IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:	)
U.S. Patent No. 11,392,818	)
Issued: Jul. 19, 2022	)
Application No.: 17/216,096	)
Filing Date: Mar. 29, 2021	)

For: **Graphically Encoded Icons Having Intrinsic Attributes Embedded Therein and Systems and Methods for Using Same**

DECLARATION OF MAJID SARRAFZADEH IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,392,818

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2. Claim 10: "The graphically encoded icon of claim 9, wherein the machine-readable indicia of the stimuli-responsive material is non-human readable." 96

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I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Abbott Laboratories ("Petitioner") to provide my opinion concerning the validity of certain claims of U.S. Patent No. 11,392,818 (attached to the accompanying Petition as Ex. 1001 and referred to as "the '818 patent") in support of Petitioner's Petition for Inter Partes Review of the '818 patent.

2. I understand that Abbott Laboratories is petitioning for IPR of claims 1 and 4-20 of the '818 patent and requests that the United States Patent and Trademark Office ("PTO") cancel those claims.

3. I received Bachelor of Science, Master of Science, and Ph.D. degrees from the University of Illinois at Urbana-Champaign in Electrical and Computer Engineering in 1982, 1984, and 1987, respectively.

4. I am a Distinguished Professor and Levi Knight Endowed Chair for Innovation at the University of California Los Angeles ("UCLA"). I have been a professor in the Computer Science and Electrical Engineering Departments at UCLA since 2000. In 2008, I co-founded and became a director of the UCLA Wireless Health Institute. I currently teach core undergraduate courses in digital design and graduate courses in embedded systems and technologies for healthcare.

5. Before working at UCLA, I was a professor in the Department of Electrical and Computer Engineering at Northwestern University from 1987 to 2000, receiving tenure in 1993.

6. I am a Fellow of the Institute of Electrical and Electronics Engineers, Inc. ("IEEE"), which "is a distinction reserved for select IEEE members whose extraordinary accomplishments in any of the IEEE fields of interest are deemed fitting of this prestigious grade elevation."

7. My areas of research interest include embedded medical systems, design and analysis of algorithms, and health analytics. My experience includes work as a system designer, circuit designer, and software designer. I have held positions as a design engineer at IBM and Motorola and a test engineer at Central Data Corporation. I was the main architect of an Electronic Design Automation ("EDA") software tool for Monterey Design Systems, Inc. ("Monterey"). I co-founded and managed the technical team at Hierarchical Design, Inc. ("Hier Design"), an EDA company that specialized in reconfigurable Field Programmable Gate Array (FPGA) systems. Hier Design was acquired by Xilinx in 2004. I cofounded Bruin Biometrics and WANDA Health.

8. I also the co-founded MediSens, which developed a Wearable Sensor Platform which is focused on addressing the unmet needs of incontinence management. This innovation received the public prize for innovation at Health Valley Event in 2018 and also won the Top 100 North America innovation award.

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9. I co-invented a first-of-its kind wound-assessment scanner that detects bed sores before they start, which was FDA-approved in 2019 and was awarded one of Time Magazine's Best Inventions of 2020.

10. I also developed WearSens, a nutrition monitoring necklace, that has been highlighted by Popular Science, CBS News, People, New York Magazine, the New York Daily News, The Daily Mail (U.K.), Yahoo Lifestyle UK, and MTV News.

11. I was also elected as a fellow in the National Academy of Inventors. The fellow award states that I have "demonstrated a highly prolific spirit of innovation in creating or facilitating outstanding inventions that have made a tangible impact on the quality of life, economic development, and welfare of society."

12. I have published over 590 papers and have received a number of best paper and distinguished paper awards. I am a co-author of the book "Synthesis Techniques and Optimizations for Reconfigurable Systems" (2003 by Springer) and a co-author of papers such as:

- Gait Analysis Utilizing an IMU for Toe Walking Detection and Intervention, EAI HealthyIoT (2021) (Best Paper Award)
- A Robust Distributed Remote Health Monitoring System for Rural Area with Limited Internet Access, 11th International Conference on Body Area Networks, Turin, Italy (2016)

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- Remote Patient Monitoring after Discharge of Hospitalized Heart Failure Patients: The Better Effectiveness after Transition - Heart Failure (BEATHF) Randomized Controlled Trial, 2016 Annual Academy Health Research Meeting, Boston, USA (2016) (Best Abstract Award)
- High Performance Multi-dimensional Signal Search With Applications in Remote Medical Monitoring, 2013 IEEE Body Sensor Network Conference, Cambridge, Massachusetts, USA (2013)
- Dynamic Self-adaptive Remote Health Monitoring System for Diabetics, 34th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Hilton Bayfront Hotel in San Diego, California, USA (2012)
- CustoMed: A Power Optimized Customizable and Mobile Medical Monitoring and Analysis System, Proceedings of the ACM HCI Challenges in Health Assessment Workshop in conjunction with Computer Human Interaction (CHI) Portland, OR (2005)

13. A full list of titles of my papers, patent filings, and other research is included in my Curriculum Vitae (Ex. 1004), also including a more detailed summary of my background, experience, and awards.

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II. SUMMARY OF MATERIALS REVIEWED AND CONSIDERED

14. All of the opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this Declaration, while drawing on my experience in the field of remote medical diagnostic monitoring, I reviewed the following documents:

Ex.	Description
1001	U.S. Patent No. 11,392,818 ("'818 Patent")
1002	File History of U.S. Patent No. 11,392,818 ("'818 FH")
1003	Declaration of Majid Sarrafzadeh ("Sarrafzadeh Decl.")
1004	Curriculum Vitae of Majid Sarrafzadeh
1005	U.S. Patent Application Publication No. US 2016/0292486 ("Prusik")
1006	U.S. Patent No. 7,691,634 ("Vaillant")
1007	U.S. Patent Application Publication No. US 2015/0308961 ("Burg")
1008	U.S. Patent No. 10,146,909 ("Dimov")
1009	Joseph Kerry & Paul Butler, *Smart Packaging Technologies for Fast Moving Consumer Goods* 33-74 (2008) ("Kerry")
1010	U.S. Patent No. 10,229,387 ("Wade")
1011	Antonacci et al., *Commercially Available (Bio)sensors in the Agrifood Sector*, 74 Comprehensive Analytical Chemistry 1 (2016) ("Antonacci")
1012	U.S. Patent No. 9,221,273 ("Hyde")
1013	U.S. Patent Application Publication No. US 2009/0020609 ("Cohen")
1014	U.S. Patent No. 7,600,912 ("Leute")
1015	U.S. Patent Application Publication No. US 2015/0021401 ("Rajagopal")

Ex.	Description
1016	Jerry Zeyu Gao et al., *Understanding 2D-BarCode Technology and Applications in M-Commerce – Design and Implementation of A 2D Barcode Processing Solution*, IEEE Xplore (Aug. 2007) ("Gao")
1017	U.S. Patent No. 9,811,632 ("Grabiner")
1018	U.S. Patent No. 5,929,422 ("Lappe '422")
1019	U.S. Patent No. 6,036,092 ("Lappe '092")
1020	U.S. Patent No. 6,685,094 ("Cameron")
1021	U.S. Patent No. 6,770,487 ("Crosby")
1022	U.S. Patent No. 10,318,781 ("Prusik '781")
1023	U.S. Patent No. 5,496,702 ("Bishop")

15. My opinions are also guided by my appreciation and understanding of how a person of ordinary skill in the art would have understood the claims of the '818 patent at the time of the alleged invention, which I have been asked to assume is November 22, 2017.

III. LEVEL OF ORDINARY SKILL IN THE ART

16. I understand that certain issues relating to validity must be judged from the perspective of a person of ordinary skill in the art ("POSITA"). I was asked to apply the November 2017 timeframe for my analysis.

17. The '818 patent related to "graphically encoded icons" (such as letters or symbols on a label) that are used to convey information about an object using "machine-readable indicia including both static and variable information." *See, e.g.*, Ex. 1001 at 1:23-27, 1:39-47, 5:41-43. The variable portion uses "stimuli-responsive

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materials" that change based on an attribute of the object. Ex. 1001 at 6:3-54. As discussed below in the Technology Overview section, this type of technology is used in a variety of industries, including the transportation, packaging, biomedical, pharmaceutical, and logistics industries. *See* Section VII.

18. A POSITA as of November 2017 would have had a bachelor's degree in computer science, electrical engineering, systems engineering, biomedical engineering (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating embedded systems, graphically encoded icons, or diagnostic systems that provide dynamic information. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. A POSITA may be part of an interdisciplinary team with others having the relevant experience set forth above.

19. In the November 2017 timeframe, I would have exceeded the level of skill of a POSITA and worked with others possessing at least the knowledge of a POSITA within that time period.

20. I understand that a POSITA is a hypothetical person who is assumed to be aware of all pertinent information that qualifies as prior art. In addition, a POSITA makes inferences and is a person of ordinary creativity.

21. I do not expect that my opinions would change under other reasonable descriptions of a POSITA.

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IV. THE '818 PATENT: SUMMARY

A. Description

22. The '818 patent is entitled "Graphically encoded Icons Having Intrinsic Attributes Embedded Therein and Systems and Methods for Using Same." I understand that the '818 patent is assigned to Newtonoid Technologies, LLC ("Patent Owner").

23. The '818 patent is directed to "graphically encoded icons" such as characters or symbols on a label that are used to convey information about an object. *See, e.g.*, Ex. 1001 at 1:23-27 ("The disclosure relates generally to the field of graphically encoded icons. More specifically, the disclosure relates to graphically encoded icons having intrinsic attributes embedded therein, and to systems and methods for using such graphically encoded icons."), 1:39-47 ("In one embodiment, a graphically encoded icon comprises a label attached to an object. The label includes a static portion and an intrinsic portion. The static portion has an area of machine-readable indicia. The intrinsic portion includes at least one area comprising a stimuli-responsive material. The stimuli-responsive material is configured to change from a first state to a second state in response to a trigger, and the change in state is based on an attribute about the object.").

24. The specification provides a timeline for the development of this technology, explaining that "[u]p until the late 1800s, commercial establishments

tracked their inventory primarily by hand." Ex. 1001 at 3:49-50. But this "[m]anual entry of large amounts of data" was "laborious," "time consuming," and "prone to error." Ex. 1001 at 3:51-54. To alleviate these issues, "machine readable indicia" were developed, including barcodes in the 1950s and two-dimensional barcodes (such as QR codes) in the late 1980s. Ex. 1001 at 3:54-5:32. Figures 1 and 2 of the '818 patent, which are reproduced below, show these well-known machine-readable barcodes and readers.

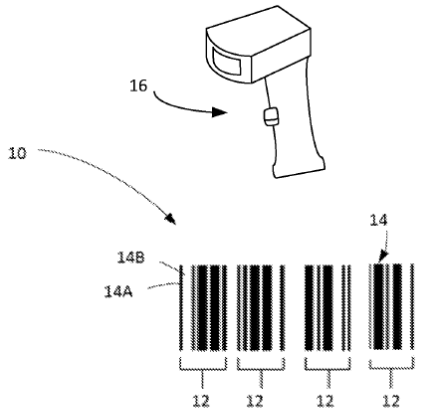


FIG. 1
(PRIOR ART)

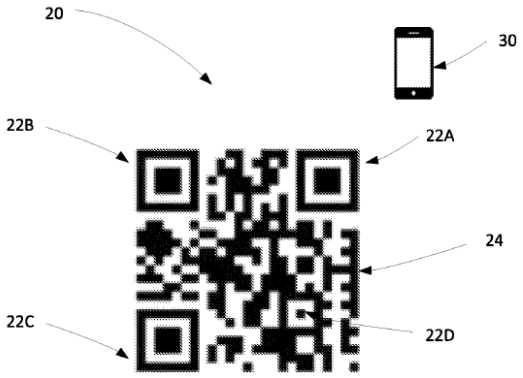


FIG. 2
(PRIOR ART)

25. By scanning these codes, these readers may collect and track product information including name, source, or price. But these well-known ways of conveying information were allegedly "limited" because "the information" is "static," meaning it cannot convey "variable information" such as the object's current temperature or quantity. Ex. 1001 at 5:36-40.

26. To overcome this, the ’818 patent discloses “machine-readable indicia including both static and variable information.” Ex. 1001 at 5:41-43. The ’818 patent accomplishes this not with any improved technology, but instead by using a known static portion such as “a traditional one-dimensional barcode” and a known variable portion (an “intrinsic attribute portion” with “stimuli-responsive materials” that change based on an attribute of the object). Ex. 1001 at 6:3-54. For example, Figure 3A, reproduced below, show a label with a “graphically encoded icon 310 [that] includes a static portion 312 and an intrinsic attribute portion 314.” Ex. 1001 at 6:3-5.

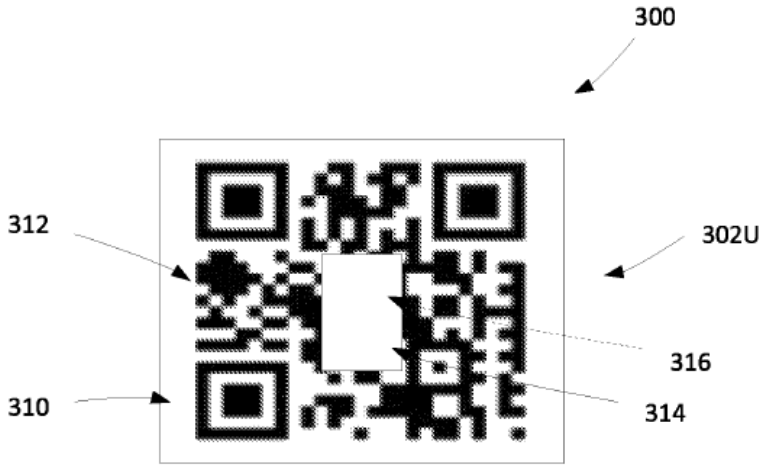


FIG. 3A

27. This intrinsic attribute portion 314 changes states based on a trigger. Ex. 1001 at 6:23-24. This portion could be, for example, “temperature sensitive ink” that is initially “invisible to the naked eye” but then appears, or changes color, “based on

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temperature." Ex. 1001 at 6:24-38. It could also be a "commercially available" item such as a litmus strip or magnetic film containing a known substance that "exhibit[s] a visible change based on factors such as humidity, pH, the wavelength and/or intensity of impinging light, an electrical field, a magnetic field." Ex. 1001 at 6:38-51. The '818 patent thus convey static and variable information by merely applying a combination of traditional and "commercially available" techniques.

28. The '818 patent further discloses a specific example of this combination in the form of a label on shrimp containers, as illustrated in Figure 4B reproduced below. In addition to the conventional QR code, the intrinsic attribute portion 414 of label 401 (left) "displays a trigger notification 420 (an X in this example)" signifying that the shrimp container was in an environment where the temperature exceeded – negative 22 degrees Fahrenheit. Ex. 1001 at 8:2-8. This indicator may use "commercially available" products like thermochromic (i.e., temperature sensitive) ink that changes colors based on temperature. Ex. 1001 at 6:35-38. The intrinsic attribute portion 414 of label 401' (shown on the right) does not display this trigger notification, meaning that the label was not exposed to a temperature exceeding 22 degrees Fahrenheit.

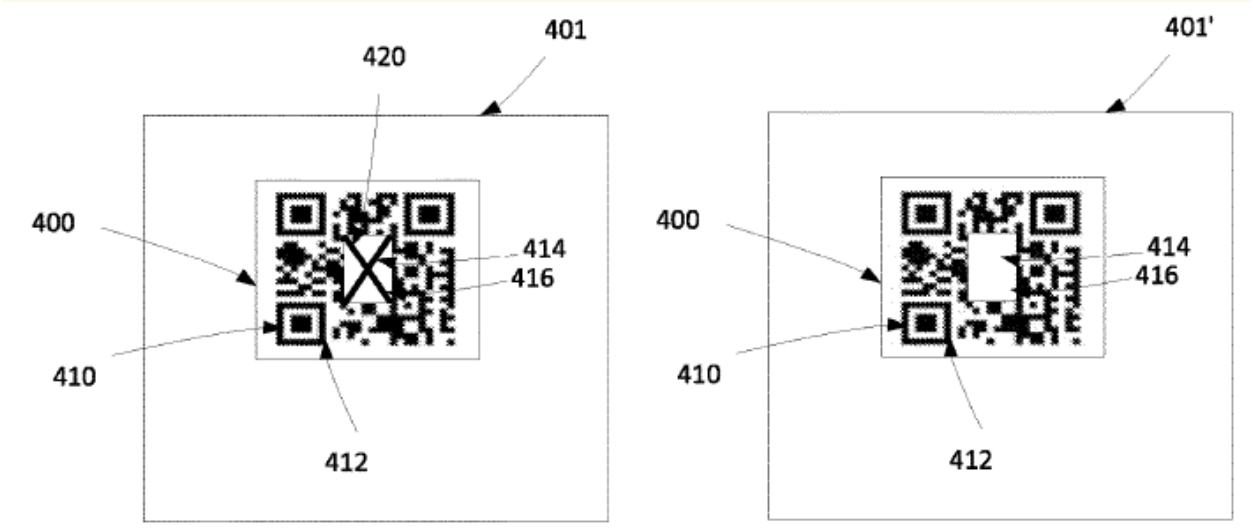


FIG. 4B

29. The human- or machine-readable variable indicator thus indicates that the shrimp labeled with label 401 may be spoiled, while the shrimp labeled with label 401' was maintained at a proper temperature. Ex. 1001 at 8:5-16.

B. The Challenged Claims

30. The '818 patent has 20 claims, including independent claims 1, 8, 14, and 16. I understand that claims 1, 4-20 are being challenged in Petitioners' petition for *inter partes* review. Each element of each challenged claim are recited below in the sections below that describe each ground of invalidity.

C. Prosecution History

31. I have reviewed the file history of the '818 patent (Ex. 1002).

32. The ’818 patent originates from U.S. Patent Application 17/216,096 (“’096 application”), filed March 29, 2021. The ’818 patent claims priority to two earlier non-provisional applications, and two provisional applications, the earliest of which was filed November 22, 2017.

33. The as-filed claims of the ’096 application were broadly directed to a graphically encoded icon with a machine-readable static portion (such as a barcode) and an intrinsic portion with stimuli-responsive material. Ex. 1002 at 152-155. The Examiner rejected claims 8-13 as anticipated by U.S. Patent Application Publication 2017/0169738 (“David,” Ex. 1024), but found that dependent claims 14 and 15 would patentable if written as independent claims. Ex. 1002 at 47-48. Specifically, claim 14 recited a “transformation of the stimuli-responsive material” to be “a change in reflection,” and claim 15 recited a “transformation of the stimuli-responsive material” to be a change in “transparency.” The Examiner also issued a nonstatutory double patenting rejection for claims 1-9, 12-20, which include limitations relating to use of the graphically encoded icon in a transaction. Ex. 1002 at 48-55.

