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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 15/251,399 filed 08/30/2016 by Andy Sturman, attorney 99174USDIV3, confirmation 9258. Also includes examiner XU, XIAOYUN, art unit 1797, notification date 01/30/2020, and delivery mode ELECTRONIC.

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ANDY STURMAN, BENEDICT ZIN,  
ALBERT NAZARETH, and HENRY BELL

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Appeal 2019-000046  
Application 15/251,399  
Technology Center 1700

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Before ROMULO H. DELMENDO, RAE LYNN P. GUEST, and  
DEBRA L. DENNETT, *Administrative Patent Judges*.

DENNETT, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

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<sup>1</sup> In our Decision, we refer to the Specification (“Spec.”) of Application No. 15/251,399 (“the ’399 App.”); the Final Office Action dated Jan. 5, 2018 (“Final Act.”); the Advisory Action dated Mar. 13, 2018 (“Adv. Act.”); the Appeal Brief filed July 3, 2018 (“Appeal Br.”); the Examiner’s Answer dated July 30, 2018 (“Ans.”); and the Reply Brief filed Sept. 28, 2018 (“Reply Br.”).

### STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>2</sup> appeals from the Examiner's decision to reject claims 1 and 4–9. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM, but denominate the affirmed rejection a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

### CLAIMED SUBJECT MATTER

The claims are directed to a diagnostic device for detecting the presence of an analyte in a fluid sample. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A diagnostic device for detecting the presence of an analyte in a fluid sample, the device comprising:

a casing having a display;

a test strip mounted in said casing, said test strip having a test result site located thereon; a processor mounted in said casing;

a sensor mounted in said casing positioned to detect light reflected from the test strip, said sensor being operatively coupled to said processor;

a light source mounted in said casing positioned to illuminate the test strip, said light source being operatively coupled to said processor;

wherein said processor is configured to receive a signal from said sensor indicative of a reading of said test strip test

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<sup>2</sup> We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Church & Dwight Co., Inc. Appeal Br. 2.

result site during a test cycle having a duration defined at least in part by a standard test result time;

wherein said processor is configured to compare the reading to an early positive result threshold value that is greater than a standard positive result threshold value during a time span in the test cycle between the standard test result time and an early positive test result time that is earlier in the test cycle than the standard test result time; and

when said reading is greater than the early positive result threshold value during the time span, said processor is configured to display a positive result on said display before the test cycle reaches the standard test result time.

Appeal Br. 8 (Claims App.).

#### REFERENCE

The Examiner relies upon Sharrock et al., *Early Determination of Assay Results*, U.S. Patent No. 7,239,394 B2 (July 3, 2007) (hereinafter “Sharrock”).

#### REJECTION(S)

The Examiner rejects claims 1 and 4–9 under 35 U.S.C. § 103 as unpatentable over Sharrock. Final Act. 2–4.

#### OPINION

We review the appealed rejections for error based upon the issues identified by Appellant and in light of the arguments and evidence produced thereon. *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) (*cited with approval in In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (“[I]t has long been the Board’s practice to require an applicant to identify the alleged error in the examiner’s rejections.”)).

Appellant argues the claims as a group. *See* Appeal Br. 4–7. We select claim 1 as representative of the group. Claims 4–9 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Sharrock discloses the limitations of claim 1 with the exception of a specific disclosure that the early positive result threshold value is greater than a standard positive result threshold value. Final Act. 3.

Figure 3 of Sharrock is reproduced below:

