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STEPHEN P. ASHBURN
P.O. Box 300
Fort Meade, SD 57741

EXAMINER	
GOUGH, TIFFANY MAUREEN	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEPHEN PATRICK ASHBURN

Appeal 2019-003230
Application 11/964,566
Technology Center 1600

Before ULRIKE W. JENKS, RACHEL H. TOWNSEND, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134(a) involving claims to a semen detection kit, a method for detecting semen, and an AP test strip assembly. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART, reversing the written description rejection of claims 1–3, reversing the obviousness rejection of claims 1 and 2, affirming the obviousness rejection of claim 3, and entering a New Ground of Rejection for claims 1 and 2 under 35 U.S.C. § 103.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Herein, we refer to the Non-Final Action mailed June 29, 2018 ("Non-Final."); Appellant's Appeal Brief filed July 12, 2018 ("Appeal Br."); and Examiner's Answer mailed January 11, 2019 ("Ans.").

STATEMENT OF THE CASE

"The present invention . . . relates to a combination of two analytical tests," that is the acid phosphatase (AP) and prostate specific antigen (PSA) tests, to detect "semen on fabrics and other surfaces." Spec. 1.[2] According to the Specification, "both PSA and AP tests for semen have been described" in the prior art, but "the combination of both tests being used synergistically as a detection kit and method has not." *Id.* at 2.

Claims 1–3 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 1 recites a kit comprised of AP and PSA test strips as follows:

> 1. A semen detection kit comprised of two main components: 1) acid phosphatase (AP) test strip assemblies consisting of a coated paper element containing 5 mg (22μmol) of citrate buffer, 1 mg (3.7 μmol) of 1-naphthyl phosphate and 1.6 mg (3.4 μmol) of Dye Fast Blue B Salt absorbed onto Grade 1 filter paper of dimensions 15 mm x 40 mm and then dried to a powder, which element reacts to the presence of semen, which is affixed to a flexible plastic backing of approximately 15 x 60 mm in dimension having a finger hold of 15 mm x 20 mm to prevent contamination from the skin, and which dimension allows the assembly to be pressed into the crotch portion of a woman's undergarment and thereby react with a wetted semen stain, and which assemblies are stored in the kit; and 2) immunochromatographic test strips for prostate specific antigen (PSA) in individual sealed pouches containing a desiccant packet.

Appeal Br. 12. Claim 2 recites a method of using the two types of strips in claim 1. It reads as follows:

[2] Our citations to the Specification refer to Appellant's Specification as filed on December 26, 2007.

> 2. A method for the detection of semen, in which an item is tested first with the AP test strip assemblies in claim 1 to provide presumptive evidence of semen, followed by testing with the more sensitive and specific PSA strips in claim 1 for confirmatory evidence.

Id. at 12–13. Finally, claim 3 is directed to the AP test strip assembly in claim 1, reciting as follows:

> 3. An AP test strip assembly consisting of an AP test paper element with Fast Blue B salt and 1-naphthyl phosphate affixed to it in powder form, and bound to a plastic backing as described in claim 1.

Id. at 13.

Appellant filed its appeal brief seeking review of the following rejections:

I. Claims 1–3 under 35 U.S.C. § 112(a), for failure to meet the written description requirement ("Written Description Rejection");

II. Claims 1 and 3 under 35 U.S.C. § 112(b), as being indefinite ("Indefiniteness Rejection"); and

III. Claims 1–3 under 35 U.S.C. § 103 as unpatentable over Arter,[3] Babson,[4] Holmes,[5] Falb,[6] Smith I,[7] Smith II,[8] Shi,[9] Menon,[10] and Diagnostics[11] ("Obviousness Rejection").

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[3] US 5,981,206, issued Nov. 9, 1999 ("Arter").
[4] US 3,002,893 issued Oct. 3, 1961 ("Babson").
[5] US 6,764,856 B2, issued July 20, 2004 ("Holmes").
[6] US 4,318,709, issued Mar. 9, 1982 ("Falb").
[7] US 2001/0019821 A1, published Sept. 6, 2001 ("Smith I").
[8] US 2003/0027350 A1, published Feb. 6, 2003 ("Smith II").
[9] US 7,883,899 B2, issued Feb. 8, 2011 ("Shi").
[10] US 2008/0145948 A1, published June 19, 2008 ("Menon").
[11] *Industry Profiler: Diagnostics*, Süd-Chemie, Inc. (2004), *http://www.jamesdawson.com/Diagnostics_Medical.pdf*.