34. In response, the applicant filed terminal disclaimers to overcome the double patenting rejections, incorporated claim 15’s elements into independent claim 8, and rewrote claim 14 as an independent claim. Ex. 1002 at 35-41.

35. In issuing a Notice of Allowance, the examiner noted the terminal disclaimer and amendment as the reasons for allowance. Ex. 1002 at 8-14. During

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prosecution, the Examiner did not consider or cite to any of the art used in the grounds of Petitioners' petition.

V. UNDERSTANDING OF LEGAL PRINCIPLES

36. I am not an attorney, but I have been informed by counsel of certain legal standards and have applied those standards, described below, in formulating my opinions.

37. I understand that the claims of a patent define the limits of the patentee's exclusive rights. I understand that to determine the scope of the claimed invention, courts may construe claim terms, the meaning of which the parties may dispute. I understand that claim terms should generally be given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of filing of the patent application.

38. I understand that claims must be construed in light of and consistent with the intrinsic evidence. In this context, I understand that intrinsic evidence includes the claims themselves, the written disclosure in the specification, and the patent's prosecution history, including prior art that was considered by the United States Patent and Trademark Office. I understand that the specification is always highly relevant to the claim construction analysis and often is the single best guide to the meaning of a disputed term. I understand that extrinsic evidence may also be considered when construing claims and may include, for example, technical

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dictionaries, technical publications and books, treatises, and expert testimony, though the intrinsic record will be more persuasive as to the meaning of a particular term.

39. I understand that a claim of a patent is anticipated when a single prior art document describes every element of the claimed invention. The reference must not only disclose all elements of the claim, but must also disclose those elements arranged or combined as in the claim.

40. I understand that a prior art reference can render a patent claim obvious to one of ordinary skill in the art if the differences between the subject matter set forth in the patent claim and the prior art are such that the subject matter of the claim would have been obvious at the time the claimed invention was made.

41. In analyzing obviousness, I understand that it is important to consider the scope of the claims, the level of skill in the relevant art, the scope and content of the prior art, the differences between the prior art and the claims, and any secondary considerations (or objective indicia of non-obviousness).

42. I understand that claimed subject matter is obvious when a person of ordinary skill in the art would have been motivated to combine preexisting elements and that combination yields no more than would have been expected.

43. I also understand that in assessing whether a claim is obvious, one must consider whether the claimed improvement is more than the predictable use of prior art elements according to their established functions. I understand that there need not

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be a precise teaching in the prior art directed to the specific subject matter of a claim because one can take account of the inferences and creative steps that a person of skill in the art would employ. I further understand that a person of ordinary skill is a person of ordinary creativity, not an automaton.

44. I understand that obviousness cannot be based on the hindsight combination of components selectively culled from the prior art. I understand that in an obviousness analysis, neither the motivation nor the avowed purpose of the inventors controls the inquiry. Any need or problem known in the field at the time of the invention and addressed by the patent can provide a reason for combining elements. For example, I understand that it is important to consider whether there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent's claims. I understand that known techniques can have obvious uses beyond their primary purposes, and that in many cases a person of ordinary skill can fit the teachings of multiple pieces of prior art together like pieces of a puzzle.

45. I understand that certain issues relating to validity must be judged from the perspective of a person of ordinary skill in the relevant art. I further understand that factors that may be considered in determining the level of skill of a person of ordinary skill in the art include, but are not limited to, (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with

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which innovations are made; (4) sophistication of the technology; and (5) the educational level of active workers in the field.

46. I have been informed and understand that a person of ordinary skill in the art is a hypothetical person who is presumed to be aware of all pertinent prior art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. Importantly, this hypothetical person is of ordinary skill in the art to which the claimed subject matter pertains.

47. I understand that, when there is a reason to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. I further understand that, if this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense, which bears on whether the claim would have been obvious.

48. I understand that secondary considerations (objective indicia) can include, for example, evidence of commercial success of the invention, evidence of a long-felt need that was solved by an invention, evidence that others copied an invention, or evidence that an invention achieved a surprising result. I further understand that such evidence must have a nexus, or causal relationship to the elements of a claim, in order to be relevant. I am unaware of any such secondary considerations for the ’818 patent.

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VI. CLAIM CONSTRUCTION

49. In my analysis, I have applied the plain and ordinary meanings of the claim terms in the ’818 patent, as a person of ordinary skill in the art would have understood them in the context of that patent in approximately November 2017. However, my analysis does not depend on any particular or precise construction of a term, because I did not find that to be necessary to provide my opinions regarding the relationship between the prior art and the claims of the ’818 patent. The opinions that I provide in this declaration would remain true under any reasonable construction of the claim terms in the ’818 patent.

VII. TECHNOLOGY OVERVIEW

50. In this section, I provide overviews of technologies and prior art pertinent to the ’818 patent and to the state of the art as of the ’818 patent’s earliest possible priority date of November 22, 2017. In later sections, I evaluate in detail how the prior art discloses and renders obvious the recitations of each limitation in the challenged claims, and the challenged claims as a whole.

51. The prior art references described below and discussions of what was known to a POSITA provide a general description of the state of the art at the time of the invention, provide additional motivation to modify the primary references evaluated in the grounds of invalidity with the knowledge of a person of ordinary skill in the art or other references cited herein, and provide support for why a person

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of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the references. The additional prior art references identified in this section are exemplary in nature and are included to provide factual support for my opinions.

52. The ’818 patent is directed to using graphically encoded icons to convey information about an object. *See, e.g.*, Ex. 1001 at 1:23-27, 1:39-47. Specifically, the ’818 patent’s system has both static and variable information. The static portion may be a conventional one-dimensional barcode, while the variable portion uses "stimuli-responsive materials" that react to changes in the object's attributes, such as temperature-sensitive inks that become visible or change color in response to temperature changes. Other examples include substances that react to humidity, pH levels, light, electrical fields, or magnetic fields, similar to existing technologies like litmus strips or magnetic films. Ex. 1001 at 6:31-54.

53. This technology was well-developed before the November 2017, the earliest priority date of the ’818 patent. Below, I discuss the basic concepts behind such graphically encoded icons that have a stimuli-responsive material.

A. Bar Codes

54. Barcodes allow information to be easily stored, transferred, processed, and validated – all in a machine-readable format. Ex. 1016 at 2. Barcodes have existed for decades, and data is traditionally stored on the barcode through parallel

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lines that have different widths. Ex. 1016 at 2. These first types of barcodes – known as 1D or 1-dimensional barcodes, could only encode numbers. Ex. 1016 at 2.

55. The first 1D barcodes were used for railway transportation and tracking of goods, and since then, have been used ubiquitously, including in manufacturing, postal, transportation, government, health care, retail business, trade show, and automotive businesses. Ex. 1016 at 2.

56. Over time, new linear barcodes were developed to encode both numbers and letters in a sequence of varying width bars and spaces so that it can be machine-read, retrieved, processed, and validated. The simplicity and low cost of using barcodes make barcodes a widely used way to encode textual information that can be easily and accurately be read using electronic readers. Ex. 1016 at 1.

57. One example of a commonly used one-dimensional barcodes is the Universal Product Code (UPC). The UPC was introduced in 1971 to provide an efficient method of matching a product against a database containing pricing and inventory information as well as for recording sales. Ex. 1013 at [0006]; Ex. 1020 at 1:18-26. When the bar codes were scanned at cash registers, the resulting transaction data was stored electronically, and by using this transaction data, businesses could track product sales. Ex. 1020 at 1:18-26.

58. A second type of bar code is CODE-39 (three of nine), which are used extensively by the Department of Defense for logistics, to inventory, track and trace

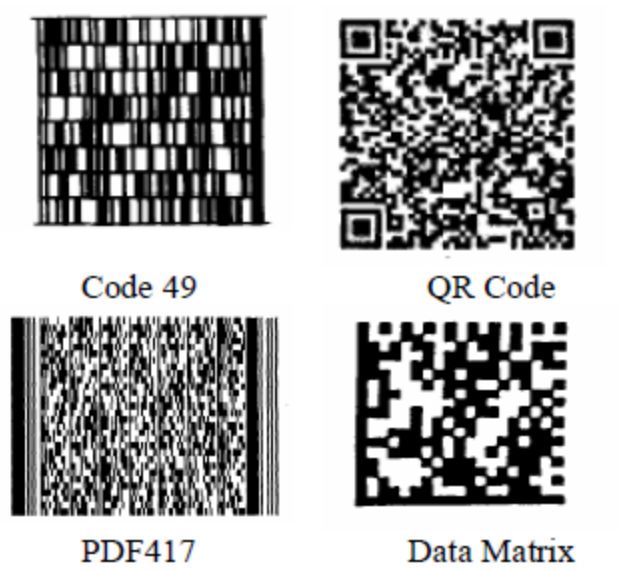
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items of interest. Ex. 1013 at [0006]. CODE-39 is an extensible code allowing for a greater quantity of data to be included in the barcode's displayed code. Ex. 1013 at [0006]. Another is POSTNET barcodes, which are used by the US Postal Service to code ZIP Code information for automatic mail sorting. Ex. 1013 at [0006]. Other examples of prior bar code designs include the European Article Number (EAN) and Japanese Article Number (JAN). Ex. 1020 at 1:26-28.

59. Research to allow for more storage data in barcodes led to the development of 2D barcodes that are used to store vastly more data in a small area. For example, a QR code can holds up to 7,089 digits, 4296 letters, and 2953 binary data. Ex. 1016 at 2. Because the earlier forms of linear barcodes only encoded numbers, 2-D barcodes were invented to allow for encoding of alphanumeric data, including letters, numbers, and punctuation marks. By the end of 1980s, 2D barcodes appeared and became popularly used in different areas since they allowed for storage of much more data. Ex. 1016 at 2.

60. 2D barcodes require sophisticated devices for decoding, which, with the advance of image processing – especially in mobile devices – let to the use of portable barcode encoding and decoding devices. Ex. 1016 at 2. In general, there are two types of 2D barcodes: (1) stacked 2D barcodes, such as Code 49 and PDF417, and (2) Matrix 2D barcodes, such as Data Matrix and QR codes. Examples of these codes are shown below.

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Ex. 1016 at 2. Each barcode type is a standard that defines the printed symbol and how a device such as a barcode scanner reads and decodes the printed symbol. These 2D barcodes have been used in various ways, including providing information such as (1) credit card information (2) product information, (3) security key information, and (3) user information. Ex. 1016 at 6. These barcodes all are all static, meaning they code for a predetermined fixed sequence of alphanumeric characters.

61. Persons of ordinary skill in the art also knew and understood for years before November 2017 that barcodes – including both 1D and 2D barcodes, encode static information. *See* Ex. 1013 at [0012]. But as I discuss in the sections directly below, "[c]onventional solutions" also teach the integration of various sensors within a barcode. *See* Ex. 1013 at [0012].

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B. Stimuli-Responsive Material and the Detection of Dynamic Information

62. While the developments in bar code technology discussed above were occurring, improvements and developments in stimuli-responsive materials such as sensors for detecting various environmental factors or for detecting the concentration of certain analytes within a fluid were also being developed.

63. Biosensors were first introduced in 1967 through the development of biosensor that is based on the immobilization of a glucose oxidase enzyme on an oxygen electrode that is used to measure glucose concentration in biological fluids. Ex. 1011 at 1. Soon thereafter, biosensors used for measuring blood glucose – like those used by diabetics – were developed. Ex. 1011 at 1. Since then, research and development efforts have been undertaken in sensor technology, highlighting the use of this technology in areas such as biomedical diagnosis, healthcare, and environmental control. Ex. 1011 at 1.

64. For example, dip stick type diagnostic strip tests have been around for decades and are used for a variety of diagnostic applications, including the diagnosis of urinary tract infections, preeclampsia, proteinuria, dehydration, diabetes, internal bleeding, and liver problems. Ex. 1021 at 1:10-11, 39-42; Ex. 1007 at [0004]. These test strips generally consist of a component such as paper or plastic with one end containing reagent pads that contain layers of chemical compounds used to detect a

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certain material within a body fluid sample such as urine or blood. Ex. 1021 at 1:11-22; Ex. 1007 at [0004]. When one end of the test strip is in contact with the body fluid, the fluid is drawn along the strip by capillary action, and as the sample passes the zones of chemical compounds, chemical reactions occur which may result in a color change. Ex. 1021 at 1:11-22. The technology for these strips is well known in the art, and it includes immunodiagnostic, enzymatic, lateral flow immunochromatography, or chemistry type reactions. Ex. 1021 at 1:23-25. The dipsticks will typically include reagent pads for detecting or measuring analytes such as glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilirubin, nitrite, leukocytes, microalbumin and creatinine. Ex. 1007 at [0004].

65. As another example, commercial biosensors in the agrifood sector have been used for enhancing quality and safety, process control, and intelligent food packaging. *See generally* Ex. 1011 at 9-21. For example, "millions of assays are performed on milk, fish, and meat to evaluate the freshness and presence of contaminants. Ex. 1011 at 9. In addition, continuous monitoring systems of industrial process are used to detect in real-time possible errors in the production chain, including for example, processes in food fermentation. Ex. 1011 at 14. Several analytical methods are used to analyze the quality and freshness of foods, controlling parameters such as acidity, temperature, and pressure. Ex. 1011 at 15. Likewise, sensors in intelligent packaging systems use biosensors for transportation and storage

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markets to monitor physical parameters such as humidity, pH, temperature, and light exposure. Ex. 1011 at 17. These types of systems were well known.

66. For example, labels that conveys temperature information by using a material that "changes properties" such as "chemical indicators, thermochromatic ink, leucodyes, fusible materials, and the like" were well known Ex, 1011 at 3:17-40, 3:35-36 (describing "well-known inks such as SunChemical's ThermaSolv"); Ex. 1020 at 4: 46-55 (listing manufacturers of thermochromatic materials and dyes); Ex. 1024 at [0026] (describing leuco dyes).

67. In addition to temperature, these dyes could be used to convey a wide variety of information. *See, e.g.*, Ex. 1017 at 17:9-42 (describing indicators that can detect, for example pH change, oxygen-sensitive dyes, and free radical-sensitive dyes); Ex. 1005 at 7:60-8:4 (describing "environmental sensors" including "temperature monitors, time, time-temperature product nuclear radiation exposure monitors" and "medical sensors" that include "recording patient thermometers; threshold assays, measuring levels to biological toxins… and includes colorimetric immunoassays for sensing of the presence of biological agents."); Ex. 1012 at 9:22-10:53 (describing inks that change based on pH, oxidation, or chemical reactions with certain components of the ink); Ex. 1023 at 1:11-55 (describing "commercially available" leuco dyes uses for assays).

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C. Integrating sensor based information with barcodes

68. The barcodes discussed in the Section VII.A all suffered from one issue – they failed to resolve the need for tracking "environmental conditions" i.e., conditions such as "location and temperature," or other dynamic data. *See* Ex. 1020 at 1:29-20. Meanwhile, as I explained in Section V.II.B, various ways of sensing these environmental conditions and other dynamic data were being developed.

69. It was not long until there were notable advancements in the integration of sensors with barcodes to enhance their functionality. One early example is US. Patent No. 6,685,094 to Cameron, which discloses a dynamic, thermochromic barcode for monitoring product temperatures. *See* Ex. 1020. This barcode uses temperature-sensitive inks that reveal different information above or below a certain temperature, effectively combining two barcodes in one space. Ex. 1020 at 2:16:-37.

70. Likewise, U.S. Patent No. 7,600,912 directed to Leute describes a temperature sensitive label attached to a temperature sensitive item. Ex. 1014 ("Leute") at Abstract. Leute's temperature sensitive label "conveys when the item has reached a predetermined or "tripping" temperature that is the "predetermined temperature at which the item may be compromised." Ex. 1014 at 2:26-32; s*ee also* Ex. 1015 at abstract (describing an "Erasable Barcode" that prevents the sale of products by invaliding a product's barcode.). Thus, well before November 2017,

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these types of barcodes that could convey dynamic information were well known to persons of ordinary skill in the art.

71. Likewise, in the healthcare industry, similar advancements in the integration of dynamic data and bar code technology was occurring decades before November 2017. One early example is U.S. Patent No. 5,929,422 to Lappe, which discloses a "machine readable assaying system" that uses a dynamic barcode system for analyzing physiological fluids. Ex. 1018 (Lappe '422) at Title, Abstract. Lappe '422's assaying system uses analysis strips that have reagents capable of indicating the presence of certain substances. Ex. 1018 at Abstract. The detection of one of these substances will result in one or more of the analysis strips to change from a first, light reflective color to a second, darker, light absorbent color. Ex. 1018 at Abstract. The pattern of analysis strips, fixed strips, and blank regions may allow for the encoding of information based on the result of the test. Ex. 1018 at Abstract. Thus, the detection of one or more substances may cause the encoded information to be altered, and "the particular pattern of bars and spaces that result from an exposure [of] the physiological fluids of a donor is contemplated to produce a distinct machine readable indicia." Ex. 1018 at Abstract.; *see also* Ex. 1019 at claims 1, 6.

72. Building on this, U.S. Patent No. 6,770,487 to Crosby extends the concept of bar code readable diagnostic strip tests to enable not just qualitative but also semi-quantitative analysis. *See* Ex. 1021 at 2:29-38 ("The present invention also

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provides a diagnostic strip test comprising at least one flow path, each flow path comprising a sample zone for application of a fluid sample, at least one test zone in fluid communication with the sample zone, the test zone of each flow path providing reagents necessary for performing an assay for the presence of an analyte, whereby an analyte assay result may be obtained, and machine readable information comprising identifying information and said analyte assay result, wherein the test zone comprises a portion of the machine-readable information.") This is achieved by incorporating multiple test zones within the barcode, each capable of detecting different analytes or varying amounts of a single analyte without altering the barcode's readability. *See* Ex. 1021 at 2:39-48.

73. Over time, other adaptable dynamic sensor-embedded barcode systems were developed, which incorporate various sensor modules directly within barcodes, each capable of encoding a wide range of properties using valid barcode characters. These properties span a comprehensive array of variables, including physical, environmental, electromagnetic, explosive, chemical, nuclear, radiological, biological, physiological, diagnostic, pharmaceutical, and food safety metrics, among others. Ex. 1013 at [0016].