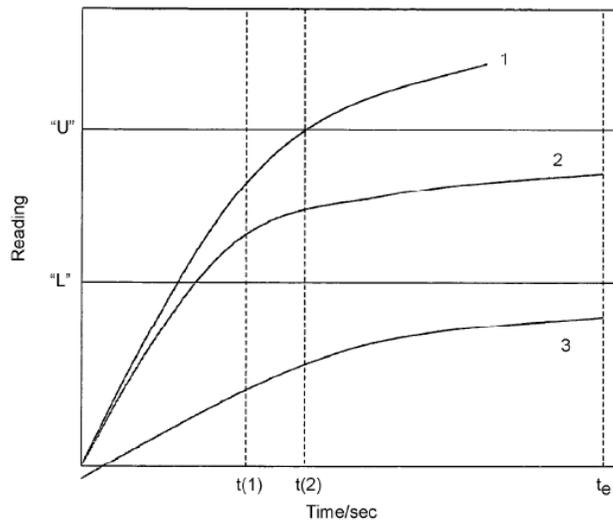


Fig. 3

Figure 3 is a graph of typical results for readings (i.e., signals) against time. Sharrock 2:56–57. The horizontal line labeled “U” is the upper threshold value; the horizontal line labeled “L” is the lower threshold value. Sharrock 8:63–65. Plots 1–3 illustrate typical graphs for liquid samples containing high (Plot 1), intermediate (Plot 2), or low (Plot 3) concentrations of analyte. Sharrock 8:56–62. If the final reading at  $t_e$  is below the value of U, the assay result is negative. Sharrock 9:21–23. Sharrock discloses that

an early positive result is indicated as soon as the analyte concentration exceeds the value of U (at time t(2) for Plot 1 in Figure 3). Sharrock 9:5–10.

The Examiner finds, *inter alia*, that Sharrock discloses, “wherein said processor is configured to compare the reading to an *early* positive result threshold value (upper threshold limit).” Final Act. 3 (emphasis added). The Examiner repeats the finding in the Answer, but finds also that “the phrase ‘greater than’ [in claim 1] is not a quantitative description, because the early positive result threshold value can be 1% greater or 0.01% greater than the standard positive threshold value” and that “the *standard* positive result threshold value (Upper threshold limit) in Sharrock is a minimum signal intensity value required at the end of the test time for a positive result.” Ans. 4 (emphasis added). According to the Examiner, “it would have been obvious to one of ordinary skill in the art to set the early positive result threshold value a little greater (e.g. 1 % higher) than a standard positive result threshold value, in order to reduce the possibility of false positive display.” *Id.* Thus, the Examiner appears to interpret claim 1 as requiring identification and comparison of two different positive result threshold values—one a standard positive result threshold and another an early positive result threshold that may be only slightly greater than the standard positive threshold, with Sharrock’s upper threshold limit U being the standard early positive result threshold. *See id.*

For the reasons below, we concur with the Examiner that find that claim 1 is not patentable over Sharrock.

We start by ascertaining the scope and meaning of the disputed claim limitation—i.e., “wherein said processor is configured *to compare* the reading to an early positive result threshold value that is greater than a

standard positive result threshold value during a time span in the test cycle between the standard test result time and an early positive test result time . . .” (emphasis added) in claim 1. *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994) (“[T]o properly compare [the prior art] . . . with the claims at issue, we must construe the [disputed limitation] . . . to ascertain its scope and meaning.”). During prosecution, an application’s claims are given their broadest reasonable scope consistent with the specification. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). The “broadest reasonable interpretation” standard does not prejudice the applicant, who has the ability to correct errors in claim language and to adjust the scope of claim protection as needed during prosecution by amending the claims. *In re Yamamoto*, 740 F.2d 1569, 1571–72 (Fed. Cir. 1984).

Although claim 1 recites “an early positive result threshold value that is greater than a standard positive result threshold value,” neither the claim itself nor the written description (remainder of the Specification and Drawings) places any quantitative limitations on the “early positive result threshold value,” “the standard positive result threshold value,” or by how much these values differ. Therefore, consistent with the Examiner’s position, we conclude that the difference between the “early positive result threshold” and the “standard positive result threshold value” may be minimal (e.g., 0.01% greater). In addition, we interpret claim 1, as broadly drafted, to require a comparison of a signal value against only “an early positive result threshold value”—not against both “an early positive result threshold value” and “a standard positive result threshold value.”

Claim 1 is a structural claim, drawn to an apparatus—a diagnostic device. *See* Appeal Br. 8 (Claims App.). An applicant is free to claim

features of an apparatus either structurally or functionally. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (citing *In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971)). Claim 1’s limitations comprise a combination of both structure and function. “Casing,” “test strip,” “processor,” “sensor,” and “light source” all recite structure. The processor also is “configured to” perform various functions—receive, compare, and display. An apparatus that is capable of performing certain functions may be anticipated by or obvious in view of a prior art apparatus that can likewise perform these functions. *Parker Vision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018).