App. Br. 3–12. Examiner subsequently withdrew the Indefiniteness Rejection in the Answer. Ans. 11. Thus, only the Written Description Rejection and Obviousness Rejection remain before us in this appeal.

I. WRITTEN DESCRIPTION REJECTION

Issue

The issue for this rejection is whether a preponderance of the evidence supports Examiner's finding that claims 1–3 fail to comply with the written description requirement.

Analysis

Examiner determines that there is no written description support for the "finger hold" limitation of claim 1. In particular, Examiner finds "[t]here is no clear indication that the 'fingerhold' space is of 15 x 20 mm dimensions" in the Specification, as filed, and no "support for the intended purpose or result of the 'finger-hold,' i.e., preventing contamination and allowing to be pressed into the undergarment." Non-Final 3–4.

Appellant responds by pointing out that the Specification describes a "15 mm by 40 mm" AP filter paper strip mounted to a plastic backing of "approximately 15 mm by 60 mm" and teaches that the "preferred method consists of holding the assembly by the plastic portion" to conduct the test. Appeal Br. 4–6 (quoting Spec. 5). Thus, urges Appellant, the "15 mm x 20 mm dimensions of the finger hold can be simply deduced by subtracting the length of the plastic backing from the length of the test paper element as described in the Specification." *Id.* at 5.

We are persuaded by Appellant's argument and agree that the Specification provides sufficient description for the "fingerhold" limitation as recited in claim 1. The Specification describes a plastic backing that is 15

mm wide and 20 mm longer than the filter paper that is mounted thereto. Spec. 5. Moreover, it teaches that this "plastic portion" is used as a handle when conducting the test (*id.* at 6) and describes conducting that test by pressing the AP test strip against "a suspect area of the garment." *Id.* at 4. Thus, while the Specification does not use the term "fingerhold," it describes that structure functionally and provides sufficient detail for one of ordinary skill to ascertain the claimed dimensions. Such a description is enough to "reasonably convey to those skilled in the art" that Appellant "had possession" of an AP strip assembly with the claimed fingerhold as of the filing date of the Specification. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Examiner separately determines that there is insufficient written description to support the "and then dried to a powder" and the "with Fast Blue B salt and 1-naphthyl phosphate affixed to it in powder form" limitations recited in claims 1 and 3 respectively. Non-Final 4–5 (emphasis removed). According to Examiner, these limitations constitute new matter because while the Specification describes the AP test strip assemblies being made by absorbing a solution containing these reagents onto filter paper and drying it, it does not state they are dried to a "powder." *Id.* at 4.

Appellant responds that the Specification "clearly describes the preparation of a test paper element containing dried solution" and it is "a common fact of chemistry" that doing so would leave a residue or powder on paper. *See* Appeal Br. 4–5.

We are again persuaded by Appellant's argument. The Specification describes the preparation of AP test strip assemblies, as follows:

> In the preferred embodiment, Whatman Grade 1 Qualitative Standard Filter Paper is used to absorb a solution of citrate buffer (prepared from equimolar amounts of citric acid and trisodium citrate), 1-naphthyl phosphate and Dye Fast Blue B Salt, and then dried and cut into strips . . . The strips are then mounted to a plastic backing . . . and stored in a canister with a desiccant cap. It should be noted that the reagents used to prepare the strips, as well as the strips themselves are hygroscopic and should be protected from moisture.

Spec. 5. While the Specification does not expressly recite a "powder," one of ordinary skill in the art would understand that drying the strips after they have absorbed the reagent solution would leave behind a solid residue of those reagents on the strip. That the reagents are in powder form on the test strip is further reinforced by the Specification's teaching that the test strip is to be protected from moisture through the use of a desiccant cap. *Id.* Accordingly, there is sufficient written description in the Specification to show Appellant was in possession of AP strips having a "powder" as recited in claims 1 and 3. *See Ariad*, 598 F.3d at 1351 (explaining that "possession" is shown where the specification "describe[s] an invention understandable to th[e] skilled artisan and show[s] that the inventor actually invented the invention claimed").