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Figure 3.7 *The TTI Cryolog system from Gentilly, France. Reproduced with permission from Cryolog S.A., Gentilly, France.*

74. For example, a French company named Cryolog has developed time-temperature indicators that are relevant to the food industry, as shown in the figure above. Ex. 1009 at 48. One of these indicators, named TRACEO, is a "transparent adhesive label" that is designed for use on refrigerated products. Ex. 1009 at 49. Using color and opacifying reactions (i.e., colorless to red), it indicates when a product is no longer fit for consumption, either because the product has reached its use-by date or because it has been subjected to a critical accumulation of ruptures in the cold chain. Ex. 1009 at 49 Once the label is red, the barcode is rejected by a scanner at check-out. Ex. 1009 at 49

75. Similarly, as shown in the figures below, the Food Sentinel System from SIRA Technologies uses a label on a package to automatically monitor proper

refrigeration and shelf life by using time and temperature sensitive barcodes. Ex. 1009 at 51. In addition, an indicator on the bar code – names, a "an extra wide, colored bar in the lower bar code," can be used to "visually identif[y] "[a]bused product." Ex. 1009 at 51, Fig. 3.9; *see also* Ex. 1011 at 20 (Fig. 11, reproduced below).



Figure 3.9 *The Food Sentinel System™ from SIRA Technologies in the USA. Reproduced with permission from SIRA Technologies Inc., USA.*



76. In addition, tracking systems for inventory management, supply chain management, and quality assurance management were developed that use markings to assist identifying an aspect or property of an item. Ex. 1010 at 1:25-29. This property can be, among others, a physical, chemical, optical, magnetic, or electrical property. Ex. 1010 at 6:52-57. In one example, this inventory management system can be used for beverages, where the beverages containers have two markers. Ex. 1010 at 14:21-61. Using two markers – one using modifying ink for changing aspects and another in non-modifying ink, like a traditional bar code, that contains information related to a non-changeable attribute or characteristics of the object. Ex. 1010 at 14:21-61. For example, the non-changeable attribute can be the beverage

container size, serial number, or the type of beverage, while the changeable attribute can be exposure of UV light. Ex. 1010 at 14:21-61.

77. Combining these markers to form one, sensor-embedded barcode, was also known before November 2017. *See, e.g.*, Ex. 1013 at Abstract (describing a "dynamic barcode" in the form of a label that can be affixed to an object that "changes to indicate exposure to, or change in, one or more properties of interest."); Ex. 1005 at Fig. 3B, 3D.

VIII. OVERVIEW OF THE PRIOR ART

78. I have been informed that the documents described in this section constitute prior art to the '818 patent. I am not a lawyer and do not purport to be an expert in whether a document constitutes prior art.

A. Prusik (Ex. 1005)

79. I have been informed that Prusik is prior art because it filed on March 30, 2016 and published on October 6, 2016.

80. Prusik was not cited or considered during prosecution of the '818 patent.

81. Prusik is titled "Two dimensional barcode with dynamic environmental data system, method, and apparatus."

82. Prusik's discloses the integration of preprinted and coded sensor information within the framework of a two-dimensional barcode. Prusik at Abstract ("Methods, systems, and apparatus for combining preprinted information together

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with coded sensor information within a two-dimensional barcode."). Specifically, Prusik combines a set of static data with a set of dynamic data within the barcode. Ex. 1005 at [0005] (disclosing "a method of generating a 2D barcode" which includes "a set of static data and a set of dynamic data," that "includes an encoded version of the set of static data" and "a dynamic region which is adapted to store the set of dynamic data").

83. This dynamic data is printed using dynamic ink that transitions in response to environmental changes. Ex. 1005 at [0005] ("[T]he 2D barcode is printed with a static ink and an encoded version of the set of the dynamic data on the dynamic region using a dynamic ink which changes states responsive to at least one environmental change, such that the set of dynamic data is in one of a plurality of states.").

84. One notable embodiment, like that described in the '818 patent, is Prusik's use of dynamic data to signal exposure to specific temperature ranges. This is exemplified in Figure 6C, which depicts dynamic ink 198 transitioning from white to black upon exceeding a predetermined temperature threshold. Ex. 1005 at [0105] ("FIG. 6C represents a 2D barcode with the set of dynamic data 136 in a first state 210 transitioning to a second state 212 in response to an environmental change such as the temperature rising above 30° C."). As Prusik explains, this irreversible change in the dynamic ink enables the decoding of dynamic data 136, thereby alerting the

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supplier to potential thermal degradation of the container's contents after exposure to temperatures above 30°C. Ex. 1005 at [0085] ("In an example embodiment, the dynamic ink may permanently change or irreversibly change in response to an environmental factor. For example, a certain chemical may experience thermal degradation when it is exposed to a certain temperature. A supplier may want to know if the chemical ever reached a temperature above 30° C. during transportation and storage. If the dynamic ink irreversibly changes, the set of dynamic data 136 may be decoded to inform the supplier that the chemical was exposed to a temperature above 30° C. and that the contents of the container may have experienced thermal degradation."); Fig. 6C.

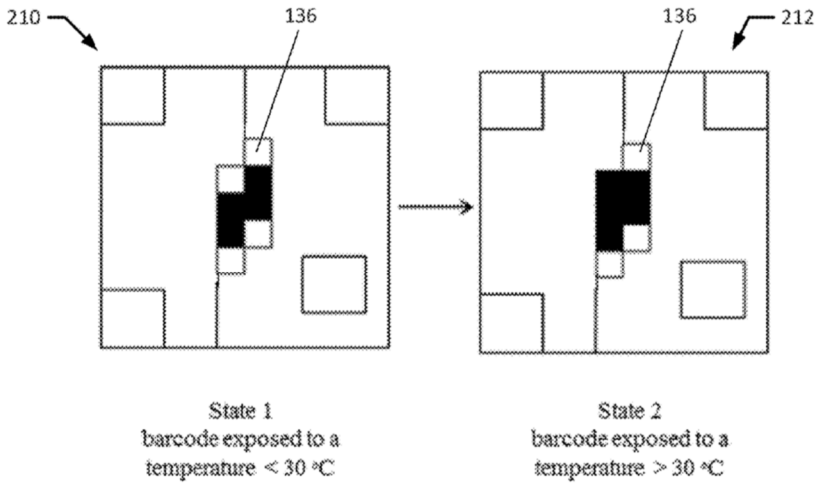


FIG. 6C

85. Prusik further explains that the dynamic ink can be used for a variety of environmental factors. These include temperature, combinations of time and

temperature, freezing conditions, radiation exposure, and toxic chemicals, showcasing the broad applicability of this technology in monitoring and reporting environmental conditions affecting the integrity of packaged goods. Ex. 1005 at [0111] ("In an example embodiment, the first dynamic ink and the second dynamic ink may be sensitive to an environmental factor such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like.").

B. Vaillant (Ex. 1006)

86. I have been informed that Vaillant is prior art because it was published in 2002 and issued in April 2010, over six years before the '818 patent's earliest claimed priority date.

87. Vaillant was not cited or considered during prosecution of the '818 patent.

88. Vaillant is titled "Method, System and Component for Controlling the Preservation of a Product."

89. Vaillant relates to controlling the preservation of a product that depends on temperature. Specifically, Vaillant discloses "systematically and automatically controlling a product, whose preservation in a distribution circuit depends on the temperature, in particular a product subjected to a cold chain." Ex. 1006 at 1:8-12. To do so, Vaillant uses a bar code that is "affixed on the product" to "manag[e] the

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marketing of the product between," for example, "a distributor and a consumer or between a pharmaceutical laboratory and a hospital." Ex. 1006 at 3:52-57.

90. Vaillant's Figure 1, reproduced below, shows the marketing of the product 1 in a cold chain. Ex. 1006 at 8:1-2. In this example, a product may be manufactured and distributed by different entities at potentially different temperatures, and the cold chain could be broken at any point by any of these entities. Ex. 1006 at 8:2-15. Thus, Vaillant explains, "it appears to be necessary to be able to perform a check of the products 1 at each step of their marketing." Ex. 1006 at 8:15-17.

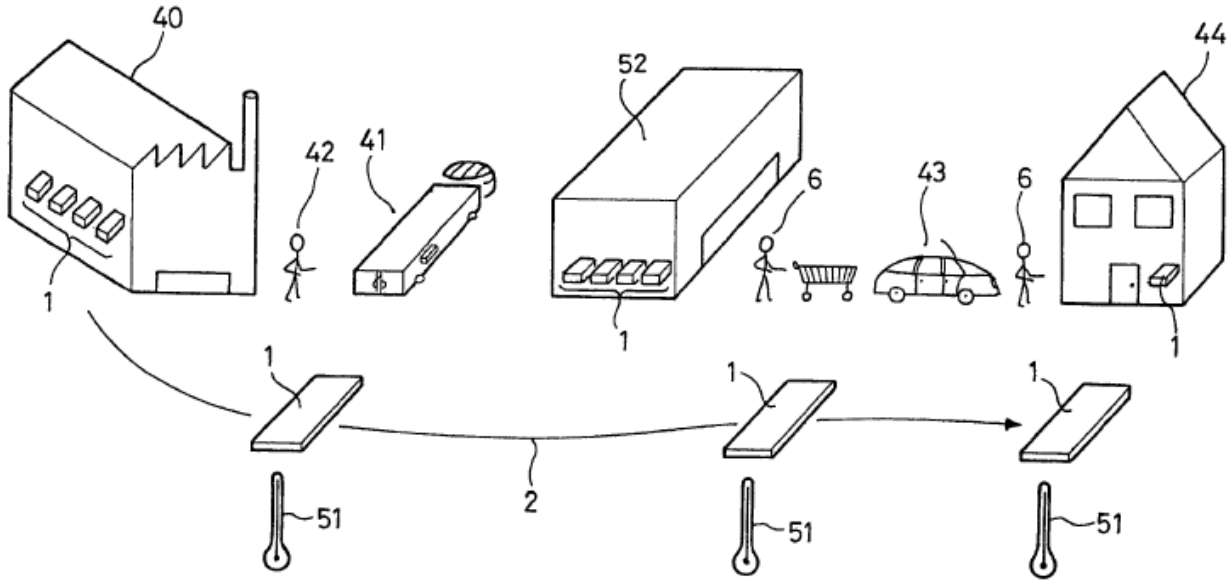


FIG_1

91. To do so, Vaillant, as shown in Figure 2 reproduced below, attaches a label component 6 to product 1. Vaillant's label component 6 can mask portions of a

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barcode affixed on the product 1 "at least temporarily, without modifying them, when the temperature of the product 1 exceeds a specific temperature threshold." Ex. 1006 at 8:35-39. Thus, "automatic processing units can no longer read the [barcode] markers 3 under these circumstances." Ex. 1006 at 10:7-9.

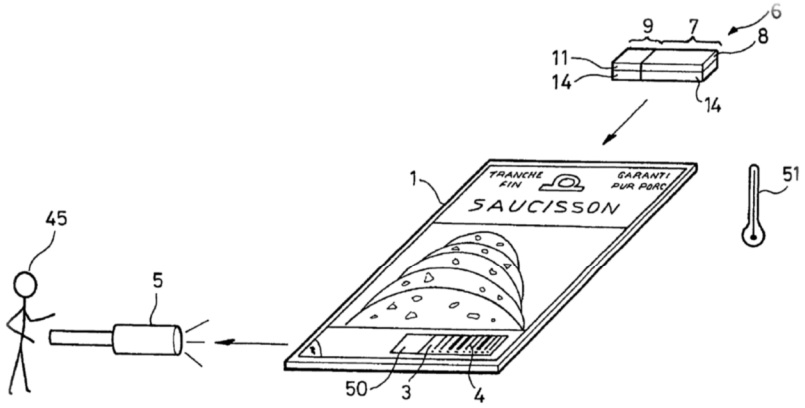
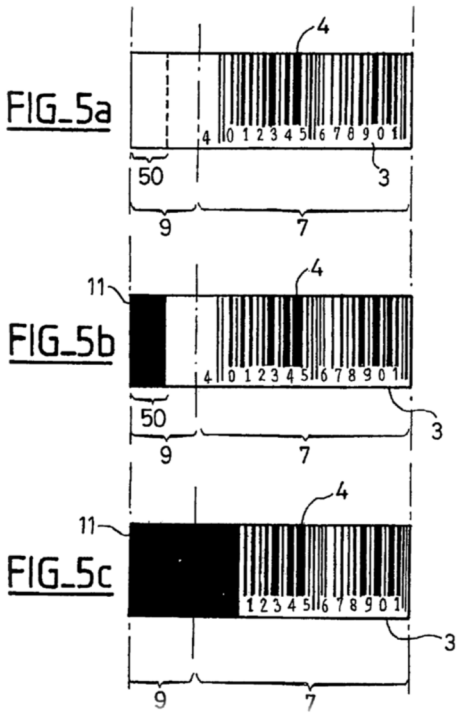


FIG_2

92. Figures 5A, 5B, and 5C, which are also reproduced below, "show the progressive masking of the marker 3" as the product and marker are exposed to temperatures exceeding a predetermined threshold. Ex. 1006 at 12:58-60, Figs. 5A-5C. Figure 5A shows a first barcode marker "not having undergone a break in the cold chain" and therefore, all the bars 4 of the bar code 3 are visible, making the marker "capable of activating the automatic processing unit 5." Ex. 1006 at 12:60-64. Figure 5B shows a second barcode marker where the "[barcode] marker 3 ha[s] undergone a brief break in the cold chain" so that "first substance 11 migrates to the surface of the marker, covering the warning zone 50," and thus, "[t]he marker can no

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longer activate the automatic processing unit 5." Ex. 1006 at 12:65-13:2. Figure 5C shows a third barcode marker 3 that has "undergone a prolonged break in the cold chain" so that the first substance 11 "form[s] a screen between the marker 3 and the automatic processing unit 5" so that "[t]he product can therefore no longer be sold." Ex. 1006 at 13:4-8.



C. Burg (Ex. 1007)

93. I have been informed that Burg is prior art because it was filed on February 27, 2015 and published on October 29, 2015.

94. Burg was not cited or considered during prosecution of the '818 patent.

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95. Burg is titled "Quantifying Color Changes of Chemical Test Pads Induced By Specific Concentrations of Biological Analytes Under Different Lighting Conditions."

96. Burg relates to methods and a device for "performing quantitative assessment of color changes induced by exposure of multiple test strips to a biological material/fluid." Ex. 1007 at [0009]. Burg discloses a system that has "a diagnostic instrument and a portable electronic device having a camera sensor for capturing a digital image of at least a portion of the diagnostic instrument and a processor." Ex. 1007 at [0014].

97. For example, Burg's Figure 1, reproduced below, shows a diagnostic instrument 10 that has test strips 14, where these test strips have "test media such as chemical test pads (CTP) 22," which in turn have a "color changing reagent for identifying the concentration of certain analytes in a patient fluid, such as urine, blood, or saliva." Ex. 1007 at [0046], Fig. 1.

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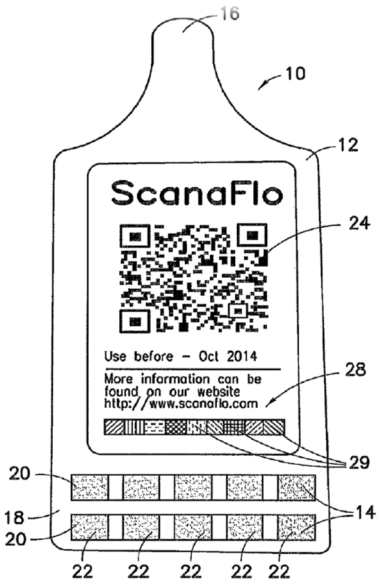


FIG. 1

98. A unique identification (UID) 24 on Burg's diagnostic instrument may "contain certain identification information about the diagnostic instrument 10, such as a list of the analytes that are being tested, expiration date of the instrument 10, the conditions that are being tested, and other identifying information." Ex. 1007 at [0050]. This identifying information "may be printed directly on or encrypted with the UID 24" in the form of either "a label or two-dimensional bar code, such as a QR code." Ex. 1007 at [0050].

99. Burg also discloses "color-based reaction testing of biological material in an automatically calibrated environment" that can be "implemented as a software application (an 'App') running on a portable electronic device, such as a cell phone, tablet PC, computer, laptop, or other dedicated electronic device." Ex. 1007 at [0044]

(further explaining that the method has been designed to "minimize user contact and manipulations of biologically sampled soils" and to avoid "modifying, compromising, and discarding raw data.").

D. Dimov (Ex. 1008)

100. I have been informed that Dimov is prior art because it was filed on April 6, 2017.

101. Dimov was not cited or considered during prosecution of the '818 patent.

102. Dimov is titled "Image-Based Disease Diagnostics Using a Mobile Device."

103. Dimov discloses a system that performs "image-based diagnostic tests" by using a mobile device and an "optical property modifying device" that has both a machine-readable code and "reaction chambers." *See* Ex. 1008 at Abstract, 1:7-9; 4:57-67 (further explaining that the optical property device has "a collection tube interface 230, one or more reaction chambers 240, an indicator 250, and a QR code 260" and that to perform a diagnostic test, the device is used "to react a biological sample (e.g., including a nucleic acid) of a patient with an optical modifying reagent in the reaction chambers 240"); Fig 2. The optical property modifying device attaches to a collection tube used to stores biological sample by "physically contacting the cartridge interface 210 of the collection tube 200 to the collection tube interface 230 of the optical property modifying device 120" so that "[w]hen attached, the collection

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tube 200 can provide a stored biological sample to the optical property modifying device 120 via the interfaces 210 and 230." Ex. 1008 at 6:19-34.

