+	–	Intermediate
Population 2	–	–	+	Intermediate
Population 1	–	–	–	Lowest

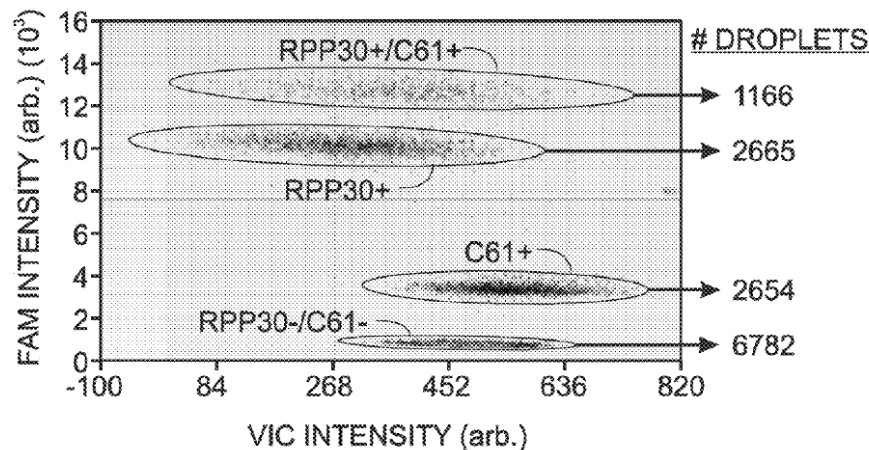
Each of the three tables – one for each system – contains a first column listing separate populations, subsequent column(s) indicating whether the target(s) for that system is/are present or absent in each population, and a

final column indicating the intensity detected, i.e., highest, intermediate or lowest, for each population. *See id.*

Saxonov exemplifies “a digital PCR assay, in which multiplexing in a single channel is used to assess copy number of the C61 gene.” *Id.* ¶ 60, Example 2. In this example, “signals from two probes, one for the gene of interest, C61, and one for a reference gene, RPP30, are collected together, as a single signal, in a single channel and used to assess the number of copies of the [C61] relative to the number of copies of the reference gene.” *Id.*

Saxonov states that Figure 5, set forth below, “is a graph showing data for the exemplary C61/RPP30 system.” *Id.* ¶ 63.

Fig. 5

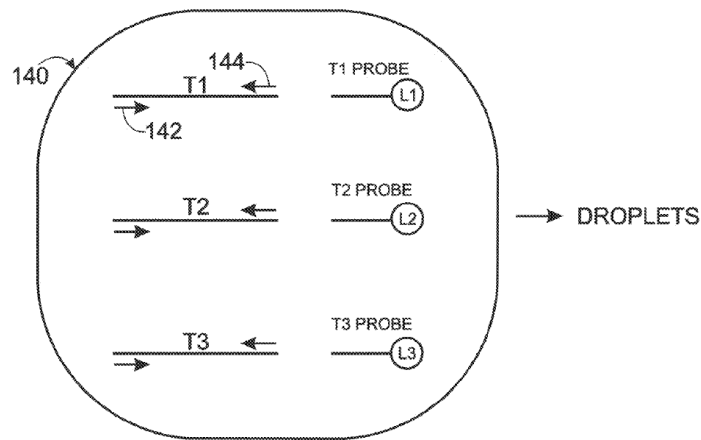


Ex. 1004, Fig. 5. Saxonov’s Figure 5 depicts a graph showing “droplet (or peak) intensities in arbitrary units (‘arb’) for a C61/RPP30 droplet assay, where data from reporters for C61 and RPP30 [genes] are collected together in the same optical channel and plotted as a function of intensity in a FAM [fluorophore] channel (vertical axis) versus intensity in a VIC channel (horizontal axis).” *Id.* ¶ 13. The RPP30-/C61- cluster of 6782 droplets “corresponds to droplets that are negative for RPP30 and C61 (i.e., droplets

