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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RHYS DE CALLIER, RICHARD L. EGAN,
WILLIAM J. FERENCZY, and MICHAEL JON HALE
(APPLICANT: QUIDEL CORPORATION)

Appeal 2018-000321
Application 13/783,065[1]
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 1 and 4–12 (Final Act. 2).[2] Examiner entered rejections under 35 U.S.C. § 112(b), 35 U.S.C. § 103(a), and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify "Quidel Corporation" as the real party in interest (Appellants' April 10, 2017 Appeal Brief (Br.) 1).
[2] Examiner's November 9, 2016 Final Office Action.

STATEMENT OF THE CASE

Appellants' disclosure "relates to a system and an apparatus for analysis of a sample to aid in medical diagnosis or detection of the presence or absence of an analyte in the sample" (Spec. ¶ 2). Claims 1, 10, and 11 are representative and reproduced below:

1. A system, comprising:

a test device comprising:

(a) a label zone comprising

(i) a first population of mobilizable, detectable particles for specific binding to a test analyte in a sample; and

(ii) a second population of mobilizable, detectable particles for specific binding to a non-test analyte but not to the test analyte; and

(b) a first detection site at a first position comprising a first binding member having specific binding affinity for detectable particles in the first population bound to the test analyte; and

(c) a second detection site at a second position that is separate from the first position, the second detection site comprising a second binding member having specific binding affinity for detectable particles in the second population bound to the non-test analyte;

an analyzer comprising:

(1) a drawer dimensioned to receive the test device,

(2) an optical system for detection of a signal generated from the first population of particles at the first position and the second population of particles at the second position when each population reaches a specific and separate position on the test device,

(3) a processor and memory resources for control of a motor and for processing data from an optics module, wherein the processor and memory resources are

> *configured to evaluate a sample using a ratio of signal detected from all or a portion of the second population of particles to signal detected from all or a portion of the first population of particles (i) to determine a time insensitive cut-off value for the analyzer, and (ii) to determine the presence or absence of analyte in the sample.*

(Br. 15 (emphasis added).)

> 10. The system of claim 1, wherein the test device is a lateral flow immunoassay.

(*Id.* at 16.)

> 11. The system of claim 10, wherein one or both of the first and second population of detectable particles is comprised of particles comprised of a fluorescing lanthanide compound.

(*Id.*)

Claims 1 and 4–12 stand rejected under 35 U.S.C. § 112(b).

Claims 1 and 4–10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito[3] and Kuo.[4]

Claims 1 and 4–10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito, Kuo, and Maher.[5]

Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito, Kuo or Maher, and Hudak.[6]

Claims 1 and 4–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Egan[7] in view of Polito.

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[3] Polito et al., US 6,136,610, issued Oct. 24, 2000.
[4] Kuo et al., US 7,784,678 B2, issued Aug. 31, 2010.
[5] Maher et al., US 2008/0081341 A1, published Apr. 3, 2008.
[6] Hudak et al., US 2009/0142856 A1, published June 4, 2009.
[7] Egan et al., US 9,207,181 B2, issued Dec. 8, 2015.

Claim Interpretation corresponding to 35 U.S.C. § 112(f):

FACTUAL FINDINGS (FF)

FF 1. Appellants' Figure 11 is reproduced below:

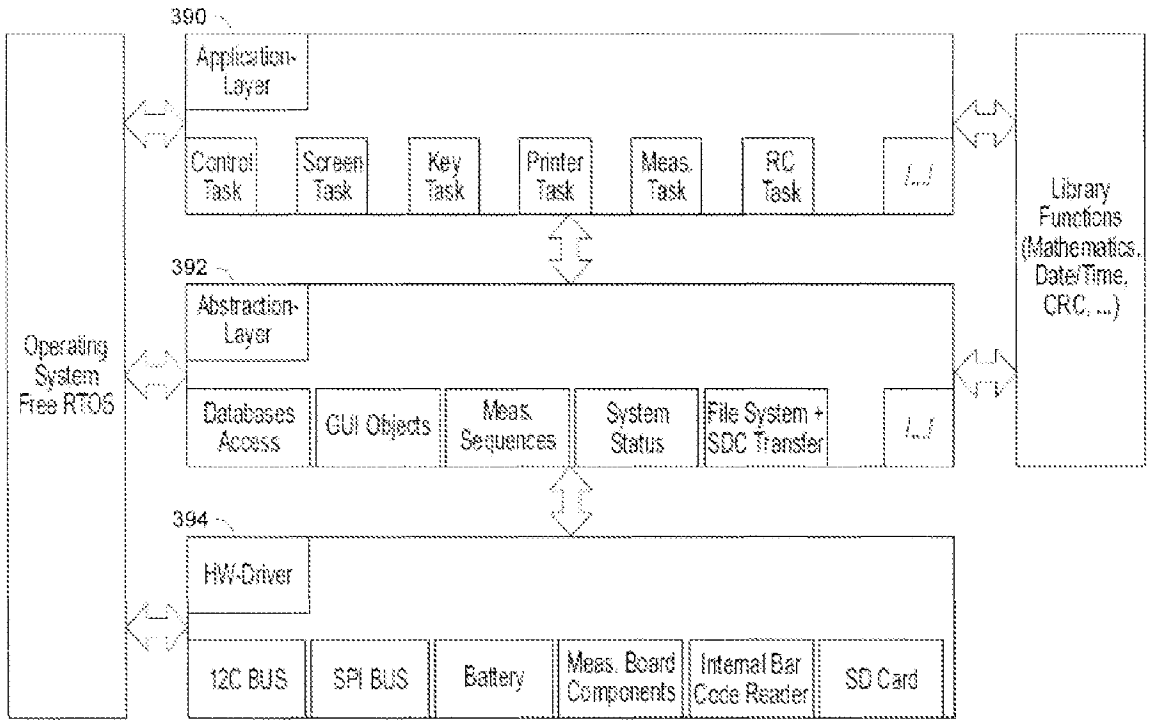

FIG. 11

Appellants' "FIG. 11 is an illustration of the software architecture of an apparatus" (Spec. ¶ 34).

FF 2. Appellants' Figure 12 is reproduced below:

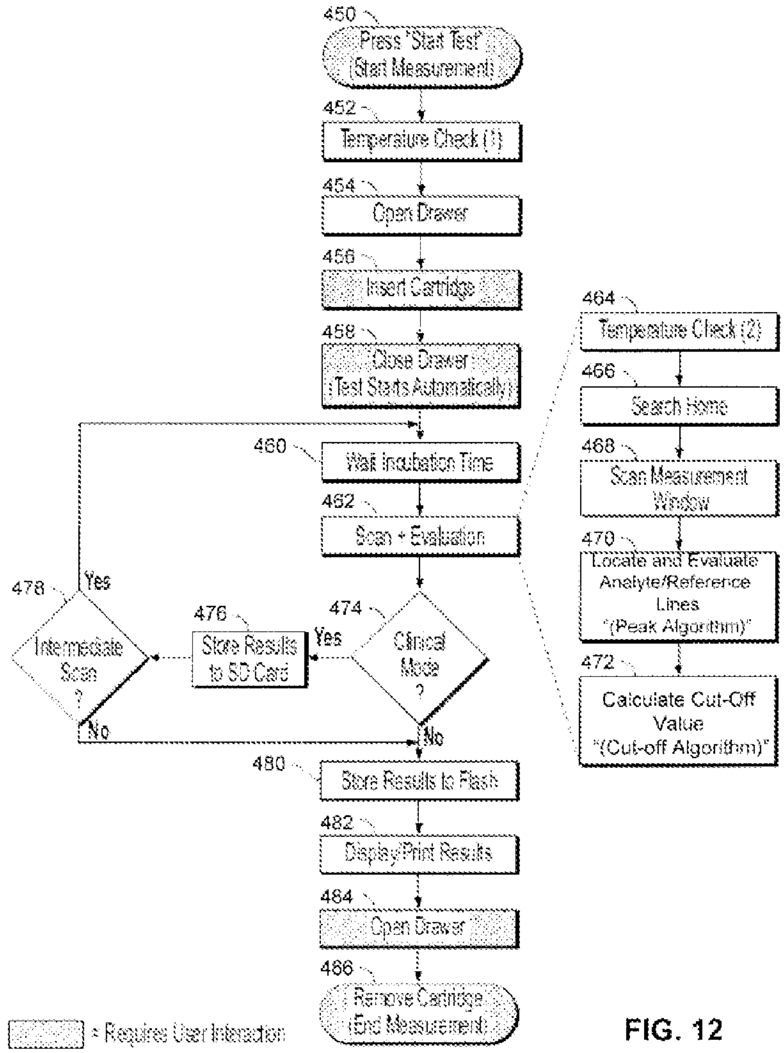

FIG. 12

Appellants' "FIG. 12 shows the sequence of events in one embodiment of a measurement procedure where an apparatus as described herein interacts with a test device, exemplified by an immunoassay" (Spec. ¶ 35).