We adopt the Examiner’s findings in the Final Office Action that Sharrock discloses the structural elements. *See* Final Act. 2–3. We find that Sharrock discloses a processor configured to receive a signal from a sensor indicative of a reading of a test strip test result site during a test cycle having a duration defined at least in part by a standard test result time. *See* Sharrock 3:5–11; 3:37–41; 3:51–56; Fig. 3. We find also that Sharrock discloses a processor configured to compare a signal accumulation value representing an accumulation of an analyte of interest against an “upper threshold value” such that signal levels below this value are regarded as negative (i.e., analyte is not present) and levels above are regarded as positive. *Id.* at 3:24–29. In this regard, Sharrock teaches that “[i]f after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the upper threshold even if the reaction were allowed to proceed to completion, and an early negative result is then displayed”—i.e., in situations where the fluid sample has a “very low analyte concentration.” *Id.*

at 3:30–36. “Conversely, a result can be promptly displayed if the rate or amount of signal accumulation crosses the upper threshold limit.” *Id.* at 3:37–39 Fig. 3. Thus, as indicated, patentability of claim 1 turns on the following limitation:

wherein said processor is configured to compare the reading to an early positive result threshold value that is greater than a standard positive result threshold value during a time span in the test cycle between the standard test result time and an early positive test result time that is earlier in the test cycle than the standard test result time.

Appeal Br. 8 (Claims App.).

If we construe the term “compare the reading” as a mental process, it is given no weight in an anticipation or obviousness analysis unless the information compared is shown to have a functional or structural relationship to the processor. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1033 (Fed. Cir. 2018). Mental steps or processes, like printed matter, are not patent eligible subject matter. *Id.* (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1378 (Fed. Cir. 2016); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011)). “Because claim limitations directed to mental steps may attempt to capture information content, they may be considered printed matter lacking patentable weight in an obvious analysis.” *Id.* Where, as in the present case, “a limitation merely claims information [e.g., the value of a signal being read] by incorporating that information into a mental step [e.g., comparing],” “the mental step will receive patentable weight only if the limitation is functionally related” to the processor. *See id.*; *see also Ex parte Nehls*, 88 USPQ2d 1883, 1889 (BPAI 2008) (precedential) (“[T]he nature of the

information being manipulated does not lend patentability to an otherwise unpatentable computer-implemented product or process.”); *Ex parte Mathias*, 84 USPQ2d 1276, 1279 (BPAI 2005) (informative) (“[N]onfunctional descriptive material cannot lend patentability to an invention that would have otherwise been anticipated by the prior art.”), *aff’d*, 191 Fed.Appx. 959 (Fed. Cir. 2006) (Rule 36); *Ex parte Curry*, 84 USPQ2d 1272, 1274 (BPAI 2005) (informative) (“Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious.”), *aff’d*, No. 06-1003 (Fed. Cir. June 12, 2006) (Rule 36).

Given the breadth of claim 1, as drafted, we find that the function of the processor has not been established to depend on the *comparison* of the value of the signal being read against some unspecified “early positive result threshold value that is greater than [some unspecified] standard positive threshold value.” The processor, so programed, will function to compare a signal and a stored value the same way irrespective of what the value of the signal means – i.e., whether that value represents and upper threshold value or a standard threshold value. The value of the signal being compared—a number—has no structural relationship to the processor either. Therefore, the limitation “configured to compare . . .” lends no patentable weight to claim 1.

Because Sharrock discloses a processor and “comparing the reading . . .”—as broadly drafted—has no patentable weight, combined with our adoption of the Examiner’s earlier findings, we find that Sharrock teaches all limitations of claim 1. *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982) (anticipation is the ultimate or epitome of obviousness).

If we do not consider “compar[ing] the reading” to be a mental step, however, and construe it as a generic function performed by a general purpose processor, we also find that Sharrock teaches all claimed limitations.

The claimed processor is configured to compare a reading to an early positive result threshold value. Appeal Br. 8 (Claims App.). An apparatus that is capable of performing certain functions may be anticipated by or obvious in view of a prior art apparatus that can likewise perform these functions. *Parker Vision*, 903 F.3d at 1361; *see also Schreiber*, 128 F.3d at 1477 (court found no dispute that claimed and prior art product had the same structure so that the prior art structure is capable of performing the recited function); *Intel Corp. v. U.S. Int’l. Trade Comm’n*, 946 F.2d 821, 832 (Fed. Cir. 1991) (courts have interpreted functional language in an apparatus claim as requiring that the prior art apparatus possess the capability of performing the recited function).