that did not include either gene).” *Id.* ¶ 64. The C61+ cluster of 2654 droplets “corresponds to droplets that are positive for C61 and negative for RPP30 (i.e., droplets that included the C61 gene but did not include the RPP30 gene).” *Id.* ¶ 65. The RPP30+ cluster of 2665 droplets “corresponds to droplets that are positive for RPP30 and negative for C61 (i.e., droplets that included the RPP30 gene but did not include the C61 gene).” *Id.* ¶ 66. The RPP30+/C61+ cluster of 1166 droplets “corresponds to droplets that are positive for both RPP30 and C61 (i.e., droplets that included both genes).” *Id.* ¶ 67.

Saxonov’s Figure 9, shown below, “is a schematic representation of an exemplary bulk phase mixture being separated into droplets during performance of an exemplary digital assay with multiplexed detection of three or more distinct targets (e.g., identified here as T1, T2, and T3).” *Id.* ¶ 17.

Fig. 9

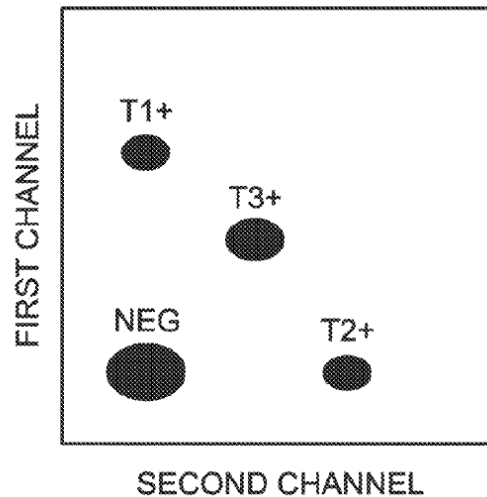


Ex. 1004, Fig. 9. Saxonov’s Figure 9 shows that “[m]ixture 140 may include a forward primer 142 and a reverse primer 144 for each target.” *Id.* ¶ 77. Saxonov describes that “luminescence from the T1–T3 probes, and more particularly, the L1, L2, and L3 luminophores, may report whether or not

target T1, T2, and T3, respectively, are present in each individual droplet.”
Id.

Saxonov’s Figure 10, shown below, “is a schematic representation of an exemplary graph showing droplet (or peak) intensities for a T1/T2/T3 droplet assay that may be performed with the droplets of FIG. 9.” *Id.* ¶ 18.

Fig. 10



Ex. 1004, Fig. 10. Saxonov’s Figure 10 shows that “[d]ata from the T1, T2, and T3 probes are collected in a first optical channel and a second optical channel and plotted as a function of intensity in the first channel (vertical axis) versus intensity in second channel (horizontal axis).” *Id.* ¶ 78.

Saxonov explains that the “[i]ntensities produced by exemplary populations or clusters of negative, T1-positive, T2-positive, and T3-positive droplets are identified by filled ellipses, with the size of each ellipse corresponding to the number of droplets in each population.” *Id.* According to Saxonov, “[t]o simplify the presentation, double-positive populations (T1+/T2+, T1+/T3+, and T2+/T3+) and the triple-positive population (T1+/T2+/T3+) are not shown.” *Id.*

2. *Prior Art Status of Saxonov*

The parties disagree as to whether Saxonov is available as prior art under 35 U.S.C. 102(e). The '051 patent issued on September 4, 2018, and claims the benefit of a provisional application filed on February 3, 2012. Ex. 1001, codes (45), (63), 1:6–11. For purposes of this proceeding, the parties agree that the '051 patent is entitled to its earliest filing date of February 3, 2012. *See* Pet. 6; Prelim. Resp. 6. Saxonov was filed on July 12, 2012. Ex. 1004, code (22). To assert Saxonov as prior art to the '051 patent, Petitioner relies on the filing date of the Saxonov provisional application, U.S. Provisional Patent Application Ser. No. 61/510,013, filed July 20, 2011 (Ex. 1007, “the '013 provisional”). Pet. 11 (citing Ex. 1004, code (60)).