FF 3. Appellants disclose the closure of the drawer 458:

> [I]nitiates a sequence of events . . . comprised of the following. The internal bar code reader scans the bar code on the test device and receives information regarding the assay type (e.g., influenza A/B, hCG, Strep A, RSV, etc.), the serial number and the expiration date of the test device, and any other information included on the bar code secured to the test device. In one embodiment, a mirror is positioned to facilitate interaction of

> the light beam from the internal bar code scanner and the bar code label on the test device. It will be appreciated that the internal bar code reader is an optional feature, as the information on the bar code label can be entered into the apparatus by a user using the key pad or via an external bar code scanner. Based on the test assay type discerned from the information on the bar code label or otherwise provided to the apparatus processor, the apparatus initiates an algorithm stored in the apparatus' memory for the assay for which the test device is designed, and based on user defined selection of read-now mode or walk-away mode, a protocol stored in memory initiates. In walk-away mode the apparatus incubates for a period of time, 460, prior to initiating a scan of the test device, 462; in read-now mode the apparatus does not wait for the preset incubation time for that particular assay, and immediately begins a scan of the test device, 462.

(Spec. ¶ 96 (emphasis omitted).)

FF 4. Appellants disclose:

> The scan and evaluation of the test device, 462, comprises another temperature check, 464, at the same or different position from the first temperature check 452. The initiated algorithm activates the optics system, including the stepper motor that moves the optics module with respect to the test device that is stationary in the apparatus. The optics system searches for its home position, 466, (described below) and then conducts a scan of the measurement window, 468, in the housing of the test device through which the reference/control and test line(s) are visible. The motor in the optics system moves the optics module incrementally from a defined start point along the length of the measurement window in the test device in accord with parameters defined by the algorithm for the particular assay being conducted. As will be described in more detail below, the optics module is moved in incremental steps by the motor in the optics system along the length of the test window, in a downstream to upstream direction with respect to sample fluid flow on the test strip, wherein the optics carriage stops at each incremental step or position to illuminate

> the position, detect emitted light after illumination at that position, before advancing upstream to the next position.

(Spec. ¶ 97 (emphasis omitted).)

FF 5. Appellants disclose:

> After collection of emitted light at each of the plurality of incremental positions along the length of the test window, the algorithm locates and evaluates the data in the data array that is associated with the reference line, 470, and conducts a qualitative, semiquantative or quantative analyte evaluation using a cut-off algorithm, 472.

(Spec. ¶ 98 (emphasis omitted).)

FF 6. Appellants' Figure 13A is reproduced below:

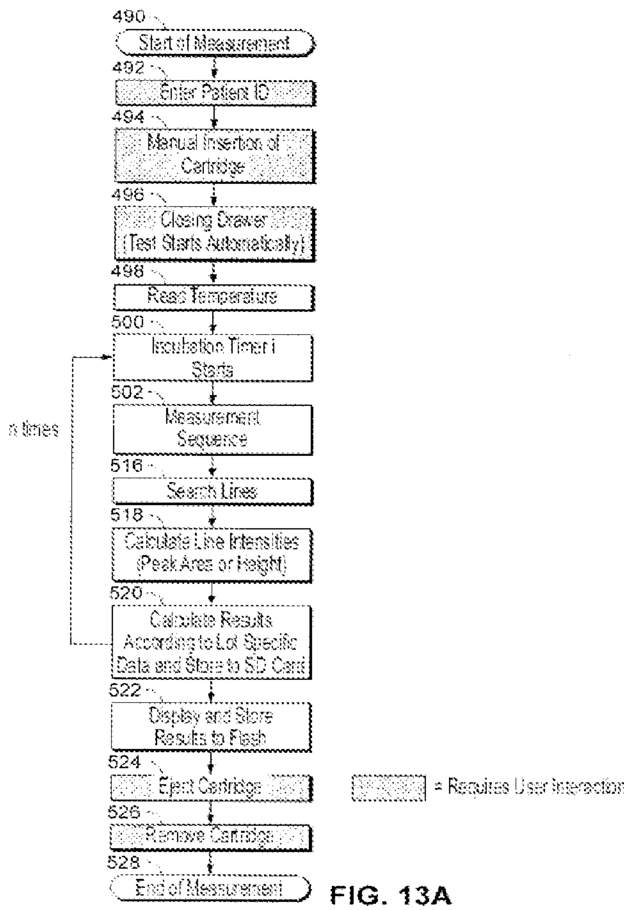

FIG. 13A

Appellants' FIG. 13A illustrates an

> exemplary test sequence for the apparatus described [in Appellants' Specification, wherein the] start of the

> measurement procedure is initiated, 490, by pressing a button or switch on the apparatus. Information regarding the patient (name, gender, age, etc.) is entered, 492, by the user via entry using the keypad on the apparatus or via an external bar code scanner. The drawer in the apparatus is opened using a button on the apparatus and the test device is inserted into the drawer, 494. Closing of the drawer manually or automatically by the apparatus initiates an automated sequence of events, 496. The sequence includes reading the temperature at one or more locations inside the apparatus, such as adjacent the test window, and/or taking an ambient temperature reading, 498. If an incubation time is commanded by a user selecting 'walk-away' mode or by a pre-programmed requirement for a particular test assay, an incubation time starts, 500. Upon completion of the incubation time or if no incubation time is required or commanded, the measurement sequence by the optics system automatically initiates.