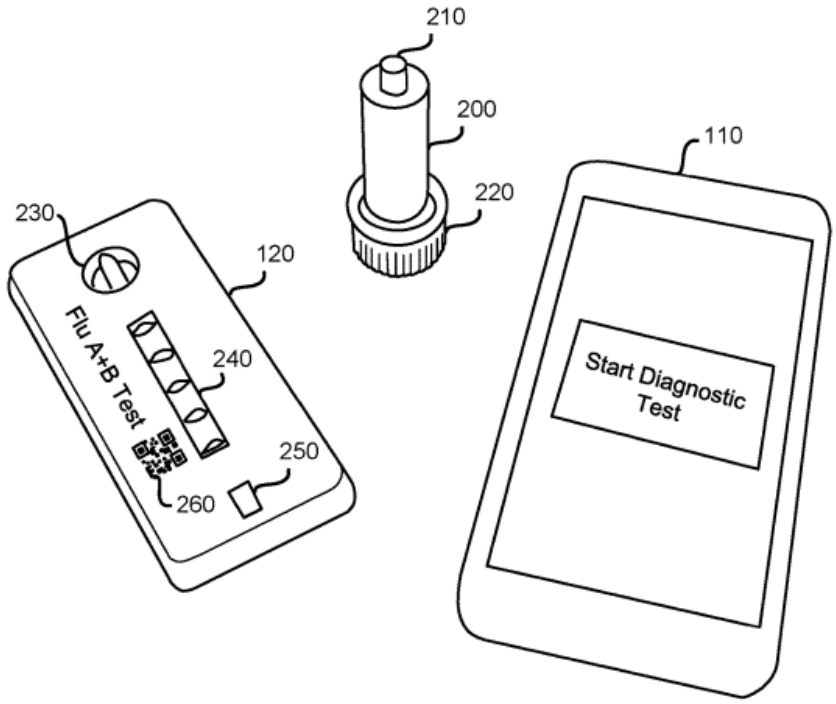


FIG. 2

104. The optical property modifying device's reaction chambers has "an optical property modifying reagent" that is used to "determine the presence or amount of a particular genetic target in a biological sample," where "the presence or amount of this target nucleic acid sequence within the biological sample may indicate that a patient is infected with a particular pathogen or carries a particular genetic disease." Ex. 1008 at 5:29-41. This optical property modifying reagent "includes a dye which changes color or fluoresces upon target amplification, resulting in a visible change in the solution's optical properties." Ex. 1008 at 5:31-44.

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105. A mobile device captures an image of the optical property modifying device using an optical sensor, i.e., a camera, that the mobile device then uses to perform an image analysis to determine the test result. Ex. 1008 at 2:25-28 ("In one embodiment, a method receives at least one image of an optical property modifying device for a nucleic acid disease diagnostic test captured by an optical sensor of a mobile device of a user."), 2:14-21 (explaining that the "diagnostic system can provide a quick diagnosis without requiring any input from health care personnel" and the test results "are mobile device hardware-independent" because the captured images can be "normalized").

106. After an image is taken of the optical property modifying device and that image is processed by an image processing engine, Dimov's image analysis engine analyzes the images and "determines one or more optical properties of the reaction chambers 240 such as the color, transparency, translucency, opacity, or uniformity of the reaction chambers 240 and/or contents within the reaction chambers." Ex. 1008 at 8:38-47 (further explaining that the images are of the reaction chambers within the optical property modifying device).

107. Dimov's optical property modifying device also has a machine-readable code, such as "a QR code 260," "a barcode, or other identifier or machine-readable signature," that is "associated with information for a disease diagnostic test such as a type of test or expiration date of the test." Ex. 1008 at 5:21-26. With this machine-

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readable code, diagnostic system can "determine the information for [the] disease diagnostic test by processing images of the QR code 260 scanned by an optical sensor of the mobile device 110." Ex. 1008 at 5:21-26.

IX. SUMMARY OF OPINIONS

108. The following table summarizes the grounds that I understand are presented in Petitioner's petition for *inter partes* review:

Ground	**Relevant Prior Art**	**Claims**
Ground 1(a) (Section X)	Prusik in view of a POSITA's knowledge	Claims 8-15
Ground 1(b) (Section XI)	Prusik in view of Vaillant	Claims 1, 4-7, and 16-20
Ground 2 (Section XII)	Burg in view of a POSITA's knowledge	Claims 8-15
Ground 3 (Section XIII)	Dimov in view of a POSITA's knowledge	Claims 8-11 and 13-15

109. In the analyses provided in Sections X-**Error! Reference source not found.**I below, I discuss each limitation in the challenged claims, and I explain how the prior art identified in the table above discloses and renders obvious each limitation, and each claim as a whole.

X. Ground 1(a): Claims 8-15 are obvious over Prusik in view of the knowledge of a person of ordinary skill in the art

110. In this section, I explain why every limitation of claims 8-15, and each of claims 8-15 as a whole, would have been obvious to persons of ordinary skill in

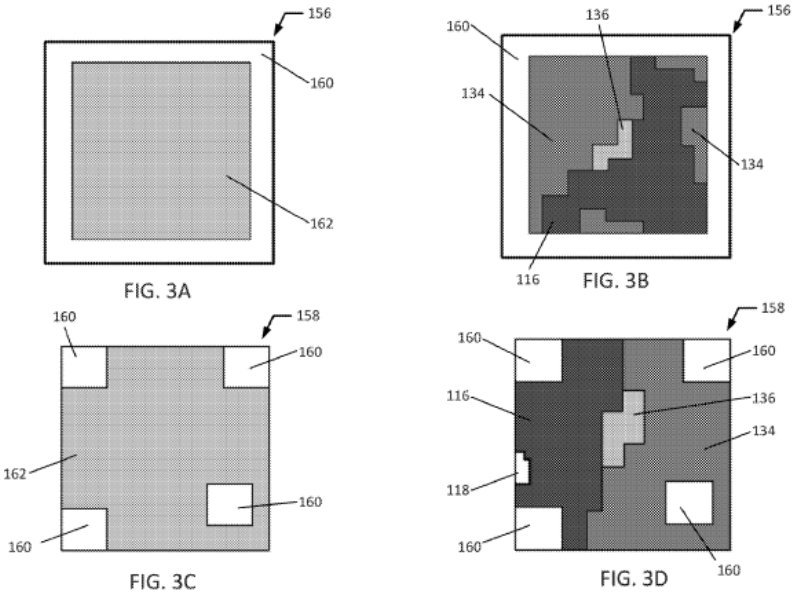
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the art over Prusik, alone or in view of the knowledge of a person of ordinary skill in the art.

A. Independents Claim 8 and 14

1. 8[pre] and 14[pre]: "A graphically encoded icon, comprising:"[1]

111. To the extent that the Patent Owner argues that the preambles of claims 8 and 14 are limiting, Prusik teaches them. At a minimum, Prusik renders these preambles obvious.



112. Prusik's Figures 3A-D, reproduced above, disclose the claimed graphically encoded icon through a two-dimensional barcode that has "dynamic environmental data." Ex. 1005 at Abstract. Specifically, this barcode combines

[1] This declaration uses the same bracketed identifiers used in Petitioners' petition.

preprinted information with sensor-derived data. Ex. 1005 at Abstract (describing "[m]ethods, systems, and apparatus for combining preprinted information together with coded sensor information within a two-dimensional barcode" where the sensor information is of "an environmental, physical or biological nature, and records a change in status of the environmental or biological condition to which the labeled product has been exposed.), Figs 3A-D.

113. Prusik's barcode uses a sensor dye chemistry to detect specific environmental conditions which prompts a change in the color of sensor dye modules within the barcode. Prusik at Abstract ("A sensor dye chemistry is employed and when a specified condition of the sensed property occurs it causes a change in the color state of sensor dye modules embedded within the sensor-augmented two-dimensional barcode, encoding sensor digital information."). This change in color encodes digital information pertaining to the environmental conditions detected. This two-dimensional barcode – the claimed graphically encoded icon – thus has encoded in it both dynamic and static barcode information.

2. 8[a]/14[a]: "a label attached to an object, the label comprising a static portion and an intrinsic portion"

114. Prusik discloses, or at a minimum renders obvious, limitations 8[a] and 14[a].

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115. Prusik discloses the claimed object by disclosing "a container holding the pharmaceutical, biological, or food product, preferably a vaccine vial" and the claimed label attached to the object through its "sensor-augmented two-dimensional barcode symbol provided on or in the container." Ex. 1005 at [0003]. ("In accordance with another exemplary aspect of the present disclosure, an article of manufacture includes pharmaceutical, biological, or food product, preferably a vaccine; a container holding the pharmaceutical, biological, or food product, preferably a vaccine vial; and a sensor-augmented two-dimensional barcode symbol provided on or in the container").

116. A POSITA would have understood that the barcode applied to the container's outside surface constitutes the claimed label attached to an object. As Prusik explains, this "sensor-augmented two dimensional barcode symbol" is "preferably applied to the outside surface of a the container. Ex. 1005 at [0003]. Prusik also explains that the applied sensor-based information "records a change in status of the environmental or biological condition to which the labeled product has been exposed." Ex. 1005 at Abstract. In addition, Prusik discloses that "the 2D barcode may be attached to various products such as food product, pharmaceutical products, etc." Ex. 1005 at [0114]; *see also* [0162] ("In an example embodiment, the two-dimensional barcode may be attached to various products such as food products, pharmaceutical products, biologics, or any other product that may benefit from

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environmental, physical, or biological monitoring. For example, the bar code may be printed on or applied to a container for such a product.").

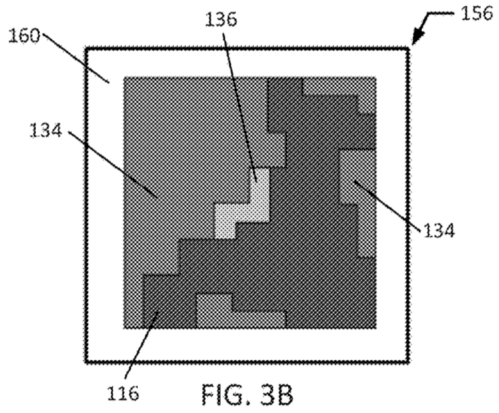


FIG. 3B

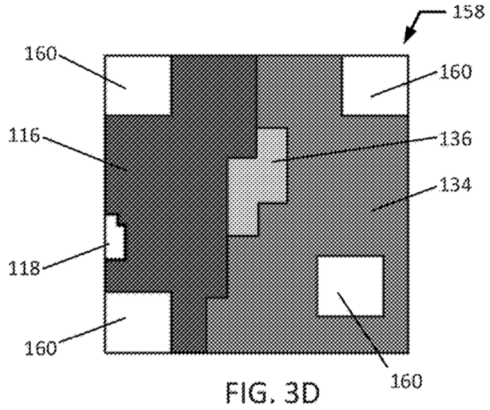


FIG. 3D

117. As shown in Figures 3B and 3D above, the two-dimensional barcode label (the claimed label attached to an object), comprises both static data (labeled 134) that corresponds to the claimed static portion and dynamic data (labeled 136) that corresponds to the claimed intrinsic portion. Ex. 1005 at [0070] ("The representation of each 2D barcode shows the reference data region 160 and the encoded data region 162. The encoded data region 162 may include static data 134, dynamic data 136, and error detection and correction data 116."), Figs 3B, 3D.

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118. Like the ’818 patent’s intrinsic portion, Prusik’s dynamic data includes “stimuli-responsive material,” namely, “dynamic ink.” Ex. 1005 at [0084]; Ex. 1001 at 1:42-44 (“In one embodiment, a graphically encoded icon comprises a label attached to an object. The label includes a static portion and an intrinsic portion.”). Prusik’s dynamic ink “may be sensitive to an environmental factor such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like.” Ex. 1005 at [0084] (“Next, the 2D barcode is printed using a static ink and an encoded version of the set of the dynamic data on the dynamic region using a dynamic ink which changes states responsive to at least one environmental change” such as “temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like.”); *see also* Ex. 1005 at [0007] (explaining that the “The first group is printed in the static ink” while the second group is printed in the dynamic ink.”).

119. This dynamic ink allows the barcode to encode information related to the product’s exposure to specific conditions. In turn, this makes the dynamic data linked to an intrinsic attribute of the product’s state. *Cf*. Ex. 1001 at 5:43-46 (“This is particularly so when the variable information conveyed by the machine-readable indicia: (a) is tied to an intrinsic attribute, e.g., of an object associated with the machine readable indicia;”). Notably, just like Prusik, the ’818 patent itself states that the intrinsic portion of a label can include “temperature sensitive ink.” Ex. 1001 at

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6:35-38 ("For example, the intrinsic attribute portion 314 may, in embodiments, include thermochromic (i.e., temperature sensitive ink) that changes colors based on temperature.").

120. For these reasons, Prusik discloses or renders obvious to a POSITA limitations 8[a] and 14[a].

3. 8[b]/14[b]: "the static portion comprises machine-readable indicia"

121. Prusik discloses, or at a minimum renders obvious, limitations 8[b]/14[b].

122. As I explained above for claim limitation 8[a]/14[a], Prusik's 2D barcode labels include "static data 134" that correspond to the claimed static portion. Ex. 1005 at [0070] ("The representation of each 2D barcode shows the reference data region 160 and the encoded data region 162. The encoded data region 162 may include static data 134, dynamic data 136, and error detection and correction data 116.").

123. A POSITA would have understood that Prusik's static data 134 comprises machine-readable indicia. For example, Prusik states that the 2D barcode label's "encoded data region 162" "may include static data 134". Ex. 1005 at [0070]. Prusik also discloses that embodiments can employ 2D barcode standards like a "Data Matrix," which is a "a two-dimensional error-correcting barcode symbol formed in

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compliance with ISO/IEC 16022 Information technology—automatic identification and data capture techniques—Data Matrix barcode symbology specification." Ex. 1005 at [0071].

124. Prusik also describes the encoding process for Data Matrix, where, for example, each module is colored black or white to represent an encoded bit. Ex. 1005 at [0073] ("Each module is a visual cell in matrix comprising the Data Matrix symbol that is used to encode one bit of data. Each module is colored either nominally black or nominally white. The module matrix is the visual manifestation of the binary bitmap matrix contained with the area of the symbol bounded by the Finder Pattern."); *see generally* Ex. 1005 at [0071]-[0082] (further describing the structure and layout of data bits in a Data Matrix).

125. From these disclosures, a POSITA would have understood that the encoded data in the Data Matrix format is specifically designed to be machine readable. *See* Ex. 1005 at [0092] (describing a "Data Matrix reader"). In addition, Prusik confirms the machine-readability of its barcodes. *See* Ex. 1005 at [0001] ("A barcode is an optical-machine readable representation of data"); [0171[(explaining that the sensor dye patch may be "machine readable to using the aforementioned Data Matrix reading techniques to recover the sensor dye modules as an image."); [0191] (explaining that "the presence of both the unactivated and activated sensor dye patch can be machine readable to a Data Matrix reader using reading methods described

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above"); Ex. 1016 at 1 (describing barcodes as "machine-readable representation of information in visual format"). Prusik also teaches that "the set of static data 134 is readable by the reader of the 2D barcode" regardless of which state the dynamic data 136 is in. Ex. 1005 at [0084]. From this machine-readable set of static data, "a reader [may] obtain the set of static data 134, such as serial number, lot number, and batch number." Ex. 1005 at [0085].

126. Further, as I explained in Section VII.A above in the Technology Overview section of this declaration, the use of machine readable barcodes was routine and conventional before November 2017.

127. Thus, for at least these reasons, Prusik discloses or renders obvious this limitation.

4. 8[c]/14[c]: "the intrinsic portion comprises an area of stimuli-responsive material"

128. Prusik discloses, or at a minimum renders obvious, limitations 8[c] and 14[c].

129. As I discussed above for limitations 8[a] and 14[a], Prusik teaches that the dynamic data 136, which corresponds to the claimed intrinsic portion, is printed using dynamic ink, which corresponds to the claimed stimuli-responsive material. Ex. 1005 at [0084] ("Next, at least part of the redundant space is designated as a dynamic region which is adapted to store the set of dynamic data 136 (block 406). Next, the

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2D barcode is printed using a static ink and an encoded version of the set of the dynamic data on the dynamic region using a dynamic ink which changes states responsive to at least one environmental change, such that the set of dynamic data 136 is in one of a plurality of states (block 408)."); [0006] ("The first group is printed in the static ink, and the second group is printed in the dynamic ink. The dynamic ink is adapted to activate in response to the occurrence of a specific environmental factor.").

130. Prusik, like the '818 patent, further discloses an embodiment that uses an ink that is sensitive to temperature, specifically disclosing "a water-based irreversible thermochromic ink designed to change permanently from white to black at 40° C." Ex. 1005 at [0084] (further explaining that the thermochromic ink may be reversable or irreversible and may be "a liquid crystal ink or a leuco dye ink" such as "QCR Solutions Reversible Thermochromic Inks and H.W. Sands Corporation inks"); *cf.* Ex. 1001 at 6:35-38 (disclosing thermochromic ink in the intrinsic attribute portion). As I explained above in the Technology Overview section, these types of inks were well-known materials that are responsive to various stimuli in the environment. *See* Section VII.B. Thus, a POSITA would have understood that Prusik's temperature-sensitive ink is a stimuli-responsive material.

131. Therefore, Prusik discloses these limitations.

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5. 8[d]/14[d]: "the stimuli-responsive material is configured to change from a first state to a second state in response to a trigger, the change in state being based on an attribute about the object"

132. Prusik discloses, or at a minimum renders obvious, limitations 8[d] and 14[d].

133. Prusik discloses a dynamic ink that can change from a first state to a second state in response to a trigger based on a change in the product's environment. For example, Prusik discloses that the "dynamic ink [] changes states responsive to at least one environmental change, such that the set of dynamic data 136 is in one of a plurality of states." Ex. 1005 at [0084] ("In an example embodiment, the 2D barcode may be attached to various products such as food product, pharmaceutical products, etc. In an example embodiment, the dynamic ink 198 may change states responsive to at least one environmental change, such that the set of dynamic data 136 is in either the first state 210 or the second state 212."). As I explained above for limitations 8[c] and 14[c], a trigger, "such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like" causes the dynamic ink to change states. Ex. 1005 at [0084]; Section X.A.4.

134. For example, Prusik's Figure 6C, reproduced below, shows dynamic ink that provides dynamic data 136 changes from a first state 210 to a second state 212 based on the dynamic ink's exposure "to an environmental change such as the

temperature rising above 30° C." Ex. 1005 at [0105] ("FIG. 6C represents a 2D barcode with the set of dynamic data 136 in a first state 210 transitioning to a second state 212 in response to an environmental change such as the temperature rising above 30° C. For example, the dynamic ink 198 used in the 2D barcode represented in FIG. 6C shows a dynamic ink 198 that activates from white to black in response to an a temperature greater than the threshold exposure temperature."). This stimulus response, however, is not limited to a color change in response to a temperature change, and Prusik discloses that they dynamic ink can also change in transparency or reflectivity. Ex. 1005 at [0084] ("The dynamic ink may change from a darker color to a lighter color, a lighter color to a darker color, may change levels of transparency or opacity, and/or may change levels of reflectivity or absorptivity, or may change any other suitable characteristic allowing the barcode to be readable in one or more states by a reader.").