A reference patent or published application may be entitled to the benefit of its provisional application’s filing date for pre-AIA 35 U.S.C. § 102(e) prior art purposes when two conditions are met: (1) the provisional provides sufficient support for at least one claim in the reference patent or published patent application; and (2) the provisional application provides sufficient support for the subject matter relied upon for prior art purposes in the reference patent or application. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1377, 1381–82 (Fed. Cir. 2015); MPEP §§ 2136 (I), 2136.03 (III), 2136 (Examples 2, 4, 7); *see, e.g., Google LLC v. Ikorongo Tech, LLC*, IPR2021-00058, Paper 14 at 10–12 (PTAB May 10, 2021). The burden of production is on the Petitioner to show in its Petition that the asserted references qualify as prior art. *See Dynamic Drinkware*, 800 F.3d at 1380 (explaining that a petitioner bears the initial burden of production to establish that the asserted references qualify as prior art).

In the Petition, Petitioner asserts that “Saxonov is § 102(e) prior art as of at least the filing of the '013 provisional, July 20, 2011, because the '013

provisional supports Saxonov's method of performing a digital assay recited in its claim 1." Pet. 11. In support of that assertion, Petitioner provides a chart indicating disclosures in the '013 provisional that Petitioner asserts support each limitation of claim 1 of Saxonov, i.e., the first condition noted above. *Id.* at 12–15. The issue here is whether Petitioner addressed sufficiently the second condition to show that Saxonov is entitled to the benefit of the '013 provisional priority date for purposes of pre-AIA 35 U.S.C. § 102(e), i.e., that the provisional provides sufficient support for the subject matter relied upon in Saxonov for prior art purposes.

Patent Owner asserts that Saxonov is not prior art because the Petitioner has not demonstrated that the relied-upon subject matter in Saxonov was carried over from the Saxonov '013 provisional. Prelim. Resp. 28. Further Patent Owner contends that the '013 provisional "does not actually disclose all of the relied-upon subject matter" because some of that subject matter was "newly added when Saxonov was converted to a non-provisional," which was filed after the '051 patent's earliest priority date. *Id.* For example, Patent Owner alleges that Saxonov Figures 9 and 10, along with paragraphs 17, 18, 37, and 76–79, which are relied upon by Petitioner, are not found in, or supported by, the Saxonov '013 provisional. *Id.* at 40–43.

We authorized additional briefing for Petitioner to address Patent Owner's contention that Petitioner failed to demonstrate in the Petition that Saxonov is prior art. *See* Ex. 3001. In that briefing, Petitioner asserts that "for every element, the Petition has not just citations to material in Saxonov that is duplicated in the '013 provisional but also added concurrent citations specifically to the provisional." Pet. Reply 1–2. Further, Petitioner alleges that none of the disputed material in Figures 9 and 10, or in paragraphs 17,

18, 37, 76, and 79 is “truly essential,” because “[w]here the Petition cites this material, it also cites other disclosure that is in both Saxonov and the ’013 Provisional.” *Id.* at 2.

Having considered the arguments and evidence, we agree with Patent Owner that Petitioner has not demonstrated sufficiently in the Petition, for purposes of institution, that all of the portions of Saxonov relied upon in the Petition are prior art. In particular, we determine that Petitioner has not established that the disputed portions of Saxonov are entitled to claim the benefit of the ’013 provisional filing date because Petitioner has failed to satisfy the second condition for this benefit, i.e., by showing that the provisional application provides sufficient support for certain subject matter in Saxonov relied upon for prior art purposes in the Petition.