(Spec. ¶100 (emphasis omitted); *see also id.* (Appellants disclose "that the test sequence is easily varied by simply varying the programming in the software programs in the device, to alter the sequence of events, time allocated to each event, etc., in a measurement procedure"); *see generally* ¶ 36.)

FF 7. Appellants' Figure 13B is reproduced below:

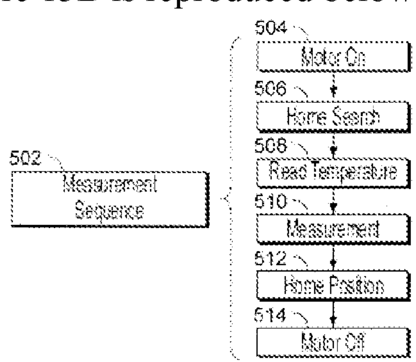

FIG. 13B

Appellants' FIG. 13B discloses

> the measurement sequence by the optics system[, which] includes activating the motor that moves the optics module,

> 504, and the optics module finding its home position, 506. A temperature reading, 508, in the vicinity of the optics system can be taken. At a first position along the optical read path that corresponds with the test window on the test device inserted in the apparatus, the illumination source in the optics module is turned on and then off, and during the off period fluorescent emission is detected by the photodetector in the optics module. The detected emission is stored in memory, and the motor in the optics system advances the optics module a fixed amount to its next position, which in an embodiment is in a direct toward the sample zone in the device so that measurement of the lines in the test window occurs in a downstream to upstream direction with respect to fluid flow on the test strip. After completion of a predefined number of incremental steps along the length of the test window and capture of light emission at each step, 510, the optics module is returned to its home position by the motor, 512, and the motor is powered off, 514.

(Spec. ¶ 101 (emphasis omitted); *see generally id.* ¶ 36.)

FF 8. Appellants disclose:

> The algorithm stored in apparatus memory for that particular assay then searches the data array for the peak emissions for each of the test and reference lines, 516, to calculate line intensities of peak area or peak height, 518. The algorithm calculates results from the data array, 520, and stores the results to memory, such as on the SD card inserted into the device. The calculated result can be displayed to the screen on the apparatus, or prompted to be printed by the user, or stored in flash memory if needed, 522. A user can then instruct the apparatus to open the drawer, to remove the test device, 524, 526, ending the measurement procedure, 528.

(Spec. ¶ 102 (emphasis omitted).)

FF 9. Appellants disclose:

> The apparatus and the reference line on the test device are designed to interact in several ways to ensure that the correct result will be determined and reported. First, the location of the reference line on the test device is used by the

> algorithm in the apparatus to determine the relative locations of the analyte-specific test lines on the test device. The software program expects the reference line to be located within a specific, pre-defined location range. The acceptable range for the location of the reference line is based on the manufacturing tolerance for placement of immunochemistry on the test strip, for location of the test strip within the housing, and for positioning of the test device (test strip in the housing (cassette)) within the drawer of the apparatus. Once the reference line is located, the positions of each of the other test lines and zones are determined by the algorithm and match the locations of the various chemistries deposited on the test strip.

(Spec. ¶ 104.)

FF 10. Appellants disclose:

> The reference line also serves as a ‘timer mechanism’ for the system, i.e., the apparatus and test strip. This is achieved by programming the analyzer with an algorithm that uses the signal (e.g., RLU, RFU) from the reference line to determine a cut-off value unique to the individual test strip inserted into the apparatus, and against which signal from the test line(s) is compared to determine a test result. As a skilled artisan will appreciate, signal from a control, test or reference line on a test strip has a strong dependency on incubation time; i.e, the elapsed time from sample placement on the strip and visual inspection of the line to determine a test result. . . . After the incubation time, RFU from the test line was read with the apparatus. The increase in RFU with increasing incubation time, at every concentration level, is apparent from the data. This data illustrates the problem with over incubation of a test strip and false positives. For example, an apparatus that is programmed with a fixed cut-off value of 7,000 RFU[], the cut-off value representing the minimum RFU value for a positive result, yields a valid result for a sample with a concentration of 10 mlU/mL only if the incubation time is at least 6 minutes. An apparatus programmed with a fixed cut-off value of 7,000 RFU would report a false negative for a sample with 10 mlU/mL incubated for less than 6 minutes.