Sharrock teaches a central processing unit or microcontroller (processor) programed to determine the rate or amount of signal accumulation and to compare the value with an upper threshold value. Sharrock 5:4–14. Sharrock teaches comparing a reading repeatedly during a time span between  $t(1)$  (the initial reading after commencement of the assay) and  $t_e$  (the predetermined endpoint time of the assay). Sharrock 8:66–9:10. Specifically, Sharrock teaches comparing and displaying a positive result at time  $t(2)$ , when the signal reading exceeds the upper threshold value, which reads on the “early positive result threshold value” claimed. *See* Sharrock 9:8–10, Fig. 3. Thus, Sharrock is capable of performing the claimed function, with the result that Sharrock anticipates claim 1. *See Schreiber*,

128 F.3d at 1478 (“[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.”) (quoting *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971)).

Claim 1 recites “said processor is configured to compare an early positive result threshold value that is greater than a standard positive result threshold value . . . .” Appeal Br. 8 (Claims App.). Claim 1 does not require the processor be configured to do anything with or to a *standard* positive result threshold value.<sup>3</sup> Therefore, a standard positive result threshold value is not required in any of processor’s comparison operations recited in the claim, and need not be taught for the claim to read on the prior art. Instead, claim 1 directly reads on Sharrock’s processor that is configured to compare a signal value to an early positive result threshold value  $U$  at time  $t(2)$ , which is an early positive test result time that is earlier in the test cycle than the standard test result time  $t_e$ .

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<sup>3</sup> Notwithstanding the fact that claim 9 is not separately argued on appeal, we note that claim 9 further recites that “said standard positive result threshold value [is] stored in a memory device.” Again, the processor taught by Sharrock includes memory that is configured to store data values, e.g., early positive result threshold value  $U$  and lower value  $T$ . Because the claim only requires storing data with no functional use of this data recited in any of the claims, the specific data stored reads on non-functional descriptive material as discussed above, and the content of the data — namely, that it represents a standard positive result threshold value — provides no further patentable weight to claim 9.

Finally, if we construe “compar[ing] the reading” as requiring a special purpose processor with special, non-generic, programming, we still find that Sharrock teaches all claimed limitations and/or renders them obvious.

For the reasons discussed above, Sharrock discloses the claimed functionality for “comparing a reading.” Thus, any difference in programming between the processor in claim 1 and the processor in Sharrock does not impart a new and nonobvious function to the claimed device. There is no patentable difference in the *structure* of the claimed apparatus compared to that of Sharrock. To the extent that the threshold values differ, this is merely a slight difference in settings of threshold values. *Cf. Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985) (a prima facie case of obviousness was established where a claimed value was sufficiently close to a prior art value). Also, inasmuch as the prior art appreciates the problem of false positives, it would have been obvious to one of ordinary skill in the art at the time of the invention to discover the optimum or workable ranges for setting an early positive result threshold value by routine optimization. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”); *see also KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

For the reasons above, we enter a new ground of rejection of claim 1 under 35 U.S.C. § 102 and/or § 103 as anticipated by and/or obvious over Sharrock. We adopt the Examiner’s findings regarding claims 4–9 in the

Final Office Action, thus also enter a new ground of rejection of claims 4–9 anticipated by and/or obvious over Sharrock.

### CONCLUSION

The Examiner’s rejection of claims 1 and 4–9 as obvious over Sharrock is affirmed.

### DECISION SUMMARY

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>	<b>New Ground</b>
1, 4–9	103	Sharrock	1, 4–9		1, 4–9
<b>Overall Outcome</b>			1, 4–9		1, 4–9

Because we recognize our Decision relies on facts and reasons not expressly stated by the Examiner, we denominate the affirmed rejection as A NEW GROUND OF REJECTION pursuant to 37 C.F.R. § 41.50(b).

37 C.F.R. § 41.50(b) provides that an appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
- (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record.

Appeal 2019-000046  
Application 15/251,399

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED  
37 C.F.R. § 41.50(b)