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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 SEAN ANDREW PARSONS

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Appeal 2019-006455
Application 14/672,789
Technology Center 1600

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Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and TAWEN CHANG, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–11, 14, 15, 18–26, 28–32, and 35–44. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

STATEMENT OF THE CASE

Appellant's invention involves the inventor's realization that "by detecting a relatively high level of LH [(luteinizing hormone)] in a

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Ellume Pty Ltd. as the real party in interest. Appeal Br. 3.

biological sample, it can be determined that the person providing the sample is relatively more likely to provide a false positive indication of pregnancy due to higher background levels of hCG [(human chorionic gonadotropin)] in the sample." Spec. ¶ 27. "Equally, by detecting a relatively low level of LH in a biological sample, it can be determined that the person providing the sample is relatively less likely to provide a false positive indication of pregnancy." *Id.*

Appellant's invention is thus directed to a pregnancy testing device that adjusts the threshold hCG concentration indicative of pregnancy based on whether the LH in the sample is above or below a particular threshold concentration. *See* Spec. ¶ 28.

Appellant's claim 1, the only independent claim on appeal, is representative and reads as follows:

> 1. A pregnancy test device for identifying pregnancy in a human or animal body based on a biological sample obtained from the human or animal body, the test device comprising:
>
> a lateral flow test strip comprising one or more test portions configured to bind:
>
> human chorionic gonadotropin (hCG), when present, in the biological sample; and
>
> luteinizing hormone (LH), when present, in the biological sample; and
>
> a reader that analyses the one or more test portions and determines a level of hCG in the biological sample based on an amount of hCG bound at the one or more test portions and determines a level of LH in the biological sample based on an amount of LH bound at the one or more test portions, wherein the reader comprises a processor and a non-transitory computer-readable memory medium, the non-transitory computer-readable memory medium comprising instructions that cause the processor to:

> determine which of a plurality of discrete LH ranges the determined level of LH falls within, wherein the processor associates a different hCG threshold level with each one of the LH ranges,
>
> wherein the plurality of discrete LH ranges comprises a first LH range below a first LH threshold level and a second LH range above the first LH threshold level, the first LH threshold level being between 10 and 30 IU/L,
>
> wherein a first hCG threshold level of between 1.0 and 3.0 IU/L is associated with the first LH range; and a second hCG threshold level that is at least 2.0 IU/L greater than the first hCG threshold is associated with the second LH range;
>
> select the hCG threshold level that is associated with the LH range which the determined level of LH falls within; and
>
> identify pregnancy in the body if the determined level of hCG is above the selected hCG threshold level..

Appeal Br. 47.

The sole rejection before us for review is the Examiner's rejection of claims 1–11, 14, 15, 18–26, 28–32, and 35–44 under 35 U.S.C. § 103(a) over Lee,[2] Polito,[3] and Williams.[4] Ans. 3–9.[5]

DISCUSSION

The Examiner's Rejection

The Examiner cited Lee as disclosing a device "capable of identifying both hCG and LH in a biological sample, as in the claimed device." Ans. 4.

The Examiner conceded that Lee's device differs from the device recited in Appellant's claims in that Lee "fails to teach a device that

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[2] US 2001/0021536 A1 (published Sept. 13, 2001).
[3] US 6,136,610 (issued Oct. 24, 2000).
[4] WO 2006/100415 A1 (published Sept. 28, 2006).
[5] The Examiner withdrew rejections for lack of eligibility and obviousness-type double patenting. *See* Ans. 10.

comprises a reader comprising a processor and a non-transitory computer readable memory medium comprising instructions to cause the processor to perform the functions as claimed." Ans. 4.

The Examiner cited Williams as also teaching a device capable of measuring both hCG and LH, noting in particular Williams's teaching as to "the ability to use the measurement of LH in order to calculate therefrom an hCG commencement day on which to start testing for hCG, see end of para 3, the device also configured to determine and display an estimated delivery date and/or estimated date of conception from the hCG data." Ans. 5.

The Examiner cited Polito as teaching that, when detecting analytes of interest in biological samples via specific binding to a substrate, it is useful to employ a positive control binding agent for the purpose of calibration, or to generate a standard curve that aids in quantitation of the analyte of interest. *See* Ans. 5–6.

The Examiner also cited Polito's teaching that the relative intensity level of binding of the control agent could be used to derive a cutoff value for which an assay result may be considered positive. Ans. 6. The Examiner cited Polito as teaching that its device included instructions for performing the required comparisons between the degrees of binding of the analyte of interest and the control binding agent. *Id.*

Based on the references' combined teachings, the Examiner reasoned that it would have been obvious to modify Lee's device

> to include as part of the pregnancy test device, the reader comprising processor and non-transitory computer-readable memory medium with instructions of Polito, in order to analyze the test portions to determine the levels of each of the hCG and LH, wherein the processor (via the instructions) determines/relates stored information regarding the level of one

> marker (e.g., LH) and correlates it with a threshold level for the other marker (i.e., determines a cutoff for the other, wherein the other is the hCG), rendering a result based on the measured level compared to the determined cutoff/threshold.

Ans. 7.

The Examiner determined that the instructions in claim 1, directing the processor to adjust the hCG concentration threshold for identifying pregnancy based on the LH concentration in the sample, are "functional [limitations], as they describe what the reader (processor and memory) do, rather than what it is." Ans. 9; *see id.* ("[T]he functions, the ranges and the specific values do not invoke/require any specific structure required to[]perform the functions (no structure other than the reader comprising processor and memory as claimed).").

Therefore, the Examiner reasoned, because the device suggested by the cited references is capable of performing the functions in the processor-implemented instructions recited in Appellant's claim 1, the cited references render the device of claim 1 obvious:

> The structure as taught by the combination of the cited art is . . . considered capable of achieving the intended use(s) as claimed, considering the reader as taught by Polito is capable of determination of measured values at test portions (control and a test analyte), and setting a level of a first analyte based on the determined second analyte level (control analyte).

Ans. 9.

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the

> record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), although the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, *id.* at 415, it also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Thus, as the Federal Circuit has since explained, "obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

We agree with Appellants that a preponderance of the evidence does not support the Examiner's conclusion of obviousness. In particular, Appellant persuades us that the Examiner has not explained sufficiently why the cited references would have suggested a pregnancy testing device with a memory containing the processor-implemented instructions recited in Appellant's claim 1.

As seen above, the pregnancy test device of Appellant's claim 1 includes a processor and a memory with instructions that cause the processor

to adjust the threshold hCG concentration for identifying pregnancy, based on the amount of LH detected in a sample. *See* Appeal Br. 47. In other words, the instructions in the memory control the conditions under which the device identifies a sample to be indicative of pregnancy. That is, the instructions in the memory control how the device functions.

Thus, contrary to the Examiner's repeated contentions (*see* Ans. 12–16), to show that the device of Appellant's claim 1 would have been obvious, the Examiner must show that the prior art would have suggested a device with a memory having the specific instructions recited in claim 1. *See In re Lowry*, 32 F.3d 1579, 1583–84 (Fed. Cir. 1994) (claim limitations regarding organization of data in memory held to distinguish over prior art); *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.").

We are not persuaded that the Examiner has shown sufficiently that the cited references would have suggested a device with a memory having the specific instructions recited in claim 1. We acknowledge the disclosure in the Lee reference that devices of the type that identify pregnancy by detecting hCG can also be used for detecting LH. *See* Lee ¶¶ 4–5.

We also acknowledge Williams's teaching that determining LH concentration in a sample can aid in estimating an implantation date, making it easier to decide when to start testing for hCG. *See* Williams 10; *see also*

id. at 10–11 (disclosing test kits including a single stick that can determine both LH and hCG concentrations).

We also acknowledge Polito's disclosure that, in devices like those of Lee and Williams that detect analytes through substrate binding, it is useful to employ a control binding agent to calibrate the device and assign a signal to cutoff value above which a positive result may be identified. *See* Polito 5:41–7:10.

The Examiner does not persuade us, however, that any of the cited references, including when viewed in combination with each other, includes teachings that are sufficiently specific to suggest a device having the particular configuration required by Appellant's claim 1, which adjusts the threshold hCG concentration for identifying pregnancy based on the amount of LH detected in a sample. We therefore reverse the Examiner's rejection of claim 1, and its dependent claims 2–11, 14, 15, 18–26, 28–32, and 35–44.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1–11, 14, 15, 18–26, 28–32, 35–44	103(a)	Lee, Polito, Williams		1–11, 14, 15, 18–26, 28–32, 35–44

REVERSED