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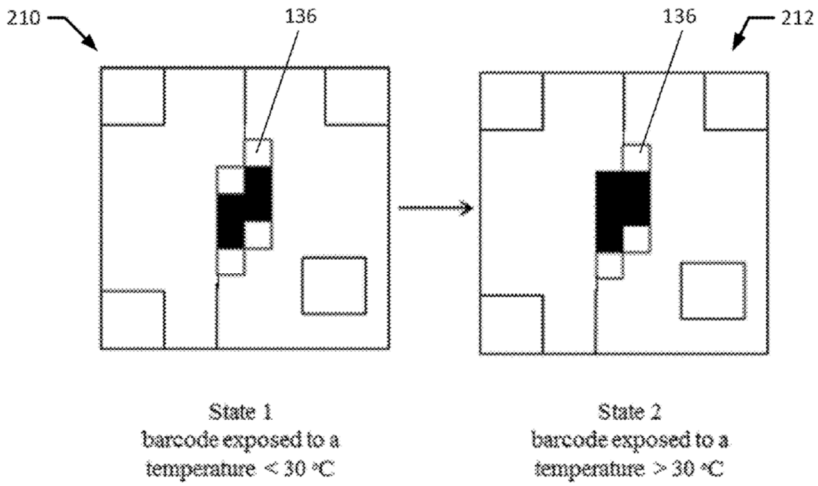


FIG. 6C

135. A POSITA would have understood that the change in state in Prusik's ink is based on an object's attribute. For example, Prusik discloses that its "bar code may be printed on or applied to a container for" "various products" including "food products, pharmaceutical products, biologicals, or any other product that may benefit from environmental, physical, or biological monitoring" which correspond to the claimed object. Ex. 1005 at [0162] ("In an example embodiment, the two-dimensional barcode may be attached to various products such as food products, pharmaceutical products, biologics, or any other product that may benefit from environmental, physical, or biological monitoring. For example, the bar code may be printed on or applied to a container for such a product."). Thus, a POSITA would have understood that the change in state is based on certain attributes, such as temperature, of those products.

136. In fact, and, as I discussed above, Prusik discloses that the change in state of the dynamic ink can be based on "an environmental factor such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like," which would correspond to the claimed attribute of the object. Ex. 1005 at [0084], [0085] (further describing dynamic ink may "permanently change or irreversibly change in response to an environmental factor" such as whether an object "ever reached a temperature above 30°C"). Therefore, Prusik's label changes states based on the temperature of the product to which the label is attached just like how the '818 patent describes a label that changes states based on the temperature of, for example, shrimp. *See, e.g.*, Ex. 1005 at [0085] (irreversible change in state of dynamic ink can indicate "that the chemical was exposed to a temperature above 30º C and that the contents of the container may have experienced thermal degradation").

137. Thus, Prusik discloses, or at a minimum renders obvious, this limitation.

6. 8[e]/14[e]: "the transformation of the stimuli-responsive material is a change in the transparency of the stimuli-responsive material"

138. Prusik discloses, or at a minimum renders obvious, limitations 8[e] and 14[e].

139. Prusik discloses that the change in state of the dynamic data of the two-dimensional bar code can include a change in transparency or a change in

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reflectiveness of the dynamic data 136. For example, Prusik explains that "[t]he dynamic ink . . . may change levels of transparency or opacity, and/or may change levels of reflectivity or absorptivity . . . ." Ex. 1005 at [0084].

140. Regarding limitation 8[e], which requires a change in transparency, Prusik discloses dynamic ink that can change from a colored state to a transparent state, or from a transparent state to a colored state. Prusik's Table 1, which is reproduced below, shows Prusik's possible changes in transparency based on dye chemistry.

TABLE 1

Types and Color Properties of Selected Sensor Dye Chemistries

Sensor dye chemistry	Unactivated State	Activated State
W→X	White	Transparent
W→B	White	Black
B→W	Black	White
B→X	Black	Transparent
X→W	Transparent	White
X→B	Transparent	Black

Ex. 1005 at [0087]

141. When transitioning from a colored to transparent state, the dynamic ink typically reveals a bit pattern when activated. Ex. 1005 at [0089] ("The sensor dye systems which go from the colored to transparent state are typically used with an underlying bit pattern that is printed in the Data Matrix, and all of the bits in that pattern are covered with sensor dye creating a uniform black or white color state

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covering those modules until activated. Once activated, the sensor dye turns transparent and the underlying bit pattern in the Data Matrix barcode is visible"). Conversely, when transitioning from a transparent to a colored state, the dynamic ink typically covers a previously-visible pattern with a new pattern. Ex. 1005 at [0089] ("Alternately dye systems which go from transparent color state to a black or white color state may selectively cover modules of a uniform black or white pattern printed in the Data Matrix symbol, and upon activation, the data encoded in the sensor dye module pattern is now visible. This latter system has the advantage that the sensor dye encoded data may be determined at the time of printing of the sensor dye modules which may be at a different time and location than the pre-printing of the Data Matrix symbol.").

142. Regarding limitation 14[e], which requires a change in reflection, Prusik repeatedly describes that the 2D barcode can use modules with "various . . . levels of reflectivity or absorptivity . . . allowing the barcode to be readable by a reader." Ex. 1005 at [0111] ("Furthermore, it should be appreciated that the first plurality of information modules 218 and the third plurality of information modules 224 and/or the second plurality of information modules 220 and the fourth plurality of information modules 226 may be various colors, levels of transparency or opacity, and/or levels of reflectivity or absorptivity, or may have any other suitable characteristic allowing the barcode to be readable by a reader."), [0084] ("he dynamic

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ink may change from a darker color to a lighter color, a lighter color to a darker color, may change levels of transparency or opacity, and/or may change levels of reflectivity or absorptivity, or may change any other suitable characteristic allowing the barcode to be readable in one or more states by a reader"), [0107] (same). A POSITA would have been motivated to have the dynamic ink transition states using a change in reflectivity because the variation of reflectivity is read by the reader as a different state and thus can easily be used to track and monitor a change of state of the object. To this end, Prusik expressly discloses "dynamic ink [that] . . . may change levels of reflectivity or absorptivity . . . allowing the barcode to be readable in one or more states by a reader." Ex. 1005 at [0084]. This confirms, or at a minimum suggests, its use in Prusik's barcode.

143. Thus, Prusik discloses, or at a minimum or renders, obvious limitations 8[e] and 14[e].

144. For these reasons, each limitation in claims 8 and 14, and claims 8 and 14 altogether, would have been obvious over Prusik.

B. Dependent Claims 9-13 and 15

145. I understand that claims 9 and 10 depend on independent claim 8.

146. Thus, it is my opinion that dependent claims 9 and 10 would have been obvious to persons of ordinary skill in the art for the same reasons as independent claim 8. *See* Section X.A.

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147. In addition, claims 9 and 10 would have been obvious for the reasons I discuss in the following subsections.

1. Claim 9: "The graphically encoded icon of claim 8, wherein the change in state of the stimuli-responsive material results in machine-readable indicia."

148. As I described directly above, Prusik renders claim 8 obvious. Prusik also discloses claim 9's additional limitation and thus renders claim 9 obvious for the reasons described below.

149. Specifically, as I discussed above for claim elements 8[b] and 14[b], a POSITA would have understood Prusik's 2D barcode to be machine readable. *See* Section X.A.3; *see also* Ex. 1005 at [0001] ("A barcode is an optical-machine readable representation of data"). Further, Prusik's barcode is machine readable under either state of the dynamic data 136, including after the change in state recited in claim 9.

150. A POSITA would have understood this because Prusik states that "the set of dynamic data 136 is readable by a reader of the 2D barcode . . . when the set of dynamic data 136 is in each one of the plurality of states." Ex. 1005 at [0084]. Thus, a reader can "read the 2D barcode both before the dynamic ink has activated and after the dynamic ink has activated from the set of dynamic data 136 in a first state to represent a set of dynamic data 136 in a second state." Ex. 1005 at [0085]. By revealing an underlying machine-readable bit pattern (if transitioning from a colored

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state to a transparent state) or by covering a portion of the barcode with a newly visible bit pattern (if transitioning to a colored state from a transparent state), the change in state results in machine-readable indicia. Ex. 1005 at [0089] ("The sensor dye systems which go from the colored to transparent state are typically used with an underlying bit pattern that is printed in the Data Matrix, and all of the bits in that pattern are covered with sensor dye creating a uniform black or white color state covering those modules until activated. Once activated, the sensor dye turns transparent and the underlying bit pattern in the Data Matrix barcode is visible. Alternately dye systems which go from transparent color state to a black or white color state may selectively cover modules of a uniform black or white pattern printed in the Data Matrix symbol, and upon activation, the data encoded in the sensor dye module pattern is now visible.").

151. Thus, Prusik renders claim 9 obvious in view of the knowledge of a POSITA.

2. Claim 10: "The graphically encoded icon of claim 9, wherein the machine-readable indicia of the stimuli-responsive material is non-human readable."

152. Claim 10 is obvious over Prusik to a POSITA.

153. As explained above for claim 9, Prusik's 2D barcode label that has encoded dynamic data uses machine-readable indicia before and after changing states. A POSITA would have understood that this machine-readable indicia has a number

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of modules with multiple states that can be easily read by a barcode reader. For example, Prusik discloses that its two-dimensional barcode can be a "Data Matrix or QR code" where "the set of static data 134 is readable by the reader of the 2D barcode and the set of dynamic data 136 is readable by a reader of the 2D barcode when the set of dynamic data is in each of the plurality of states." Ex. 1005 at [0001] ("A barcode is an optical machine-readable representation of data. A two dimensional (2D) barcode (e.g., Data Matrix or QR Code), is a two dimensional way to represent information in a bar code."), [0084] ("Next, the 2D barcode is printed using a static ink and an encoded version of the set of the dynamic data on the dynamic region using a dynamic ink which changes states responsive to at least one environmental change such that the set of dynamic data 136 is in one of a plurality of states.").

154. A POSITA would have understood that Prusik's 2D barcode, including the machine-readable indicia of the dynamic ink, is non-human-readable. For example, Prusik discloses that its sensor dye modules can be encoded with an error-correcting code, which a human could not readily decode, to account for cases where "the entire sensor-augmented two-dimensional barcode may not have been exposed uniformly to the condition activating each sensor dye module." Ex. 1005 at [0096] ("encoding this sensor data itself in an error correcting code is useful when the sensor color change activation threshold is not precise for each sensor dye module; where

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the entire sensor-augmented two-dimensional barcode may not have been exposed uniformly to the condition activating each sensor dye module.").

155. In any event, using a 2D barcode that does not have any human-readable component would have been obvious to a POSITA because it was known to make barcode either human readable, machine-readable, or both. *See, e.g.*, Ex. 1014 at 4:47-49 (describing a temperature sensitive label 102 that "may be readable either by a machine, human, or both"). Further, a POSITA would have found a non-human readable bar code to be obvious to allow for the transmittal confidential information to be encoded and transmitted. In fact, it was known to use non-human readable bar codes to encode confidential information related to, for example, security and financials. *See* Ex. 1016 at 6 (describing 2D barcodes that include credit card information, security key information, and user information); Ex. 1018 at Abstract ("The transformation which occurs on the test card will be uninterpretable by the administrator of the test, thus preserving the anonymity and privacy of the tested individual").

156. Thus, both the use of and benefits of having 2D barcodes that lack any human-readable component was well known to POSITAs, and a POSITA would have been motivated to use these types of barcodes. For these reasons, this claim is rendered obvious by Prusik in view of an expert's knowledge.

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3. Claim 11: "The graphically encoded icon of claim 10, wherein the machine-readable indicia of the static portion is non-human readable"

157. Prusik discloses, or at a minimum renders obvious claim 11.

158. As I explained above for claim 10, Prusik's two-dimensional barcode can be a "Data Matrix or QR code") that is encoded with static data 134 (the claimed static portion) and dynamic data 136 that are both "readable by a reader of the 2D barcode." Ex. 1022 at 1:14-17, 10:55-59. For the reasons I discussed above for the intrinsic portion containing stimuli-responsive material (claim 10), the static portion as recited in claim 11 of Prusik's two-dimensional barcode is also non-human readable, and a non-human-readable barcode would have been obvious to a POSITA. *See* Section X.B.10.

4. Claim 12: "The graphically encoded icon of claim 8, wherein the trigger is a change in temperature, and wherein the trigger occurs when the change in temperature is above or below a predetermined threshold."

159. Dependent claim 12 is disclosed by, or at a minimum rendered obvious, over Prusik to a POSITA.

160. As discussed above for claim elements 8[c] and 14[c], Prusik's dynamic ink changes states based on a trigger "such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors, or the like." Ex. 1005 at [0084]; Section X.A.4. In addition, as I discussed above for limitation 8[e],

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Prusik describes that "[t]he dynamic ink . . . may change levels of transparency or opacity, and/or may change levels of reflectivity or absorptivity . . . ." Ex. 1005 at [0084].

161. In one example, Prusik's dynamic ink is configured to change from a first state 210 to a second state 212 based on exposure "to an environmental change such as the temperature rising above 30° C." Ex. 1005 at [0105]. Figure 6C, reproduced below, shows the dynamic ink in Prusik's 2D barcode "activat[ing] from white to black in response to [] a temperature greater than the threshold exposure temperature." Ex. 1005 at [0105].

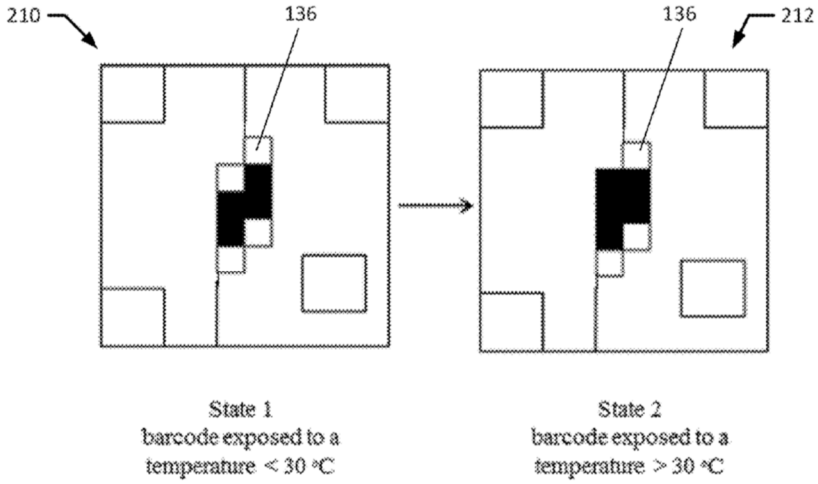


FIG. 6C

162. A POSITA would have understood that Prusik's "threshold exposure temperature" is predetermined as claim 12 requires because the threshold exposure temperature is "specified in the set of static data 134" as shown in Figure 6A,

reproduced below. Thus, because the static data 134 does not change, the threshold is predetermined at the time of the static data 134 is printed. A POSITA would have understood and appreciate that using a predetermined threshold is important in many situations such as ones where a supplier needs to know if a chemical "is exposed to a certain temperature" due to thermal degradation at that certain temperature. Ex. 1005 at [0085]. As I explained above in Sections VII.B and C, this is particularly helpful in the pharmaceutical and food industries where keeping objects below a certain temperature is critical for safety.

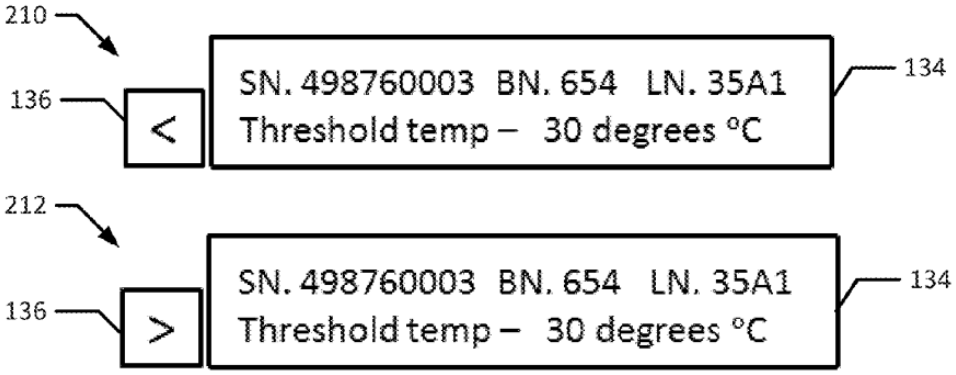


FIG. 6A

163. Likewise, Figure 6D, reproduced below, shows a change in state of the dynamic ink from black to white based on exposure to a temperature below 0ºC. Ex. 1005 at [0105].

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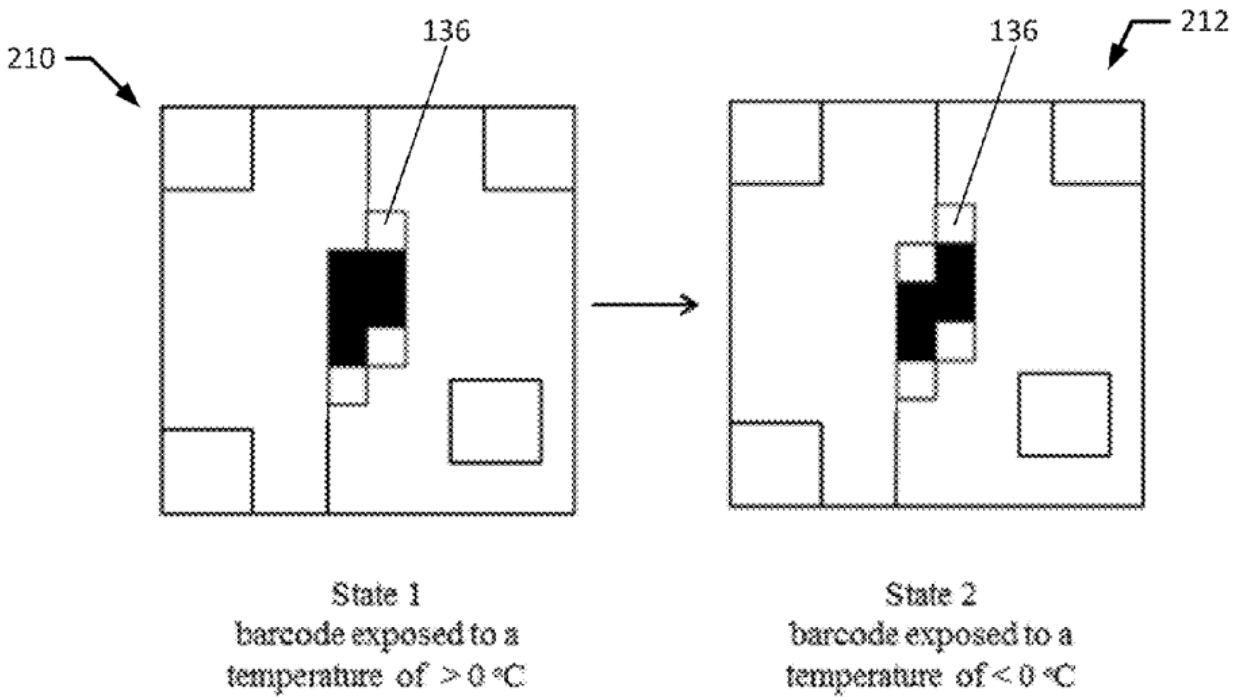


FIG. 6D

164. Prusik's ink is not limited to only changing color in response to the temperature crossing a threshold exposure temperature. Rather, Figures 6C and 6D are mere "example" processes based on "an example embodiment." Ex. 1005 at [0029]. In fact, Prusik's dynamic ink "may change any other suitable characteristic" including "transparency or opacity." Ex. 1005 at [0084].