To begin, we determine, contrary to Petitioner’s assertion, that the Petition relies upon Saxonov Figures 9 and 10, and Saxonov paragraphs 17, 18, 37, 76, and 79 for its obviousness contentions. Petitioner’s reliance on these disclosures in the Petition is apparent upon review of its discussion of how Saxonov allegedly teaches or suggests elements of the challenged claims. *See, e.g.*, Pet. 29–49, 57. We also note that Patent Owner has provided a table in the Preliminary Response that itemizing references to Saxonov in the Petition. *See* Prelim. Resp. 41–43. Petitioner does not establish that those disclosures are not relied upon by merely asserting that “[w]here the Petition cites this material, it also cites other disclosure that is in both Saxonov and the ’013 Provisional,” *see* Pet. Reply 2, without persuasively demonstrating that references to the disputed disclosures in Saxonov are not essential to Petitioner’s contentions. Insofar as Petitioner relies upon the Board to assume this task, we decline to do so.

In this regard, we note, however, that based upon our review of the Petition, we find a number of references to the disputed disclosures in Saxonov in Petitioner’s discussion of the challenged claim elements without any concurrent citations to the ’013 provisional. *See, e.g.*, Pet. 30–49, 57. Even where Petitioner provides citations to the ’013 provisional in the Petition, Petitioner does so as part of a string cite without any parenthetical describing the cited disclosure in ’013 provisional or how it alone supports the challenged claim element. *See id.* So, even in those instances, it is not readily apparent to us that the reliance upon Saxonov is not essential.

We next consider whether Petitioner has shown sufficiently in the Petition that the subject matter in Saxonov cited and relied upon – in particular, the disputed disclosures in Saxonov Figures 9 and 10, and Saxonov paragraphs 17, 18, 37, 76, and 79, are found in or supported by the ’013 provisional. According to Petitioner, it has shown how the disputed disclosures in Saxonov were carried forward from the ’013 provisional by citing in the Petition “specific supporting disclosure from the ’013 provisional.” Pet. Reply 2. We disagree. While we have determined that parallel citation to identical or nearly identical disclosures in a provisional application may be sufficient to support priority, we have explained that such is not the case where the significance of a citation to the provisional as it relates to the relied upon art is not readily apparent. *See, e.g., Google*, IPR2021-00058, Paper 14 at 13–15. Here, we do not focus on Petitioner’s parallel citations to the provisional for Saxonov disclosures that are identical or nearly identical in the provisional. Rather, Patent Owner’s contentions and our analysis focus on the disputed disclosures in Saxonov, i.e., the figures and paragraphs in Saxonov that do not appear in the ’013 provisional.

For its part, in the Reply, Petitioner generalizes the disclosures of Figure 10 and paragraphs 18 and 76–79 of Saxonov as “all pertain[ing] to Example 4 of Saxonov, where three targets are detected using just two colors, a scenario that yields eight distinct populations of droplets.” Pet. Reply 2. Petitioner then asserts that “the ’013 provisional teaches detecting more targets than there are colors on page 9.” *Id.* at 3. Petitioner also directs us to a single page in the Petition that discusses how the provisional allegedly supports this description of Saxonov Figure 10 and paragraphs 18, 76–79. *See id.* (citing Pet. 57). This is the only discussion in the Petition identified by Petitioner regarding how the ’013 provisional allegedly supports any of the disputed disclosures in Saxonov.

However, even here, the discussion is insufficient. We note in the same paragraph at page 57 of the Petition, Petitioner additionally relies on Saxonov Figure 10 and paragraph 78 to assert that, “[i]mportantly, Saxonov contemplates that if droplets are generated that have combinations of multiple targets, the droplets with the different combinations of targets can be distinguished from one another.” Pet. 57 (citing Ex. 1004 ¶ 78). Petitioner’s citation to Saxonov alone for that assertion includes a parenthetical quote from Saxonov paragraph 78 describing Figure 10, which explains that the “double-positive populations (T1+/T2+, T1+/T3+, and T2+T3+) and the triple-positive population (T1+/T2+/T3+) are not shown.” *Id.* (quoting Ex. 1004 ¶ 78). Petitioner has not identified any discussion in the Petition of how the ’013 provisional supports this aspect of Figure 10 and paragraph 78. Instead, Petitioner offers in the Reply that, “[a]s to the eight populations of droplets described in Figures 10 and ¶ 78, the ’013 provisional at 5:19-6:3, discloses precisely this, teaching assays that can be ‘extended’ and explaining that such an assay for three targets generates