> The system of the present invention resolves this issue, by providing a reference line on the test strip that is used by the apparatus to determine an individual cut-off value for the test strip. In this approach, the signal (RFU, RLU) emitted from the reference line is detected by the apparatus and mathematically transformed to determine a cut-off value. This transformed cut-off value represents an individualized value for the particular test strip, and renders the test strip insensitive to incubation time. . . . Signal from the reference line was mathematically transformed using exponentiation to determine a transformed cut-off value. In some embodiments, the exponentially transformed signal was further adjusted by a constant value that is empirically determined for each manufacturing lot of test strips. . . . A skilled artisan will appreciate that for some assays the same antibody for both spotting onto the test strip and attaching to the conjugate beads can be used.
>
> Signal detected from all or a portion of the population of particles captured at the test line was compared to the transformed cut-off value, and if the signal from the test line was above the transformed cut-off value the apparatus reported a positive test result. If the signal from the test line was below the transformed cut-off value the apparatus reported a negative result.

(Spec. ¶¶ 107–109.)

FF 11. Appellants disclose:

> At the end of a scan of lines in the window, the data collected consists of emission signals from the test strip at the position when LED is on (365 nm) and emission signals from test strip at that position when LED is off. The difference between these values at each position is taken, and stored in memory as a one-dimensional array of the difference in emissivity at each position when LED is on and when LED is off. The data processing algorithm smoothes the data array using a local polynomial regression (of degree k) on the series of differential emissivity values equally spaced in the series (such as the Savitzky-Golay method), to determine a smoothed value for each point. In one embodiment, the algorithm smoothes 13

> points in the array, and the first derivative of the smoothed data array is taken, and the peak/trough of the derivative peak height is determined to be the raw cut-off value. The raw cut-off value is transformed, preferably using a[n] exponential transformation (e.g, raising the raw signal cut-off value by an exponent in the range of 1.2-1.9), to yield a transformed cut-off value unique to the test strip. A signal to transformed cut-off ratio corresponds to a simple ratio of the signal in RFUs obtained at a test line divided by its transformed cutoff. Signal data that is collected is processed using a Savitzky-Golay smoothing algorithm that uses a weighted average smoothing method that reduces unwanted electronic noise, while preserving actual test signals, including maxima, minima and peak width with little impact on their actual dimensions.

(Spec. ¶ 113.)

ANALYSIS

On this record, Examiner finds that Appellants'

> [c]laim 1 as amended recites "a processor and memory resources for control of the motor and for processing data from the optics module[,]" and as a result invokes 35 U.S.C. 112(f) because "a processor and memory resources" is a general purpose computer and [Appellants'] originally filed [S]pecification fails to include an algorithm to transform the general purpose computer into a special purpose computer.

(Ans. 3–4; *see also id.* at 24 ("[I]t is [Examiner's] position . . . that one of ordinary skill would not know how to program the computer to perform the necessary steps described, there no algorithm which meets the description requirements, disclosed by Appellant to transform the general purpose computer into a special purpose computer.")).) In this regard, Examiner finds that the "generalized algorithm [set forth in Appellants'] originally filed disclosure fails to provide specific structure in terms of a specific algorithm such that [it] would limit the claim and transform the general purpose computer into a special purpose computer" (Ans. 25).

A processor, "microprocessor or general purpose computer lends sufficient structure only to basic functions of a microprocessor. All other computer-implemented functions require disclosure of an algorithm." *EON Corp. IP Holdings LLC v. AT&T Mobility LLC*, 785 F.3d 616, 623 (Fed. Cir. 2015). Thus, "when the disclosed structure is a computer programmed to carry out an algorithm, 'the disclosed structure is not the general purpose computer, but rather that special purpose computer programmed to perform the disclosed algorithm.'" *In re Aoyama*, 656 F.3d 1293, 1297 (Fed. Cir. 2011) (quoting *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)); *see also Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1338 (Fed. Cir. 2008) (The written description of the Specification must at least disclose the algorithm that transforms the general purpose microprocessor to a special purpose computer programmed to perform the disclosed algorithm.).

In response, Appellants direct attention to their Figures 11–13B and paragraphs 96–98, 102, 104, 107–109, and 113 of their Specification to support a contention that their "disclosure provides ample guidance and details for how the processor is used to execute the claimed steps" (Br. 3; *see also id.* at 4; *see generally* FF 1–11). We are not persuaded.

There is no doubt that Appellants' Specification and Figures recite the word "algorithm" (*see e.g.,* FF 2–5 and 8–11). Appellants, however, fail to specifically identify, and we do not find, an evidentiary basis on this record to support a finding that those of ordinary skill in this art would understand "from [Appellants'] disclosed architecture [or] flow charts, how to program/instruct the computer in order to perform the necessary steps" recited in the claims (e.g., the "configured to" limitation of claim 1) (Ans.