165. To the extent Patent Owner argues that Prusik does not explicitly disclose changing transparency in response to a threshold exposure temperature, it would have been obvious to a POSITA at least because Prusik suggests a change in transparency in response to a threshold exposure temperature. Prusik discloses "6

types of sensor dye chemistries," including a change in color and transparency, as discussed directly above and for limitation 8[e]. Ex. 1005 at [0086]; *see also* Section X.A.6. Further, in the same paragraph as the disclosure regarding changes in response to stimulus threshold, Prusik also describes thermochromic ink. Ex. 1005 at [0084]. Thus, the use of sensor dye chemistry of W→X (White to Transparent) or B→X (Black to Transparent) instead of W→B or B→W (as Prusik expressly discloses in Figures 6C/6D) is a simple substitution of one known, equivalent element for another to obtain predictable results, as Prusik's Table 1 (reproduced below) shows:

TABLE 1

Types and Color Properties of Selected Sensor Dye Chemistries

Sensor dye chemistry	Unactivated State	Activated State
W→X	White	Transparent
W→B	White	Black
B→W	Black	White
B→X	Black	Transparent
X→W	Transparent	White
X→B	Transparent	Black

166. Thus, claim 12 is obvious to a POSITA over Prusik.

5. Claims 13 and 15: "wherein the trigger occurs automatically based on a predetermined condition about the attribute of the object."

167. Claim 13, which depends from claim 8, recites: "wherein the trigger occurs automatically based on a predetermined condition about the attribute of the

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object." Claim 15, which depends from claim 14, has identical language to claim 8. Prusik discloses these limitations.

168. As I discussed above for claim elements 8[c] and 14[c], Prusik discloses that the change in state of the dynamic data 136 from a first state to a second state in the two-dimensional barcode can be based on predetermined environmental factors "such as temperature, time, time and temperature, freezing, radiation, toxic chemicals, or a combination of such factors." *See* Section X.A.4; Ex. 1022 at 1:54-61, 10:60-63. Prusik further discloses a "thermochromic ink" "designed to change permanently from white to black at 40° C." Ex. 1022 at 10:64-67. As I discussed above for claim 12, a POSITA would have understood that these environmental factors are a predetermined condition about the attribute of the object. *See* Section X.B.4 A POSITA would also understand that the trigger (reaching a temperature of 40°C) automatically occurs. This is because, as Prusik discloses, the trigger is based not on an action, but on an "environmental, physical or biological condition." Ex. 1005 at [0002]; *see also, e.g.*, [0105] ("[T]he dynamic ink 198 may activate from black to white in response to an environmental change 506….").

169. Thus, Prusik discloses claims 13 and 15.

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XI. Ground 1(b): Claims 1, 4-7 and 16-20 are unpatentable over Prusik in view of Valliant

170. Like claims 8-15, which, as I explain above, are obvious based on Prusik in view of the POSITA's knowledge, independent claims 1 and 16 recite: (1) a graphically encoded icon, (2) a static portion, (3) an intrinsic portion, and (4) a stimuli-responsive material that transforms from a first state to a second state that results in a machine-readable indicia. However, claims 1 and 16 recite additional limitations related to a transaction. In this section, I explain why Prusik in view of Vaillant renders these claims, along with dependent claims 4-7 and 17-20, obvious.

A. Reasons Persons of Ordinary Skill in the Art Would Combine Prusik and Vaillant

171. Prusik discloses a barcode that has (1) a static portion and (2) a dynamic portion that is machine-readable both before and after the dynamic portion changes states in response to an environmental trigger. Thus, the barcode has information encoded within it whether the product labeled by the barcode has been exposed to, e.g., a temperature exceeding a predetermined threshold. *See* Ex. 1005 at [0084] ("[T]he set of dynamic data 136 may include information that when decoded by a reader informs a user whether the product exceeded the threshold exposure temperature.").

172. Prusik suggests but does not expressly disclose how one might use the encoded information about the product's exposure to a certain temperature. As a

result, a POSITA would have looked to other prior art teachings about uses of temperature exposure information and would have found Vaillant. Notably, Vaillant is cited on the face of the patent that issued from Prusik (Ex. 1022).

173. Vaillant teaches the "marketing," i.e., the process of bringing to market, of products through a "cold chain" using an automatic processing unit. Vaillant discloses a temperature-sensitive mask that covers the barcode on a product to indicate that the product has "undergone a prolonged break in the cold chain" and "can therefore no longer be sold." Ex. 1006 at 13:2-8. Thus, Vaillant teaches that information about whether a product has been exposed to temperatures above or below a certain threshold can be used to permit or deny a user to engage in a transaction.

174. A POSITA would have been motivated to apply Prusik's machine-readable dynamic barcodes to Vaillant's marketing management system for various reasons. Prusik teaches that its barcode "may be attached to various products such as food products, pharmaceutical products, biologics, or any other product that may benefit from environmental, physical, or biological monitoring" including temperature monitoring. Ex. 1005 at [0162] (further explaining that "the bar code may be printed on or applied to a container for such a product"), [0067] (describing examples of environmental sensors and medical sensors). Likewise, a goal for Vaillant's marketing management system "is to make it possible to systematically

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and automatically control a product 1, whose preservation in a distribution circuit 2 depends on the temperature 51." Ex. 1006 at 6:6:58-61; Figure 1. In addition, Prusik and Vaillant use barcode modification as a way to determine whether a product has been exposed to a predetermined temperature threshold.

175. Using these dynamic and thus modifiable barcodes, Prusik and Vaillant both provide to users temperature exposure information regarding a product for preservation, and thus safety, purposes. Vaillant provides the information through a mask that covers the barcode when the product has been exposed to temperatures above or below a certain predetermined threshold temperature and thus makes the barcode unreadable. Once the barcode is masked, "[t]he product 1 can therefore no longer be sold." Ex. 1006 at 13:4-8. Prusik discloses a barcode that remains readable after the change in state triggered by the temperature. *E.g.*, Ex. 1005 at [0084]. Prusik's barcode thus enables a reader to decode the specific temperature that was exceeded. For example, the static portion 134 of a barcode can encode a temperature threshold (e.g., 30 degrees) and the dynamic portion 136 can indicate whether the temperature was exceeded. Ex. 1005 at [0084]. In applying Prusik to Vaillant's system, when the reader decodes from Prusik's barcode that an unacceptable temperature has been exceeded, a POSITA would have understood that the product could "therefore no longer be sold."

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176. A POSITA would have also known and recognized that applying functionality that would accept or reject a sale to Prusik's barcode reader is a mere application of a known method of product monitoring, handling, and processing. This application to Prusik's system predictably results in preventing the sale of products that have been exposed to improper or potentially hazardous environmental conditions.

177. In other words, Vaillant provides a known technique that a POSITA could and would have implemented with Prusik's barcode system. A POSITA would have understood that Prusik's machine-readable two-dimensional barcodes that change in response to exposure to predetermined environmental conditions (like temperature) would logically be suited for allowing or preventing the sale (or other transaction) of certain products when they are scanned by a barcode reader. Therefore, a POSITA would have had plenty of motivation to modify Prusik's system that includes a barcode reader to include an automatic processing unit as disclosed by Vaillant in order to prevent the sale of a product when the dynamic data in the two-dimensional barcode shows that the product has been exposed to a temperature that exceeds a certain, predetermined threshold.

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B. Independent Claim 1

1. 1[pre]: "A user instrument for engaging in a transaction"

178. To the extent Patent Owner argues that it is limiting, Prusik in view of Vaillant renders this obvious to a POSITA.

179. Prusik discloses a "labeled product" that has a "two dimensional barcode with dynamic environmental data." Ex. 1005 at Abstract. A POSITA would have understood that this label that attached to the product corresponds to the claimed "user instrument for engaging in a transaction." In fact, dependent claim 4 recites that the user instrument can be a label. Vaillant likewise discloses a system that has "a marker" that is "affixed on the product" and is used to "systematically and automatically control[s] a product" which is "subjected to a cold chain." Vaillant Abstract ("The invention pertains to a method, a system and a component for systematically and automatically controlling a product, whose preservation in a distribution circuit depends on temperature, in particular a product subjected to a cold chain."), 10:14-29 ("The masking means 8 comprise an impermeable, flat pouch 21, containing physicochemical reagents. In case of a break in the cold chain, i.e., when the specific temperature is exceeded, the physicochemical reagents diffuse a first substance 15 acting as a screen on the surface of the marker 3, inside the impermeable, flat pouch 21, by means of a migrant physicochemical reaction. Thus, when the specific temperature is exceeded, the first substance 15 progressively forms a screen

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between the marker 3 and the automatic processing unit 5. The automatic processing unit 5 is then deactivated.").

180. Specifically, Vaillant's system "identifies by automatic processing units managing the marketing of the product between," for example, "a distributor and a consumer or between a pharmaceutical laboratory and a hospital." Ex. 1006 at 1:8-12 ("The present invention pertains to a method, a system and a component for systematically and automatically controlling a product, whose preservation in a distribution circuit depends on the temperature, in particular a product subjected to a cold chain"), 3:52-57 (The system comprises: a marker, affixed on the product, comprising elements, in particular the bars of a bar code, intended to be identified by automatic processing units managing the marketing of the product between the economic participants in question, in particular between a distributor and a consumer or between a pharmaceutical laboratory and a hospital…"). Thus, a POSITA would have understood that when Prusik's label is used for "managing the marketing of the product" as disclosed in Vaillant, it is a user instrument for "engaging in a transaction" between the parties, including consumers, that are involved in bringing the product to market.

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2. 1[a]: "a graphically encoded icon"

181. Limitation 1[a] is identical to limitation 8[pre]/14[pre] and thus would have been obvious for the same reasons as I discuss above for claim element 8[pre]/14[pre]. *See* Section X.A.1.

3. 1[b]: "a static portion"

182. Prusik discloses this limitation for the reasons I discussed above for the "static portion" recited in limitations 8[a]/14[a] and 8[b]/14[b]. *See* Sections X.A.2, X.A.3.

4. 1[c]: "an intrinsic portion comprises an area of stimuli-responsive material defining a first machine-readable indicia"

183. Prusik discloses this limitation for the reasons described above for limitations 8[c]/14[c] and claim 9. For example, Prusik discloses that its indicia are machine-readable both before and after a change of state triggered by the environment. Ex. 1005 at [0084] (""the set of dynamic data 136 is readable by a reader of the 2D barcode . . . when the set of dynamic data 136 is in each one of the plurality of states."). Thus, Prusik's dynamic ink defines a machine readable indicia as claimed. *See* Sections X.A.4, X.B.1.

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5. 1[d]: "at least a portion of the stimuli-responsive material transforms from a first state to a second state in response to a trigger"

184. Prusik discloses this limitation for the same reasons I described above for limitations 8[d]/14[d]. *See* Section X.A.5.

6. 1[e]: "the transformation from the first state to the second state of the portion of the stimuli-response material results in a second machine-readable indicia

185. Prusik discloses this limitation for the same reasons I described above for claim 9. *See* Section X.B.1.

7. 1[f]: "the second machine-readable indicia comprises information to permit or deny the user to engage in a transaction via the user instrument."

186. The combination of Prusik and Vaillant render this limitation obvious to a POSITA.

187. After transforming from a first state to a second state, Prusik's dynamic portion includes information that the product was exposed to certain environmental conditions, such as a threshold temperature. Ex. 1005 at [0084] ("[T]he set of dynamic data 136 may include information that when decoded by a reader informs a user whether the product exceeded the threshold exposure temperature."). For example, as I explained above for claim 12 in Ground 1(a), Prusik's static information 134 can include the threshold exposure temperature (e.g., 30 degrees as shown in Figure 6A, reproduced below), and Prusik's dynamic information 136 can include

whether that threshold was exceeded (“>”) or not (“<”). Ex. 1005 at [0105] (“FIG. 6C and FIG. 6D are flow chart diagrams illustrating the dynamic data of a 2D barcode changing from a first state to a second state. For example, the set of static data 134 includes product information such as serial number (SN), batch number (BN), and lot number (LN). In this example, the serial number is 498760003, the batch number is 654, and the lot number is 35A1. The set of static data 134 does not change. Additionally, the set of dynamic data 136 is shown in a first state 210 (top) and a second state 212 (bottom) in FIG. 6A. For example, the set of dynamic data 136 may be printed with a dynamic ink 198 that changes from a first state 210 to a second state 212 upon reaching a threshold exposure temperature above 30° C. The textual representation of the set of dynamic data 136 in the first state 210 is “<” (i.e., less than) the threshold exposure temperature specified in the set of static data 134, and the textual representation of the set of dynamic data 136 in the second state 212 is “>” (i.e., greater than) the threshold exposure temperature specified in the set of static data 134, in this case 30° C.”); Section X.B.4.

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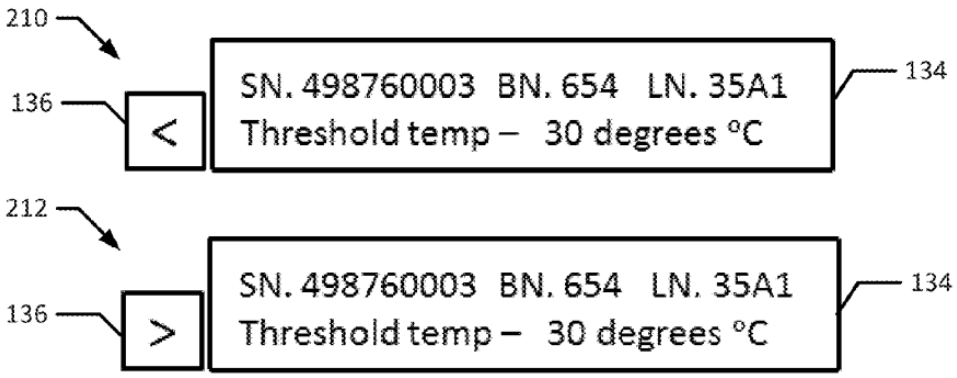


FIG. 6A

188. When Prusik's discloses are applied to Vaillant's marketing management system, a POSITA would have understood that the information about an exposure to the environmental condition corresponds to the claimed information to permit or deny the user to engage in a transaction through the 2-D barcoded label (i.e., the user instrument).

189. For example, Vaillant's system has bar codes that are "identified by automatic processing units" that manage the transaction of the product "between a distributor and a consumer or between a pharmaceutical laboratory and a hospital." Ex. 1006 at 3:52-57. When the barcode indicates that a temperature threshold has been exceeded, "the product can [] no longer be sold." Ex. 1006 at 13:4-8. Vaillant accomplishes this goal by masking the barcode to prevent it from being read, while Prusik discloses a dynamic barcode that enables the reader to decode information telling it that the product has been exposed above a threshold temperature. Ex. 1005 at [0084] ("Additionally, the set of dynamic data 136 may include information that

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when decoded by a reader informs a user whether the product exceeded the threshold exposure temperature"). Thus, by combining Prusik and Vaillant, Prusik's dynamic information 136 would "comprises information to permit or deny the user to engage in a transaction via the user instrument" as recited in limitation 1[f].

C. Dependent Claims 4-7

190. I understand that claims 4-7 depend on independent claim 1. Dependent claims 1-7 would have been obvious to persons of ordinary skill in the art for the reasons I discuss in the following subsections.

1. Claim 4: "The user instrument of claim 1, wherein the user instrument is a label"

191. Prusik discloses this element for the reasons described above for 1[pre]. *See* Section XI.B.1.

2. Claim 5: "The user instrument of claim 1, further comprising a second area of stimuli-responsive material configured to transform in response to a trigger, wherein the transformation of the stimuli-responsive material of the second area results in human readable indicia"

192. The combination of Prusik and Vaillant renders this obvious. Specifically, Prusik discloses a sensor dye (the claimed stimuli-responsive material) that may include "visual patterns and images of any type, such as ISO or ANSI or ISO warning signs or symbols, or any other type of designed graphic." Ex. 1005 at [0101]. A POSITA would have understood that the visual pattern or image would be designed to be human readable to alert the human reader to the intended warning

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since the purpose of a warning sign or symbol, especially one of a standardized nature like Prusik discloses, is to provide visual information to a human reader.

3. Claim 6: "The user instrument of claim 5, wherein the second area of stimuli-responsive material forms a part of the graphically encoded icon"

193. As I explained above for Claim 5, Prusik discloses a second area of stimuli-responsive material that can show "visual patterns and images." *See* Section XI.C.2. From Prusik's disclosures, a POSITA would have understood that this second area would also form part of the graphically encoded icon because these visual patterns and images form part of the 2D barcode. Specifically, Prusik explains that these visual patterns and images occupy components of the 2D barcode, including a "number of bits" and "utahs" (groups of modules roughly shaped like Utah). Ex. 1005 at [0101] ("Other types of sensor digital information may be encoded in the sensor dye module pattern. This includes visual patterns and images of any type, such as ISO or ANSI or ISO warning signs and symbols, or any other type of designed graphic. The number of bits which are encoded and the number of utahs deliberately damaged in the process (which is affected by the physical extent of the visual pattern on the underlying Data Matrix symbol) as well as the size of the underlying Data Matrix and its available number of RSEC codewords all affect the visual pattern and image encoding capability."); [0076] (explaining that a "'utah' is an arrangement of 8 modules to encode 1 codeword."). Thus, this second area of stimuli-responsive

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material is part of the Data Matrix two-dimensional barcode that forms the graphically encoded icon.

4. Claim 7: "The user instrument of claim 1, wherein the machine-readable indicia is non-human readable"

194. Claim 7 does not specify whether it relates back to the "first" or "second machine-readable indicia" of claim 1; nevertheless, the first and second machine-readable indicia are both non-human readable for the same reason. Specifically, as I explained above for claim 10, a POSITA would have understood that Prusik's 2D barcode, including the machine-readable indicia of the dynamic ink, is nonhuman readable. *See* Section X.B.2; *see also* Ex. 1005 at [0001] ("A barcode is an optical machine-readable representation of data"), [0084] (describing a two-dimensional barcode encoded with the static data 134 and dynamic data 136 that can be a "Data Matrix or QR code" where "the set of dynamic data 136 is readable by a reader of the 2D barcode when the set of dynamic data is in each of the plurality of states.").