II. OBVIOUSNESS REJECTION

Issue

The issue for this rejection is whether the preponderance of evidence of record supports Examiner's conclusion that the cited prior art renders Appellant's claims obvious.

Findings of Fact

FF1. Arter teaches a "dry analytical element" for the detection of prostatic acid comprising an aromatic phosphate substrate for the analyte which produces a phenol reaction product, a "diazonium or tetrazolium salt . . . to produce a chromophore for detection," and a buffer to maintain "it at the proper pH during the assay." Arter, Abstr. Arter teaches that the aromatic phosphate may be "α-naphthyl phosphate." *Id.* at 4:13. Arter further teaches that both the aromatic phosphate and the diazonium or tetrazolium salt is generally present in an "amount within the range of from about 0.005 to about 5 g/m^2 (dry weight)." *Id*. at 6:19–28. Arter also teaches that citrate is a useful buffer for such compositions. *Id*. at 5:58–60.

FF2. Arter teaches that its analytical element may take the form of "test strips" composed of "filter paper" disposed on a dimensionally stable support comprising a plastic such as polycarbonate. Arter, 2:58–3:5. Arter further teaches that "depending upon the method and equipment for assay," these strips "can be configured in a variety of forms and shapes." *Id.* at 6:34–38.

FF3. Babson teaches a method for determination of acid phosphate in serum. Babson, 1:10–15. This method employs "a substrate comprising a buffer and a salt of α-naphthyl phosphate" that when incubated with the test serum and an azonium salt allows for the rapid determination of acid phosphatase in the sample. *Id.* at 2:15–39. Babson teaches that the presence of "about 0.4 to about 1 mg. of the α-naphthyl phosphate salt and about 10 to about 25 mg buffer is a particularly effective range" for the amounts of those components. *Id.* at 3:12–14. Babson further teaches that any "azonium salts useful in the manufacture of commercial dyes can be used" and that "tetrazotized o-dianisidine (Naphthanil Diazo Blue B) is particular effective since with this material an unusually deep color is obtained with very small

amounts of" color forming ingredient. *Id.* at 4:1–13. According to Babson, the various reagents can be formulated in solid tablets and added to serum to test for acid phosphatase therein. *Id.* at 3:20–24, 4:16–20.

FF4. Holmes teaches a system and method for detecting the presence of semen on material comprising a detection solution containing, *inter alia*, dye fast blue salt and naphthyl acid phosphate. According to Holmes' method, a "suspected stain or stain area" is blotted with absorbent paper "so as to transfer the moisture from the wetted suspected semen stain or stain area on the material to the absorbent paper." Holmes, Abstr. The detection solution is then applied to the absorbent paper and if the paper turns purple it indicates that semen is present. *Id.*; *see also id.*, Fig. 2. Holmes teaches that the amount of dye fast blue salt and the amount of naphthyl acid phosphate both range from "about 1% to about 10% by weight" of the detection solution. *Id.* at 2:16–28.

FF5. Falb teaches test strips for determining the ionic strength of specific gravity of an aqueous test sample in the form of a "filter paper strip" containing the test reagents that is "mounted on a clear plastic backing material." Falb, Abstr., 12:10–12. In Falb's example the strip comprised a plastic backing "measuring about 3.5 in. by 0.2 in., one end of which bore a square of the impregnated filter paper measuring 0.2 in on a side." *Id.* at 12:14–18. Falb teaches that the additional length of the plastic backing "serve[s] as a handle" when contacting the filter paper with a sample. *Id.* at 12:18–19.

FF6. Smith I describes processes for manufacturing dry chemistry dipsticks (DCD). Smith ¶ 40. According to Smith I, the manufacturing process for such,

> includes impregnating onto an absorbent, solid carrier (e.g., paper) the chemical constituents which have been dissolved in a liquid solvent, evaporating the solvent and mounting this 'reaction paper' on a sturdy plastic 'handle'; this device is then dipped into the test sample, withdrawn, and the visible color produced is observed and compared to a chart which relates specific colors or shades of the same color to a range of concentrations of the target analyte.

Id. ¶ 51.

FF7. Smith II similarly describes the manufacture of DCD test strips by "impregnating onto absorbent paper the chemical constituents which have been dissolved in a liquid format, evaporating the liquid, and mounting this 'test paper' on a sturdy plastic handle." Smith II ¶ 27.

FF8. Diagnostics describes commercially-available desiccant containers, stoppers, and packets. Diagnostics, 1–2. Diagnostics teaches that tubes with "desiccant stoppers protect diagnostic test kits and strips from moisture and breakages . . . thus extending shelf life." *Id.* at 1. According to Diagnostics, "desiccant packets are another popular choice of the diagnostics industry." *Id.* at 2.

Analysis

According to Examiner, claims 1–3 are obvious over the combination of Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, and Diagnostics. Specifically, Examiner finds that Arter teaches AP test strip assemblies comprising a naphthyl phosphate salt, a citrate buffer and a diazonium salt, and teaches that "the salts are present in approximately a 1:1 ratio as claimed." Non-Final 6–9. Examiner finds Babson and Holmes teach similar AP tests using the claimed diazonium salt, Fast Blue B. Non-Final 7–8. Examiner determines that Holmes further teaches contacting a

filter paper strip to a suspected semen stain in an undergarment. *Id.* at 8. Examiner finds that Falb, Smith I and II, Shi and Menon all teach "diagnostic test strips comprising paper coated elements affixed to a plastic backing" and that Falb describes the use of that plastic backing as "a handle, i.e., a fingerhold." *Id.* at 10. Examiner determines "one of ordinary skill in the art would be apprised of cutting or designing the test strip to specific dimensions depending on its intended use," and therefore the features of the AP test strip assembly in claim 1 would have been obvious because all of the "elements were known in the prior art and one skilled in the art could have combined the elements . . . with no change in their respective functions and the combination would have yielded predictable results." *Id.* at 10. Finally, Examiner determines that Diagnostics teaches the storage of such strips in a canister with a desiccant cap. *Id.* at 11.

Appellant contends that Examiner failed to make out a prima facie case of obviousness for various reasons and that there was no apparent reason to combine the elements of the cited references in the fashion claimed. *See* Appeal Br. 7–9. In addition, Appellant urges that Falb, Smith I and II, Shi, and Menon teach away from its claimed invention because they teach test strips for other purposes than "determining the presence of semen in dried stains on garments." *Id.* at 10. Finally, Appellant contends that the "present invention represents an improvement over the prior art in that it contains two types of semen detection strips." *Id.* at 11.[12]

[12] In addition, Appellant suggests claims 1–3 should be allowed because claims to "[a] very similar test assembly w[ere] granted [in] US Pat. 8,137,956 . . . the only difference being the method of preparation." Appeal Br. 3. We disagree. Our review is focused on the specific rejections of the particular claims presented in this appeal. *See In re Hutchison*, 154 F.2d

With respect to claim 3, which is directed solely to an "AP test strip assembly," we are unpersuaded by Appellant's arguments. The record supports Examiner's determination that Arter, Babson, and Holmes teach AP tests comprising the claimed reagents in a range of quantities that encompass the amounts recited in Appellant's claims. FF1–FF4. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("[W]e and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness."). In addition, Falb, Smith I and Smith II teach test strip assemblies comprising filter paper containing the test reagents bound to a longer plastic backing that serves as a handle, or fingerhold, for the strip. FF5–FF7.

We also agree it would have been obvious to combine the AP test in Arter, Babson, and Holmes with the test strip features taught in Falb, Smith I, and Smith II to arrive at the recited test strip assemblies. Babson and Holmes teach that Fast Blue B salt is an effective dye for an AP test. FF3, FF4. Falb, Smith I, and Smith II teach that a plastic handle or fingerhold is a useful feature for a test strip. FF5–FF7. Those teachings provide a sufficient motivation for the combination articulated in Examiner's rejection. Moreover, the record supports there would have been a reasonable expectation of success because the rejection merely combines known prior art features (i.e., using Fast Blue B as the diazonium salt for the test and

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135, 137 (CCPA 1946) ("We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the . . . claims on appeal were properly rejected, and this we pass upon without further reference to, and without comparing them with, the claims [that have been allowed]."). The claims allowed in the '956 patent are not relevant to those rejections.

binding the filter paper to a longer plastic backing to provide a fingerhold) for their established functions. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

In addition, we agree with Examiner's finding that the dimensions of Appellant's test strip assembly would have been obvious over these references. Non-Final 10. Arter teaches an assembly comprising filter paper with a supporting plastic backing and explains that the size of the strip will vary depending on the method of the assay. FF2. And, based on the method taught in Holmes, one of ordinary skill would have been motivated to use a strip of a size amenable to directly contacting the suspect area in an undergarment. FF4. Regarding the claimed "fingerhold," Falb describes a test strip similar to that in Appellant's claims in that both are rectangular with a filter paper test portion mounted to and extending the full width of one end of a longer plastic backing whose other end serves as a handle to use when contacting a reactive portion of the strip to the sample. FF5. There is nothing in the record that suggests that the specific dimensions recited in the claims here would not have been an obvious application of these prior art teachings. *See Gardner v. TEC Syst., Inc.*, 725 F.2d 1338, (Fed. Cir. 1984) (affirming obviousness determination where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device).

Appellant's attempts to distinguish Arter, Babson, and Holmes are unpersuasive. *See* Appeal Br. 8–9. Appellant argues that Arter does not teach the use of "hygroscopic" 1-naphthyl phosphate or "sodium dyhydrogencitrate" as the citrate buffer. *Id.* at 8. But the AP test strip assembly in Appellant's claims is not so limited and encompasses the aromatic phosphate reagent and buffer taught in Arter. FF1. Appellant's remaining arguments (*see* Appeal Br. at 8–9) are premised on differences between the individual references and the claimed AP test strip assembly. Such arguments are unpersuasive because they do not distinguish the Obviousness Rejection which is based on a combination of the reference teachings. *See Soft Gel Techs., Inc. v. Jarrow Formulas, Inc.*, 864 F.3d 1334, 1341 (Fed. Cir. 2017) ("[N]on-obviousness cannot be established by attacking references individually where the rejection is based on the teachings of a combination of references.") (quoting *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986)).

We are also unpersuaded by Appellant's argument that there is "no apparent reason to combine the elements in the fashion claimed," i.e., to add the claimed "fingerhold" to Arter's AP test strip assembly. Appeal Br. at 9–10 (emphasis removed). Falb, Smith I, and Smith II specifically teach that is useful to have a plastic handle to hold the filter paper containing the reagents when placing the test strip into a test sample. FF5–FF7. Accordingly, the record support's Examiner's finding that a skilled artisan would have a reason to include a fingerhold on Arter's AP test strip assembly.

Nor are we persuaded by Appellant's argument that Falb, Smith I and II, Shi, and Menon "teach away" from the claimed invention because they teach test strips for other purposes. Appeal Br. 10. A "teaching away" that

is probative of non-obviousness requires that the reference "criticize, discredit, or otherwise discourage the solution claimed" by Appellant. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Here, none of the references cited by Examiner criticize, discredit or otherwise discourage testing for AP on a test strip to detect semen. To the contrary, Arter specifically teaches a test strip assembly comprising filter paper with a plastic backing to detect AP in various specimens, including semen. FF1–FF2. The fact that some of the other cited references individually teach other types of tests does not distinguish the combination of references on which the rejection is based. *See Soft Gel*, 864 F.3d at 1341 (explaining that attacking references in a combination individually does not demonstrate non-obviousness).

For all these reasons, the preponderance of the evidence supports Examiner's conclusion that the AP test strip assembly recited in Appellant's claims would have been obvious to one of ordinary skill in the art in view of Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, and Diagnostics. Since claim 3 is limited to just that assembly, we affirm the rejection of claim 3.

However, we reach a different conclusion with respect to claims 1 and 2. Unlike claim 3, claims 1 and 2 recite the presence or use of PSA strips in addition to the claimed AP test strip assembly. Examiner has not found that PSA strips are taught in Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, or Diagnostics. Instead, Examiner points to the disclosure of PSA

strips in two other references, Pang[13] and An[14], that were not included in Examiner's statement of the rejection. Non-Final 6. Examiner continues this error on appeal. *See* Ans. 8–9 (relying on Pang and An to support the Obviousness Rejection). Because Pang and An were not included in the statement of the Obviousness Rejection, Examiner could not rely on their teachings to establish obviousness. *See* MPEP 706.02(j) ("Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection."); *In re Hoch*, 428 F.2d 1341, 1342 n.3 (CCPA 1970) ("Where a reference is relied on to support a rejection . . . there would appear to be no excuse for not positively including the reference in the statement of rejection."). For this reason alone, we determine that the preponderance of the evidence does not support Examiner's conclusion that claims 1 and 2 are obvious.