‘eight clusters or populations of data, separated by intensity,’ just as in Figure 10.” Pet. Reply 3. According to Petitioner, it is sufficient that it cited to this portion of the provisional elsewhere in the Petition, without explaining anywhere in the Petition how it supports this aspect of Figure 10 and paragraph 78. *See id.* at 2–3. We disagree.

Petitioner also asserts for the first time in the Reply that one of the tables in Saxonov paragraph 41, which appears in the ’013 provisional at 9:4–10:3 and is cited in the Petition, is, “[i]n essence, . . . Figure 10 of Saxonov in tabular form.” *Id.* at 3–4. Petitioner has not provided persuasive evidence to support that assertion. Further, although we authorized Petitioner to file a Reply addressing Patent Owner’s contention in the Preliminary Response that the Petition does not demonstrate the cited material in Saxonov is prior art, *see* Ex. 3001, Petitioner was not authorized to use the Reply as a means to supplement its Petition with descriptions of how the ’013 provisional allegedly supports the relied-upon Saxonov disclosures that are missing in the Petition.

For Saxonov Figure 9 and paragraphs 17, 37, and 77, Petitioner similarly refers us to instances in the Petition wherein those citations appear, while asserting that the Petition also cites supporting disclosures from the ’013 provisional. Pet. Reply 4 (citing Pet. 35, 41, 46–47). We find that assertion misleading. For example, at page 35 of the Petition, we find a citation to Saxonov Figure 9 and paragraph 77 without a corresponding citation to the ’013 provisional. *See* Pet. 35. Petitioner asserts that this page of the Petition cites to the ’013 provisional at 13:14–17, however, that citation does not appear alongside the reference to Saxonov Figure 9 or paragraph 77. In another instance, a citation to the ’013 provisional appears along with cites to a number of disclosures in Saxonov, such that it is

unclear to which citations in Saxonov they purport to support. In each instance, in any event, Petitioner has not shown that the Petition describes how the cited provisional disclosure supports the relied-upon disclosure in Saxonov. Here again, insofar as Petitioner relies upon the Board to assume this task, we decline to do so.

Thus, because Petitioner has not shown sufficiently that the Petition explains how each of the relied-upon disclosures in Saxonov Figures 9 and 10, and Saxonov paragraphs 17, 18, 37, 76, and 79, which are not present in the '013 provisional, are supported by the '013 provisional, we determine that Petitioner has not shown that those cited portions of Saxonov are entitled to the priority date of the '013 provisional. Accordingly, on this record, we determine that those relied-upon portions of Saxonov do not qualify as prior art to the '051 patent.

3. *Conclusion*

For this ground based on Saxonov alone, which relies on portions of Saxonov that Petitioner has not shown to be prior art to the '051 patent, we determine that Petitioner has failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '051 patent based on this reference.

E. Remaining Grounds

Each of the remaining grounds asserted in the Petition relies on Saxonov to reach a number of limitations of independent claim 1 and the challenged dependent claims. Because Petitioner has not shown that all of the relied-upon portions of Saxonov are prior art to the '051 patent, we determine that Petitioner has failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '051 patent in any of the remaining grounds.

F. 35 U.S.C. § 314(a)

Because we deny institution upon consideration of the merits of Petitioner's challenges, Patent Owner's argument that we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution is moot.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not established a reasonable likelihood of prevailing in its assertion that at least one challenged claim of the '051 patent is unpatentable. Accordingly, we deny the Petition and decline to institute the requested *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no trial is instituted.

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