D. Independent Claim 16

1. 16[pre]: "An article"

195. Prusik discloses a "labeled product" that has a "two dimensional barcode with dynamic environmental data." Ex. 1005 at Abstract. This labeled product corresponds to the claimed "article."

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2. 16[a]: "a user instrument associated with a user, the user instrument comprising a graphically encoded icon"

196. Prusik discloses this limitation for the reasons that I discussed above for claim limitations 1[pre]/1[a]. *See* Sections XI.B.1, XI.B.2. In addition, A POSITA would have understood that the label (the claimed user instrument) of the labeled product is associated with a user at least to the extent that the user wishes to use the label to further the marketing of the product (e.g., to purchase the product or move it along the cold chain) in the Prusik/Vaillant combination.

3. 16[b]: "the graphically-encoded icon comprising an area of stimuli-responsive material defining a machine-readable indicia; wherein"

197. Claim element 16[b] would have been obvious for the same reasons as I described above for claim element 1[d]. *See* Section XI.B.5.

4. 16[c]: "wherein: the stimuli-responsive material is configured to change from a first state to a second state in response to a trigger"

198. Claim element 16[c] would have been obvious for the same reasons as I described above for claim element 1[d]. *See* Section XI.B.5.

5. 16[d]: "after the change of the stimuli-responsive material from the first state to the second state, the machine-readable indicia comprises information to permit or deny a user to engage in a transaction using the user instrument."

199. Claim element 16[d] would have been obvious for the same reasons as I describe above for claim element 1[f]. *See* Section XI.B.7.

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E. Dependent Claims 17-20

200. I understand that claims 17-20 depend on independent claim 16.

201. Thus, it is my opinion that dependent claims 17-20 would have been obvious to persons of ordinary skill in the art for the same reasons as independent claim 61. *See* Section XI.D.

202. In addition, claims 17-20 would have been obvious for the reasons I discuss in the following subsections.

1. Claim 17: "The article of claim 16, wherein the user instrument is selected from the list consisting of: a label, a credit card, and a badge"

203. Claim 17 would have been obvious for the same reasons as I described above for limitation 1[pre] and claim 4: the user instrument is a label. *See* Sections XI.B.1, XI.C.1.

2. Claim 18: "The article of claim 16, wherein the user instrument is selected from the list consisting of: a label, a credit card, and a badge"

204. The combination of Prusik and Vaillant renders this claim obvious for the same reason that Prusik's barcode renders it obvious and as I described above for claim 10 in Ground 1(a). *See* Section X.B.2.

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3. Claim 19: "The article of claim 16, wherein the trigger occurs automatically based upon a predetermined condition"

205. The combination of Prusik and Vaillant renders this claim obvious for the same reason as I described above for Prusik's barcode in relation to claims 13 and 15 in Ground 1(a). *See* Section X.B.5.

4. Claim 20: "The article of claim 16, wherein the graphically encoded icon is configured as a QR code"

206. As I discussed above for claim 10, Prusik discloses that its two-dimensional barcode can be a "Data Matrix or QR code." Ex. 1 at [0001]; *see* Section X.B.2; *see also* Prusik at [0109] (describing a 2D barcode as a QR code).

XII. GROUND 2: CLAIMS 8-15 ARE OBVIOUS OVER BURG IN VIEW OF THE KNOWLEDGE OF A PERSON OF ORDINARY SKILL IN THE ART

207. In this section, I explain why every limitation of claims 8-11 and 13-15, and each of claims 8-11 and 13-15 as a whole, would have been obvious to persons of ordinary skill in the art over Burg.

A. Independents Claim 8 and 14

1. 8[pre] and 14[pre]: "A graphically encoded icon, comprising:"[2]

208. Burg discloses the preamble of claim 8 and claim 14.

[2] This declaration uses the same bracketed identifiers used in Petitioners' petition.

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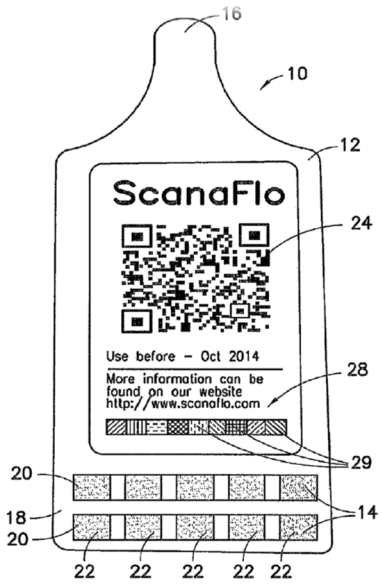


FIG. 1

209. Burg's diagnostic instrument allows for a "quantitative assessment" of color changes to test strips caused by exposure to biological material or fluid. Ex. 1007 at [0009] ("Generally provided are a method and electronic user device for performing quantitative assessment of color changes induced by exposure of multiple test strips to a biological material/fluid.").

210. As Burg's Fig. 1, which is reproduced above, shows, the diagnostic instrument has a paddle with (1) a unique identification (UID) 24, which can be a two-dimensional bar code such as a QR code, and (2) test strips 14 with "a plurality of test media such as chemical test pads (CTP) 22, containing a color changing reagent for identifying the concentration of certain analytes in a patient fluid, such as urine, blood, or saliva." Ex. 1007 at [0046] ("The diagnostic instrument is configured

to test a patient fluid sample for a variety of diseases and patient conditions to increase the likelihood that a variety of conditions may be identified during a testing activity"), [0047] ("With reference to FIG. 1, and in one preferred and non-limiting embodiment, provided is a diagnostic instrument 10, including a paddle 12 for holding at least one test strip 14. The paddle 12 includes a handle 16 and a testing region 18 adapted to hold a plurality of test strips 14. The testing region 18 includes a plurality of indentations 20 for holding at least one individual test strip 14. The test strip 14 may be a reagent dipstick. In that case, each test strip 14 includes a plurality of test media, such as chemical test pads (CTP) 22, containing a color-changing reagent for identifying the concentration of certain analytes in a patient fluid, such as urine, blood, or saliva. The user exposes the diagnostic instrument 10, including the test strips 14, to the fluid sample by dipping the instrument 10 into the patient fluid sample to submerge the test strips 14."), [0050] (explaining that "the diagnostic instrument 10 further includes an identification label, such as a unique identification (UID) 24….the information may be printed directly on or encrypted with the UID 24, such as is the case with a label or two-dimensional bar code, such as a QR code.").

211. Together, the UID and test strips on the paddle correspond to the claimed graphically encoded icon.

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2. 8[a]/14[a]: "a label attached to an object, the label comprising a static portion and an intrinsic portion"

212. Burg discloses limitations 8[a] and 14[a].

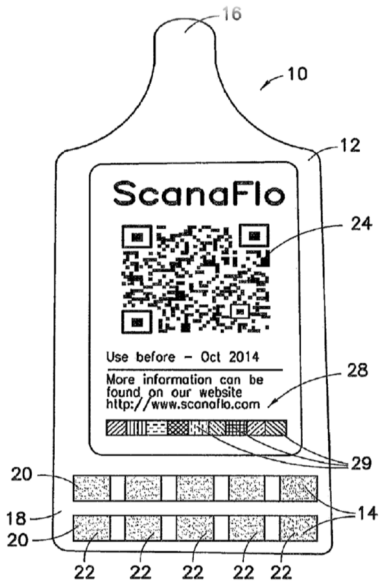


FIG. 1

213. Burg's diagnostic instrument has a paddle 12 with a static portion that includes an identification label with identification code (UID 24), and Burg explains that this identification code can be a "two-dimensional bar code, such as a QR code." Ex. 1007 at [0050]. Fig. 1. The diagnostic instrument also has an intrinsic portion that is made up of test strips 14 attached to the paddle. Ex. 1007 at [0047] ("The paddle 12 includes a handle 16 and a testing region 18 adapted to hold a plurality of test strips 14. The testing region 18 includes a plurality of indentations 20 for holding at least one individual test strip 14. The test strip 14 may be a reagent dipstick."). Burg's test trips are designed to display intrinsic attributes of the tested biological fluid, and

each test strip "contains a color-changing reagent for identifying the concentration of certain analytes in a patient fluid, such as urine, blood, or saliva." Ex. 1007 at [0047].

214. A POSITA would have understood that Burg's two dimensional barcode and test strips that are attached to the paddle correspond to the claimed label attached to an object. The paddle is a separate object to which the barcode and test strips are attached to: as Burg explains, handling a used test strip which is "soiled by biological samples such as urine, blood, feces, etc., is undesirable" and thus, Burg's paddle with the two dimensional barcode and test strips attached helps the user "confidently perform the test" without "worrying that he or she will accidently contact patient fluid." Ex. 1007 at [0048], [0051].

3. 8[b]/14[b]: "the static portion comprises machine-readable indicia"

215. Burg discloses limitations 8[b] and 14[b].

216. As I explained in the preceding sections, the UID of Burg's diagnostic instrument corresponds to the claimed static portion. This UID can be a "two-dimensional bar code, such as a QR code," which a POSITA would have known and understood to be a machine-readable indicia. Ex. 1007 at [0050]. Further, Burg discloses a portable electronic device which includes "an optical reader (e.g. bar code, matrix bar code reader, two-dimensional bar code reader, or a QR code reader)" that is "associated with the portable electronic device" and used to take an image of the

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diagnostic instrument, Ex. 1007 at [0065]. This is used to "scan the captured digital image to locate the UID." Ex. 1007 at [0065] ("Specifically, an optical reader (e.g. bar code, matrix bar code reader, two-dimensional bar code reader, or a QR code reader), associated with the portable electronic device, is used to scan the captured digital image to locate the UID."). The UID "includes or corresponds to" information about the diagnostic instrument that is being tested, and "software is configured to ensure that the diagnostic instrument is safe for use and suitable for a specific application, based on the identification information from the UID." Ex. 1007 at [0065].

4. 8[c]/14[c]: "the intrinsic portion comprises an area of stimuli-responsive material"

217. Burg discloses limitations 8[c] and 14[c].

218. Burg's diagnostic instrument comprises the claimed intrinsic portion via test strips made of a stimuli-responsive material that changes color in response to exposure to chemical analytes in patient fluid. For example, Burg describes that the test strips include test media "such as chemical test pads (CTP) 22, containing a color-changing reagent for identifying the concentration the concentration of certain analytes in a patient fluid." Ex. 1007 at [0047]. Burg explains that these chemical test pads change color "over a range of analyte concentrations or titration level (e.g. absent, normal, positive, very positive . . .)." Ex. 1007 at [0068].

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5. 8[d]/14[d]: "the stimuli-responsive material is configured to change from a first state to a second state in response to a trigger, the change in state being based on an attribute about the object"

219. Burg discloses limitations 8[d] and 14[d].

220. As discussed above for claim limitations 8[c] and 14[c], Burg discloses that the chemical test pads of the test strips change color from a first state to a second in response to a trigger, i.e., the of exposure to analytes in a patient fluid. Section XII.A.4; Ex. 1007 at [0047] ("The test strip 14 may be a reagent dipstick. In that case, each test strip 14 includes a plurality of test media, such as chemical test pads (CTP) 22, containing a color-changing reagent for identifying the concentration of certain analytes in a patient fluid, such as urine, blood, or saliva. The user exposes the diagnostic instrument 10, including the test strips 14, to the fluid sample by dipping the instrument 10 into the patient fluid sample to submerge the test strips 14.").

221. A POSITA would have understood that the level of analytes in the patient fluid that paddle has been in contact and thus to which the test pads have been exposed corresponds to the claimed attribute of the object. For example, Burg explains that a user exposes "the diagnostic instrument to a biological sample, which exposes the plurality of CTP to analytes contained in the sample and begins a chemical reaction between the CTP and analytes." Ex. 1007 at [0063]. In response to being exposed to a chemical analyte, i.e., the claimed trigger, the CTP changes from

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a first color to a second color being of "a range of possible color changes of the CTP being tested." Ex. 1007 at [0068].

6. 8[e]/14[e]: "the transformation of the stimuli-responsive material is a change in the transparency of the stimuli-responsive material"

222. Burg discloses limitation 8[e] and 14[e].

223. Burg explains that a color change where "the intensity of a color change of the test strip is an indication of the concentration of the analyte or disease marker in the patient fluid" is the result of exposing the CTP to a biological fluid containing levels of chemical analyte. Ex. 1007 at [0045]. A POSITA would have understood that this change in color intensity is the claimed change in transparency or reflection of the CTP because the color of a sample corresponds to the wavelength of light that is reflected by the sample and similarly, the intensity of the color corresponds to how much light reflects versus passes through the sample (e.g., how transparent the color is). Thus, a POSITA would have understood that changing a color at different intensities also changes its reflection and transparency.

224. To the extent Patent Owner argues that this limitation is missing in Burg, a POSITA would have found it obvious. For example, the intensity of the color change can be attributed to the transparency of a material. Thus, when more light passes through a more transparent CTP and onto the white surface of the strip behind

it, the color is perceived to be less intense than with an opaque strip that reflects all of the light at a given color/wavelength.

225. In addition, a POSITA would have known that the stimuli-responsive material in diagnostic test strips, such as dip sticks, are colorless to begin and transform to a colored state when exposed to a certain analyte or disease agent. For example, U.S. Patent 5,496,702 describes the state of the art as early as 1996. Ex. 1023 at 1:11-23. Even then, "[v]arious dry analytical assay elements [were] commercially available" as well as "known dry multilayer immunoassay elements [that] include a layer comprising a leuco dye." Ex. 1023 at 1:11-14. Specifically, it was known that the leuco dye "is oxidized *to a colored form*" from a colorless form when it is exposed to a specified analyte in the course of an assay. Ex. 1023 at 1:14-17.

226. A POSITA would have thus been motivated to apply these well-known leuco dyes to Burg's dipsticks and immunoassay, which does not require its test to have an initial color or limit its changing stimuli-responsive material. *See* Ex. 1007 at [0004] (describing reagent dipsticks and immunoassays), [0006] (same). Thus, the use of these well-known leuco dyes, which start as transparent and become colored, would have been nothing more than the use of a known technique to a known device (Burg's dipsticks and immunoassays) that results in a predictable result.

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227. A POSITA would have also found it obvious for the transformation to be a change in the reflection of the material. Specifically, a POSITA would have understood that when leuco dyes change to a colored form, "the reflection density of the color is proportional to the concentration of analyte in the sample," a fact that was "well known" as early as 1996. Ex. 1023 at 1:17-19; 1:19-20 (describing the measurement of reflection density through a reflectometer). This reflection density corresponds to the color change "intensity" disclosed in Burg. Ex. 1007 at [0145].

228. Thus, Burg renders limitations 8[e] and 14[e] obvious to a POSITA

B. Dependent Claims 9-13 and 15

229. I understand that claims 9-13 depend on independent claim 8.

230. I also understand that claim 15 depends from claim 14 but recites the same limitation as claim 13.

231. Burg renders each of these dependent claims obvious in view of a POSITA's knowledge.

1. Claim 9: "The graphically encoded icon of claim 8, wherein the change in state of the stimuli-responsive material results in machine-readable indicia."

232. Burg discloses this limitation through its "computer-implemented method for quantifying color change of at least one test medium." Ex. 1007 at [0010].

233. Burg explains that the CTP are analyzed by a portable electronic device configured "to determine a test result including an analyte concentration of the

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biological sample being tested" based on an image captured by the device after the CTP change colors in response to being exposed to a chemical analyte. Ex. 1007 at [0014]; [0063]; [0068]. Burg also discloses methods of performing "color-based reaction testing of biological material in an automatically calibrated environment" that can be "implemented as a software application (an 'App') running on a portable electronic device, such as a cell phone, tablet PC, computer, laptop, or other dedicated electronic device." Ex. 1007 at [0044].

234. As Burg further explains, the electronic device has a processor that "controls a digital image analyzer 120 for identifying regions of a digital image containing relevant data, color correcting the digital image, and comparing the corrected portions of the digital image to table entries of the MICC to determine test results." Ex. 1007 at [0058]. Thus, a POSITA would have understood that the change in color of the CTP when exposed to a chemical analyte results in machine readable indicia because the color changes of the CTP are analyzed by an electronic device that uses a software application on a processor.

2. Claim 10: "The graphically encoded icon of claim 9, wherein the machine-readable indicia of the stimuli-responsive material is non-human readable."

235. Burg renders claim 10 obvious.

236. Burg teaches that the system has a benefit of not being reliant on visual interpretation of CTP color changes by a human. Ex. 1007 at [0120]. Specifically, the

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disclosed methods and system are "quite tolerant of nonlinearities, and do[] not require a unitary relationship with any human visual properties, making its numerical value and interpretation independent of the color vision of the observer, ambient lighting when the digital image was taken, residual metamerism, or indeed most commonly encountered errors, for which calibration and compensation did not formerly exist." Ex. 1007 at [0120].

237. Further, just like embodiments in the '818 patent, Burg's machine-readable indicia does not include symbols that are readable to a human with the naked eye, such as Arabic numerals, Greek numerals, Chinese numerals, or the Roman alphabet. *See* Ex. 1001 at 5:6-10 (unlike Arabic numerals, "humans are typically unable to decipher such machine-readable indicia using the naked eye").

238. Thus, Burg's disclosed method applies computer-implemented image processing techniques to "automatically read[] test strips…, which uses a digital image captured environment." Ex. 1007 at [0008]. Burg's system is also "configured to automatically calibrate the digital image to correct any color deficiencies, artifacts, or other ambiguities." Ex. 1007 at [0008]. Finally, Burg's system "also automatically identif[ies] the relevant portions of the digital image, regardless of how the test strip and/or color reference are positioned in the digital image." Ex. 1007 at [0008]. Thus, a POSITA would have understood that Burg's CTP captured in a digital image are non-human readable.

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3. Claim 11: "The graphically encoded icon of claim 10, wherein the machine-readable indicia of the static portion is non-human readable"

239. Burg renders this claim obvious.

240. As discussed above for claims 8 and 14, Burg's diagnostic instrument has a UID that is the claimed static portion. Burg's UID can be a "two-dimensional bar code, such as a QR code" that includes machine-readable indicia that are non-human readable. Ex. 1007 at [0050]. Burg further explains that "the UID 24 may be configured to contain certain identification information about the diagnostic instrument 10, such as a list of the analytes that are being tested, expiration date of the instrument 10, the conditions that are being tested, and other identifying information" and that this information may be "encrypted with the UID 24." Ex. 1007 at [0050]. Further, like embodiments in the '818 patent, Burg's machine-readable indicia does not include symbols that are readable to a human with the naked eye, such as Arabic numerals, Greek numerals, Chinese numerals, or the Roman alphabet. *See* Ex. 1001 at 5:6-10. Thus, a POSITA would have understood that this encrypted information contained within the UID is also non-human readable.