III. NEW GROUND OF REJECTION

We enter a new ground rejecting claims 1 and 2 under 35 U.S.C. § 103 over Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, Diagnostics, and Pang.

Pang teaches that the "strip PSA test has been available commercially from various manufacturers for many years" and "is commonly used to detect semen in forensic significant samples taken from sexual assault

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[13] B.C.M. Pang et al., *Identification of Human Semenogelin in Membrane Strip Test as an Alternative Method for the Detection of Semen*, Forensic Sci. Int'l, Vol. 169, 27–31 (2007) ("Pang").
[14] Chang Kok An et al., *Evaluation of a Rapid Qualitative Prostate Specific Antigen Assay, the One Step PSA™ Test*, Cancer Letters, Vol. 162, 135–139 (2001) ("An").

cases." Pang, Abstr. Pang further teaches that the "[a]cid phosphatase test remains one indispensable screening test for semen in sexual assault cases." *Id.* at 30. Pang describes testing in which both the PSA and AP tests were performed on the same samples. *See id.* at 29–30 (Section 3.5). The data in Pang Table 2 shows that in a few instances the same sample yielded a positive result for one test, but not the other. *Id.*; *see also id.* (reporting that among "12 recent casework samples tested positive for . . . PSA, 11 of them were also tested positive for acid phosphatase).

In addition to these findings, we refer to Examiner's prior findings regarding Pang and the other cited references as set forth on pages 6–11 and 15–19 of the Non-Final action and pages 6–10 of the Answer, which we agree with (*see* FF1–FF8) and incorporate by reference herein. In light of the foregoing facts, we agree with Examiner's determination that "it would have been obvious to one of ordinary skill in the art to include an immunochromatographic test strip for PSA in a semen detection kit with the test strips of Arter and Babson for the detection of PSA in semen because the tests strips are disclosed in the art and are known for their claimed purpose, i.e., semen detection." Non-Final 9. This combination of known prior art tests according to their established function of determining whether or not semen is present is sufficient to demonstrate a prima facie case of obviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

We are not persuaded by Appellant's argument that it is unclear whether Pang "used AP strips as opposed to a liquid-based test." Appeal Br. 11. Arter teaches AP test strips. FF1. And, as explained above, the claimed "AP test strip assemblies" would have been obvious over the combination of Arter with other of the cited references. Thus, the fact that Pang by itself does not employ an AP test strip assembly does not distinguish the combination of Pang with Arter and the other cited references. *See Soft Gel*, 864 F.3d at 1341.

We are likewise unpersuaded by Appellant's suggestion that the combination of the two tests provides an unexpected "synergistic . . . increase [in the] specificity of detection" evidencing that the combination would not have been obvious. *See* Appeal Br. 11. As noted above, the data in Pang shows that the same sample may test positive for one test, but not the other. Accordingly, one of ordinary skill in the art would reasonably expect to see an increase in specificity and accuracy by combining the two tests. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art."); *In re Skoner*, 517 F.2d 947, 950 (CCPA 1975) ("Expected beneficial results are evidence of obviousness of a claimed invention."). For these reasons, we enter a new ground of rejection of claims 1 and 2 under section 103 based on the combination of Pang with the other references cited in the Obviousness Rejection.

CONCLUSION

For the reasons explained above, we find the preponderance of the evidence does not support the Written Description Rejection of claims 1–3

and the Obviousness Rejection of claims 1 and 2. We determine that the Obviousness Rejection of claim 3 is supported by a preponderance of the evidence and enter a new ground of rejection under 35 U.S.C. § 103 of claims 1 and 2.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed	New Ground
1–3	112(a)	Written Description		1–3	
1–3	103	Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, Diagnostics	3	1, 2	
1, 2	103	Arter, Babson, Holmes, Falb, Smith I, Smith II, Shi, Menon, Diagnostics, Pang			1, 2
Overall Outcome			3	1, 2	1, 2

FINALITY AND RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the 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. . . .

AFFIRMED-IN-PART; 37 C.F.R. 41.50(b)