24–25). *See, e.g., Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003) ("The duty of a patentee to clearly link or associate structure with the claimed function is the quid pro quo for allowing the patentee to express the claim in terms of function under section 112, paragraph 6.") (*citing Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1377 (Fed. Cir. 2001)); *see also Valmont Indus., Inc. v. Reinke Mfg. Co., Inc.* 983 F.2d 1039, 1042 (Fed. Cir. 1993) ("The [A]pplicant must describe in the patent [S]pecification some structure which performs the specified function."). As Examiner explains, Appellants' Specification, including Appellants' Figures,

> fails to indicate how the processor is used in terms of how to operate the process to execute the series of steps set forth. For example, the cited flow chart[s] fail to reference the "optics module" and the Figures and cited disclosure fails to indicate an algorithm or how it is controlled such to describe a specific execution. Further, it is not readily apparent how one would implement the generalized algorithm disclosed in order to use the processor and memory resources themselves, in order to "control the motor" and "process the data" that is obtained "from an optics module" (claim 1) to result in evaluation of the sample.

(Ans. 25.)

For the foregoing reasons, we find no error in Examiner's claim interpretation under 35 U.S.C. § 112(f) (*see* Ans. 2–4 and 23–25).

Definiteness:

ISSUE

Does the preponderance of evidence support Examiner's conclusion that the phrases: "memory resources," "a processor and memory resources," and "wherein the processor and memory resources are configured to evaluate a sample" are indefinite?

ANALYSIS

A claim element that is treated as a "means-plus-function" element subject to the requirements of 35 U.S.C. § 112, sixth paragraph, is indefinite under 35 U.S.C. § 112, second paragraph, if the specification does not sufficiently identify adequate structure for performing the recited function. *See Aristocrat*, 521 F.3d at 1336–37. Simply stated, to satisfy the definiteness requirement, a means-plus-function claim requires sufficient disclosure of the underlying structure.

Based on Examiner's claim interpretation, discussed above, Examiner finds that Appellants' Specification "discloses no corresponding algorithm associated with 'a processor and memory resources [which are configured to evaluate a sample]'" (Ans. 4). Thus, Examiner finds that the phrase "'memory resources' does not further limit with regard to how the computer or computer component performs the claimed function, and as such is [indefinite]" (*id.* at 5). Examiner further finds the phrase "wherein the processor and memory resources evaluate a sample" indefinite for reciting a method step in an apparatus claim (*id.*).

In response, Appellants contend that their Specification "provides adequate disclosure of the corresponding structure of the memory resources in order to show sufficient detail about the memory resources," because their Specification:

> [D]iscloses that the processor and memory are configured with an algorithm stored in the memory (see ¶ [0096]). Further, paragraph [0097] describes that the processor algorithm activates the optics system to move the optics module and the

> manner in which the processor moves the optics module. This paragraph also describes how the processor operates the optics module to scan the test device. Further, and with regard to processing the data, paragraphs [0098], [0102], [0104] (locating and evaluating data in data array), [0107]-[0109] (use signal from reference line to determine a cut-off value unique for the test strip), and [0113] (smoothing the data array) provide examples of guidance for how the processor and memory controls process the data as presently claimed.

(Br. 4–5 (alteration original).) We are not persuaded.

As Examiner explains, Appellants' "original disclosure fails to identify a sufficient algorithm associated with 'a processor and memory resources,'" thus, the phrase "'memory resources' does not further limit with regard to how the computer or computer component performs the claimed function" (Ans. 26; *see id.* (Examiner finds that the phrase "'memory resources' adds an undefined component to the computer system")). "In summary, [Examiner finds that] because [Appellants'] disclosure fails to provide structure, the processor and memory resources are interpreted as a general purpose computer, and therefore the claims fail to provide adequate disclosure of the corresponding structure to satisfy the requirements of 35 U.S.C. 112(b)" (*id.*).

In addition, Examiner correctly finds that "Appellant[s] assert[] no specific arguments against the rejection of claim 1 regarding the limitation 'wherein the processor and memory resources evaluate a sample' for being indefinite as this particular limitation appears to recite a process step" (Ans. 26). For example, the claim states that the processor and memory are configured to evaluate a sample using a signal ratio and determine a time-insensitive cutoff value. Appellants identify disclosure in the Specification where such steps are said to be described, but do not explain how such disclosure supports the claim. Thus, the claim is indefinite, as found by the Examiner, because is it unclear how the recited function is performed.

CONCLUSION

The preponderance of evidence supports Examiner's conclusion that the phrases: "memory resources," "a processor and memory resources," and "wherein the processor and memory recourses evaluate a sample" are indefinite. The rejection of Appellants' claim 1 under 35 U.S.C. § 112(b) is affirmed. Appellants' claims 4–12 are not separately argued and fall with Appellants' claim 1.