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4. Claims 13 and 15: "wherein the trigger occurs automatically based on a predetermined condition about the attribute of the object."

241. Claim 13 depends from claim 8 while claim 15 depends from claim 14. They have identical language, and for the reasons I explain below, Burg discloses these limitations.

242. As I discussed above for limitations 8[d]/14[d], Burg's test strips have CTPs that change color in response to being exposed to a biological fluid that have chemical analytes (the claimed trigger). The exposure to the analytes (trigger) occurs automatically when the test strips are placed into contact with the biological fluid containing the analytes. The trigger is based on a predetermined condition, namely, the level of exposure to a chemical analyte that triggers color change. This level of exposure is about the attribute of the object (the concentration of a chemical analyte in the fluid contained on the paddle) because the CTP's color automatically changes to a color intensity that is indicative of the concentration of that chemical analyte in the biological fluid. Ex. 1007 at [0063], [0068], [0009] (disclosing that "color changes [are] induced in various test strips by exposure to the [biological] sample."). Further, because a computer can determine the level of chemical analytes from the color change, the level of analytes that generate the change in state is predetermined value.

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XIII. GROUND 3: CLAIMS 8-11 AND 13-15 ARE OBVIOUS OVER DIMOV IN VIEW OF A POSITA'S KNOWLEDGE

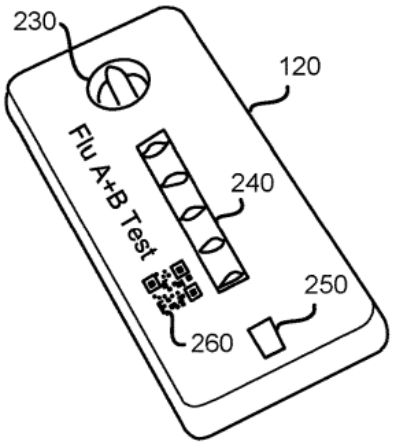
243. In this section, I explain why every limitation of claims 8-11 and 13-15, and each of claims 8-11 and 13-15 as a whole, would have been obvious to persons of ordinary skill in the art over Dimov.

A. Independents Claim 8 and 14

1. 8[pre] and 14[pre]: "A graphically encoded icon, comprising:"

244. To the extent that these preambles are limiting, Dimov discloses a graphically encoded icon through its "image-based diagnostic test," which uses an "optical property modifying device" that has a "reaction chambers" and a QR code that correspond to the claimed graphically encoded icon. *See* Ex. 1008 at 1:7-9 ("This description generally relates to disease diagnostics, and particularly to a portable system to perform image-based disease diagnostic tests"); 4:57-67 ("FIG. 2 is a diagram of the optical property modifying device 120 for use with a mobile device 110 according to one embodiment. In the embodiment shown in FIG. 2, the optical property modifying device 120 (also referred to herein as a "cartridge") includes a collection tube interface 230, one or more reaction chambers 240, an indicator 250, and a QR code 260. To perform a disease diagnostic test, a user uses the optical property modifying device 120 to react a biological sample (e.g., including a nucleic

acid) of a patient with an optical property modifying reagent in the reaction chambers 240.").



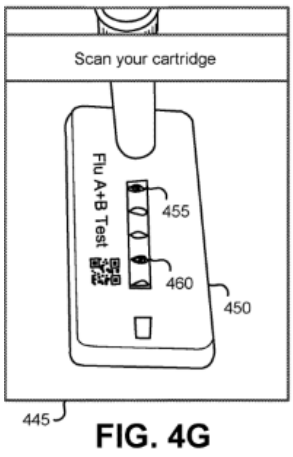
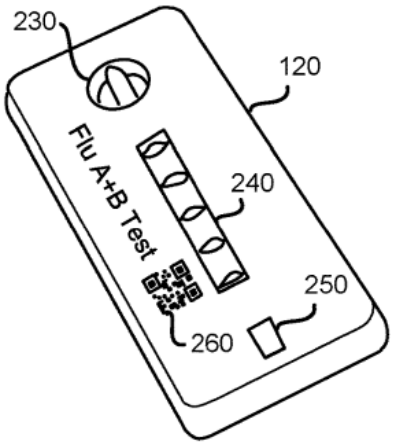


FIG. 4G

Dimov Figure 2 (excerpted) **Dimov Figure 4G**

2. 8[a]/14[a]: "a label attached to an object, the label comprising a static portion and an intrinsic portion"

245. Dimov discloses, or at a minimum suggests, limitations 8[a] and 14[a].



Dimov Figure 2 (excerpt)

246. Dimov discloses an optical property modifying device 120 that has a QR code 260 (static portion) and a reaction chambers 240 (intrinsic portion). Ex. 1008 at 5:21-33. The reaction chambers 240 has "a dye which changes color or fluoresces upon target amplification, resulting in a visible change in the solution's optical properties." Ex. 1008 at 5:31-44. The static portion includes the QR code and the intrinsic portion includes the reaction chambers. Ex. 1008 at 5:21-33. The collection tube and optical property modifying device attach to one another by "physically contacting the cartridge interface 210 of the collection tube 200 to the collection tube interface 230 of the optical property modifying device 120." Ex. 1008 at 6:23-27. The static portion includes the QR code and the intrinsic portion includes the reaction chambers. Dimov 5:21-33

247. A POSITA would have known and understood that the QR code and reaction chambers on the optical property modifying device correspond to a label attached to an object. The optical property modifying device, when attached to a collection tube as shown in the figures below, is an object to which the label is attached.

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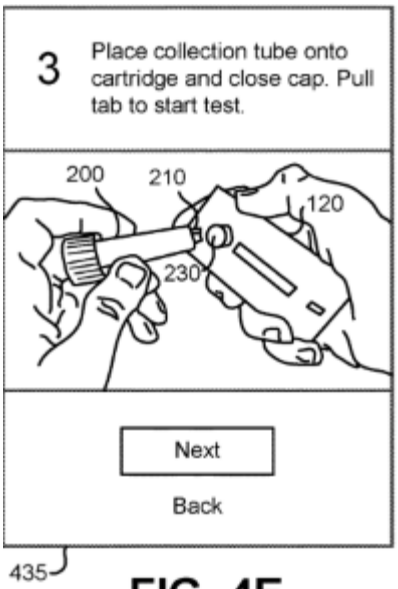


FIG. 4E

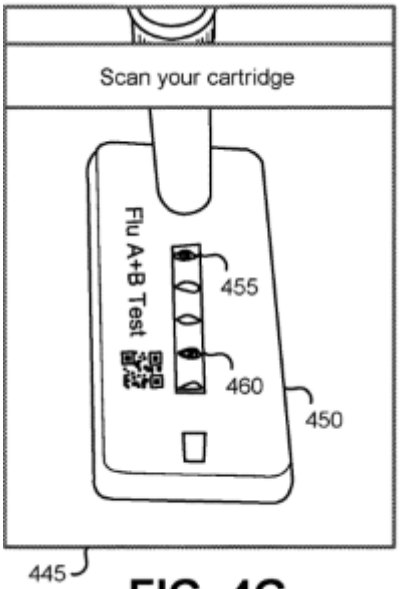


FIG. 4G

248. Thus, Dimov discloses, or at a minimum renders obvious, this limitation.

3. 8[b]/14[b]: "the static portion comprises machine-readable indicia"

249. Dimov discloses limitations 8[b] and 14[b].

250. As I explained above for limitations 8[a] and 14[a], Dimov discloses a "QR code 260" that corresponds to the claimed static portion. For example, the QR code "may be associated with information for a disease diagnostic test such as a type of test or expiration date of the test." Ex. 1008 at 5:21-23.

251. A POSITA would have known and understood that this QR code comprises machine readable indicia. As Dimov explains, this QR code is machine-readable because the "diagnostic system 100 can determine the information for [the] disease diagnostic test by processing images of the QR code 260 scanned by an optical sensor of the mobile device 110." Ex. 1008 at 5:23-26. In addition, Dimov

explains that "[t]he QR code 260 can also be another type of code, such as a barcode, or other identifier or machine-readable signature." Ex. 1008 at 5:26-28.

252. Thus, Dimov discloses, or at a minimum renders obvious, this limitation.

4. 8[c]/14[c]: "the intrinsic portion comprises an area of stimuli-responsive material"

253. Dimov discloses limitations 8[c] and 14[c].

254. As I explained above for limitations 8[c] and 14[c], Dimov's reaction chambers 240 (the claimed intrinsic portion) use an optical property modifying reagent to determine the presence or amount of a particular genetic target in a biological sample using a "solution comprising nucleic acid enzymes and primers which specifically [] target [a] nucleic acid sequence specific to an organism of interest." Ex. 1008 at 5:33-38. A POSITA would have understood that this optical property modifying reagent is a stimuli-responsive material because it has "a dye which changes color or fluoresces upon target amplification," resulting in "a visible change in the solution's optical properties." Ex. 1008 at 5:41-44.

255. Thus, Dimov discloses these limitations.

5. 8[d]/14[d]: "the stimuli-responsive material is configured to change from a first state to a second state in response to a trigger, the change in state being based on an attribute about the object"

256. Dimov discloses limitations 8[d] and 14[d].

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257. As explained above for claim elements 8[c] and 14[d], Dimov's optical property modifying reagent uses "a dye which changes color or fluoresces" to create a visible change in the solution's optical properties" upon "target amplification," i.e., when the solution is in "the presence…of a particular genetic target in the biological sample." Ex. 1008 at 5:29-44.

258. A POSITA would have understood that this change from a first state (the original color) to a second state (the second color or fluorescing) is in response to a trigger (the "presence or amount of a particular genetic target"). A POSITA would have also understood that the color change in the optical property modifying reagent is based on an attribute of the object, namely, the biological sample stored in the collection tube that ultimately enters the reaction chamber. This is because the change in color is designed to occur if there is a particular genetic target present in that sample. As Dimov explains, "the presence or amount of this target nucleic acid sequence within the biological sample may indicate that a patient is infected with a particular pathogen or carries a particular genetic disease." Ex. 1008 at 5:38-41. Thus, just like how the label of the '818 patent changes states based on the temperature of shrimp, Dimov's prior art optical property modifying reagent changes colors or fluorescence based on the presence (or presence of a certain amount of a particular genetic target in the biological sample that is found in the claimed object.

259. Accordingly, Dimov discloses or renders obvious this limitation.

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6. 8[e]/14[e]: "the transformation of the stimuli-responsive material is a change in the [transparency/reflection] of the stimuli-responsive material"

260. Limitation 8[e] recites: "the transformation of the stimuli-responsive material is a change in the transparency of the stimuli-responsive material." Limitation 14[e] uses similar language but recites that "the transformation of the stimuli-responsive material is a change in the reflection of the stimuli-responsive material." Dimov discloses, or at a minimum renders obvious to a POSITA, these limitations.

261. As I explained above for claim elements 8[d] and 14[d], Dimov's optical property modifying reagent includes a "dye which changes color or fluoresces." Ex. 1008 at 5:41-43. For the same reasons discussed above in Ground 2 for limitations 8[e] and 14[e], a POSITA would have known and understood that a change in color or fluoresces that results in "a visible change in the solution's optical properties" is a change in the transparency and reflection of the stimuli-responsive material. Ex. 1008 at 5:41-44; Section XII.A.6 In fact, Dimov explains that the system determines "transparency, translucency, [and] opacity" when analyzing the color change. Ex. 1008 at 8:38-47. A POSITA would have also understood that Dimov determines these properties because they are designed to change based on the trigger.

262. To the extent Patent Owner argues that this limitation is missing in Dimov, including it in Dimov's system also would have been obvious to a POSITA.

For example, Dimov measures the transparency, translucency, and opacity of the reaction chambers. Thus, a POSITA would have found it obvious for the stimuli-responsive material in the chambers to change transparency, translucency, and opacity (including reflection, which is an aspect of translucency and opacity) in response to the trigger based on Dimov's suggestion.

263. Further, as I explained above for Ground 2, a POSITA would have known that well-known leuco dyes were commonly used for diagnostic tests to transform from a transparent state to a colored one when exposed to a certain analyte or disease agent. Ex. 1023 at 1:11-23; *see* Section XII.A.6. A POSITA would have thus been motivated to apply such well-known leuco dyes to Dimov's solution, which uses has an "optical property modifying reagent [that] includes a dye which changes color or fluoresces upon target amplification, resulting in a visible change in the solution's optical properties." Ex. 1008 at 5:41-44. Therefore, using a well-known leuco dye that starts as transparent and changes to a colored form would have been nothing more than the use of a known technique to a known device (Dimov's diagnostic system) that has a predictable result.

264. In addition, for the same reasons that I explained above for Ground 2, it also would have been obvious to a POSITA for the transformation to be a change in the reflection of the material. *See* Section XII.A.6.

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265. Thus, Dimov discloses, or at a minimum renders obvious to a POSITA, limitations 8[e] and 14[e].

B. Dependent Claims 9-13 and 15

266. I understand that claims 9-13 depend on independent claim 8.

267. I also understand that claim 15 depends from claim 14. Claim 15 recites an identical limitation as claim 13.

268. In the following sections, I explain why Dimov renders each of these dependent claims obvious in view of a POSITA's knowledge.

1. Claim 9: "The graphically encoded icon of claim 8, wherein the change in state of the stimuli-responsive material results in machine-readable indicia."

269. Dimov discloses this limitation and thus renders claim 9 obvious.

270. As I explained above for limitation 8[c]/14[c], Dimov teaches the claimed "change in state of the stimuli-responsive material by its disclosure of an "optical property modifying device" with an "optical property modifying reagent" which has a "dye which changes color or fluoresces" when a targeted nucleic acid sequence within a biological sample is detected. Ex. 1008 at 5:33-48; Section XIII.A.4.

271. A POSITA would have known and understood that this change in state results in a machine-readable indicia. As explained below, Dimov discloses an image analysis engine that determines the reaction chambers' optical properties.

Specifically, Dimov' s diagnostic system uses a mobile device to "acquire[] images of an optical property modifying device 120 using the image processing engine 320 and provides the images to the diagnostic server 150 for further processing by the image analysis engine 325." Ex. 1008 at 8:42-55. The image analysis engine analyzes images acquired and processed by the image processing engine and "determines one or more optical properties of the reaction chambers 240 such as the color, transparency, translucency, opacity, or uniformity of the reaction chambers 240 and/or contents within the reaction chambers." Ex. 1008 at 8:38-47.

272. For example, Dimov's image analysis engine "determines information about the optical properties of the reaction chambers" such as "the average and variance of color of a group of pixels in an image corresponding to each reaction chamber." Ex. 1008 at 8:48-52. Then, the image analysis engine determines "test results for a disease diagnostic test by comparing the determined color information of a reaction chamber 240 to reference information that indicates one or more color ranges." Ex. 1008 at 9:1-4. Based on at least these disclosures, a POSITA would have understood that the change in state of the stimuli-responsive material—i.e., the change in optical properties—results in machine-readable indicia because the "image analysis engine" is a machine that uses information from the optical properties changes of the reaction chambers to determine the test results for a diagnostic test.

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2. Claim 10: "The graphically encoded icon of claim 9, wherein the machine-readable indicia of the stimuli-responsive material is non-human readable."

273. A POSITA would have found it obvious for Dimov's machine-readable indicia of the stimuli-responsive material to be non-human readable based on Dimov's disclosures. As I explained above, the stimuli-responsive material in the reaction chambers results in a change in optical properties when a certain targeted nucleic acid sequence within a biological sample is detected. *See* Section XIII.A.5, XIII.B.1. Dimov also explains that the purpose of Dimov's system is to provide a "reliable and portable end-to-end system that patients can complete in the comfort of their homes." Ex. 1008 at 1:36-39. As Dimov explains, one issue with traditional disease diagnostic tests is that "trained personnel such as a nurse, physician, or lab technician must analyze" the diagnostic test results. Ex. 1008 at 1:17-20. To overcome this, Dimov teaches that its system for performing disease diagnostic tests uses an "image processing engine 320, image analysis engine 325, [and] diagnostic test engine 330" to analyze the machine-readable indicia. Ex. 1008 at 8:35-41, 6:35-55. Further, Dimov explains that the diagnostic system "can provide the test result and relevant metadata" to healthcare providers, meaning that the machine-readable indicia of the stimuli-responsive material itself is not read by a human. Ex. 1008 at 2:5-8; Fig. 4H (showing test results on a mobile device as a binary "Positive" or "Negative" indication). Instead, only the test result can be read by a human.

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274. In addition, like embodiments described in the '818 patent, Dimov's machine-readable indicia does not include symbols that are readable to a human with the naked eye, such as Arabic numerals, Greek numerals, Chinese numerals, or the Roman alphabet. *See* Ex. 1001 at 5:6-10. Thus, a POSITA would have understood that the machine-readable indicia of the stimuli-responsive material could and would be non-human readable.

3. Claim 11: "The graphically encoded icon of claim 10, wherein the machine-readable indicia of the static portion is non-human readable"

275. As I explained above for claim elements 8[b] and 14[b], Dimov discloses that a "QR code 260 [] may be associated with information for a disease diagnostic test such as a type of test or expiration date of the test." Ex. 1008 at 5:21-28; Section XII.A.3. Further as I discussed in Ground 1(a) and Ground 2 for claim 11, a POSITA would have understood that a QR code is non-human readable. *See* Sections XI.C.4, XII.B.3.

4. Claims 13 and 15: "wherein the trigger occurs automatically based on a predetermined condition about the attribute of the object."

276. Dimov discloses or at a minimum renders obvious these limitations.

277. As I explained above for limitations 8[d]/14[d], Dimov's optical property modifying reagent uses "a dye which changes color or fluoresces" that causes in "a visible change in the solution's optical properties" upon "target

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amplification," meaning, when the solution is in "the presence…of a particular genetic target in the biological sample." Ex. 1008 at 5:29-44. A POSITA would have understood that the change in optical properties from, for example, one color or fluorescence to a second color or fluorescence, is in response to the claimed trigger (the exposure to the "presence or amount of a particular genetic target" that is sufficient to change the optical properties) that occurs automatically based on an object's attribute (the amount of the particular genetic target that is contained in the biological sample).

XIV. Conclusion

278. For these reasons, it is my opinion that claims 1 and 4-20 of the '818 patent are unpatentable under 35 U.S.C. § 103.

279. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, I am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001. I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 21, 2024 in Corona Del Mar, California.



Dr. Majid Sarrafzadeh

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