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

ANALYSIS

The rejection over the combination of Polito and Kuo:

Examiner finds that the limitation in Appellants' claim 1 that requires the processor and memory resources to be configured to evaluate a sample using a "ratio of signal from all or a portion [of] the second population [of particles] to . . . signal [detected] from all or a portion of the first population [of particles] . . . to determine a time insensitive cut[-]off value" for the analyzer is "a recitation of the intended use of [Appellants'] claimed invention" (Ans. 10). Thus, Examiner reasons that Polito is "considered capable of using a ratio of signal detected from all or a portion of the second population of particles to signal detected from all or a portion of the first population of particles to determine a cutoff value for the analyzer and to determine the presence or absence of analyte in the sample" because

> At col. 14, line 30 Polito et al. teach a cut-off ratio is specified to determine whether a given measurement zone of an analyte binding zone is positive or negative (indicate presence of analyte); and at col. 14, line 38-40 teach cut-off as a variable input to an algorithm (referring to the algorithm for determining analyte), enabling the cut-off to be altered as the need arises. At col. 6, lines 62-68, Polito et al. teach, exemplified with two control lines, using the respective values of high and low controls (i.e. control sites being equivalent to the second detection site) to fit a standard curve, to be used as a calibration parameter to determine the quantitative value for the analyte binding zone (i.e. determine value (signal) from the first population at the first detection site); further teaching (into col. 7), amount of control agent quantified can be mapped onto a more meaningful measurement scale, such as relative intensity (RI) (thereby incorporating signal from the second population), and RI value can be assigned concentration values of analytes of interest, teaching signal cutoff values may be derived from the RI value (thereby addressing step by step algorithm for determining a cutoff, i.e. addressing the use of signal detected from all or a portion of the second population (the control) to determine signal from the first population). Polito teach the determination of the cutoff is carried out using the algorithm in the analyzer system of Polito, which uses the signal from a portion of the second population (i.e. signal from the control zone) to determine the presence or absence of analyte in the sample (i.e. signal at the detection zone). This is additionally addressed at col. 14, lines 51-55; Polito et al. teach the algorithm analyzes results by generating a baseline, quantifying the measurement zones with respect to the control binding zones and analyte binding zones.

(Ans. 9–10.) Stated differently, Examiner reasons that

> because [Appellants'] [S]pecification provides no specific structure (merely a general algorithm, insufficient structure to satisfy the requirements under 35 U.S.C. 112(b)), the processor

> of Polito does address the processor as recited by the claims. Specifically, Polito does teach a processor that is used to determine a cutoff value based on signal detected at the control population of particles. Polito teach the determination of the cutoff is carried out using the algorithm in the analyzer system (i.e. the processor is what is performing the algorithm, therefore is carried out using the processor), which uses the signal from a portion of the second population (i.e. signal from the control zone) to determine the presence or absence of analyte in the sample (i.e. signal at the detection zone). The algorithm of Polito is performed by the processor, and as such it is the processor which is determining the cutoff as described. . . . Examiner maintains the position that the limitations are directed toward intended use. The inquiry considered by . . . Examiner is whether or not the prior art structure is capable of performing the intended use, and as such whether it meets the claim. . . . Examiner has determined no structural difference between the claimed invention and the prior art. . . . Furthermore, it is noted that Appellant[s] provide[] no specific arguments and/or evidence indicating why the structure disclosed by the prior art would not be capable of performing the function as claimed, such that would distinguish the claimed invention from the cited prior art.

(*Id.* at 27–28.) We are not persuaded.

Notwithstanding Examiner's assertions to the contrary, Examiner failed to establish an evidentiary basis on this record to support a conclusion that Polito or the knowledge and ordinary creativity ascribed to one of skill in this art would have led one to create a system comprising an analyzer that is capable of performing the function discussed above. The "configured to" language of Appellants' claim 1 imposes a structural limitation on the analyzer of the claimed apparatus and, therefore, is not simply a recitation of its intended use as Examiner asserts. *See In re Noll*, 545 F.2d 141, 148 (CCPA 1976) ("[T]he claimed invention . . . comprises physical structure, including storage devices and electrical components uniquely configured to perform specified functions through the physical properties of electrical circuits to achieve controlled results. Appellant's programmed machine is structurally different from a machine without that program."). When the functional language is associated with programming or some other structure required to perform the function, that programming or structure must be present in order to meet the claim limitation. *See Typhoon Touch Techs., Inc. v. Dell, Inc.,* 659 F.3d 1376, 1380 (Fed. Cir. 2011); *see also Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1328–29 (Fed. Cir. 2011) ("[P]rogramming creates a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software."). The Examiner made no finding that the processor and memory resources are configured to detect a signal "ratio" as required by all the rejected claims.

Examiner relied upon Kuo to disclose "analytical strip device reader apparatus . . . comprising a delivering device for placing the analytical strip inside the apparatus" and reasoned that Kuo's "delivering device (which [Examiner] considered to be a drawer) serves the purpose of supporting the analytical strip test and moving it into or out of the housing" (Ans. 11). Examiner failed, however, to establish that Kuo makes up for the foregoing deficiency in Polito.

For the foregoing reasons, we agree with Appellants' contention that

> neither of Polito nor Kuo show or suggest a processor configured to use a ratio of signal from a second population of particles to signal detected from a first population of particles to determine a time insensitive cut-off value for the analyzer, and to determine the presence or absence of analyte in the sample.

(Br. 7.)

The rejection over the combination of Polito, Kuo, and Maher:

Examiner relies on Maher to disclose, *inter alia*, an influenza immunoassay (*see* Ans. 15–16). Therefore, based on the combination of Polito, Kuo, and Maher, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious

> to have targeted Influenza A as an analyte of interest, as taught by Maher et al., when using the system for analysis as taught by Polito[] specifically because Maher[] teach that influenza A is one of the most commonly associated diseases in humans, that it is highly contagious, and that rapid detection allows timely administration of antiviral drugs; that this is important because influenza is highly occurring among pediatric patients, and also dangerous to the elderly population as a result of introducing serious complications to elderly patients. The ordinarily skilled artisan would have a reasonable expectation of success using the system of Polito[] to target the analyte Influenza A because the invention of Polito[] is capable of detection/analyzing viruses and viral particles.

(Ans. 16.) We are not persuaded.

Examiner failed to establish an evidentiary basis on this record to support a conclusion that Maher makes up for the foregoing deficiency in the combination of Polito and Kuo. As Appellants explain:

> Nowhere does Maher make any mention of a system including a processor and memory resources configured to use a ratio of signal detected from all or a portion of the second population of particles to determine a time insensitive cut-off value for the analyzer and determine the presence or absence of analyte in the sample. Thus, the combined teaching of Polito, Kuo and Maher fail to show or suggest a system comprising a processor and memory resources that are configured to use a ratio of signal detected from all or a portion of the second population of particles to determine a time insensitive cut-off value for the

> analyzer and determine the presence or absence of analyte in the sample as presently claimed.

(Br. 12 (emphasis omitted)).

The rejection over the combination of Polito, Kuo or Maher, and Hudak:

Examiner relies on Hudak to disclose, *inter alia*, "the use of fluorescent detectors to increase assay sensitivity in a membrane strip device" (Ans. 17). Therefore, based on the combination of Polito, Kuo or Maher, and Hudak, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious "to have implemented europium, lanthanide fluorescent particles as detectable particles, as taught by Hudak[], into the assay system as taught by Polito[] and Kuo[] (or alternatively, the system of Polito[], Kuo[] and Maher[])" (*Id.* at 18.) We are not persuaded.

Examiner failed to establish an evidentiary basis on this record to support a conclusion that Hudak makes up for the foregoing deficiency of Polito in combination with either of Kuo or Maher. As Appellants explain:

> Nowhere does Hudak make any mention of a system including a processor and memory resources that are configured to use a ratio of signal detected from all or a portion of the second population of particles to determine a time insensitive cut-off value for the analyzer and determine the presence or absence of analyte in the sample.

(Br. 13.)

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness.

The rejection of claims 1 and 4–10 under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito and Kuo is reversed.

The rejection of claims 1 and 4–10 under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito, Kuo, and Maher is reversed.

The rejection of claims 11 and 12 under 35 U.S.C. § 103(a) as unpatentable over the combination of Polito, Kuo or Maher, and Hudak is reversed.

Obviousness-type Double Patenting:

ISSUE

Should the obviousness-type double patenting rejection on this record be summarily affirmed?

ANALYSIS

Appellants' claims 1 and 4–12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Egan in view of Polito (*see* Ans. 18–23; *see also* Final Act. 20–24).

Appellants do not address the merits of this ground of rejection.

If a ground of rejection stated by Examiner is not addressed in Appellants' Brief, Appellants waived any challenge to that ground of rejection and that ground of rejection will be summarily sustained by the Board. *See* 37 C.F.R. § 41.37(c)(iv) ("[A]ny arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal."). Therefore, we summarily affirm the nonstatutory obviousness-type double patenting rejection on this record.

CONCLUSION

The rejection of Appellants' claims 1 and 4–12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Egan in view of Polito is summarily affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED