

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALERE INC.
Petitioner

v.

REMBRANDT DIAGNOSTICS, LP
Patent Owner
U.S. Patent No. 8,623,291

Case No. IPR2016-____

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 8,623,291
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104**

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I. MANDATORY NOTICES

A. Real Party-in-Interest

Alere Inc. (“Petitioner”) is the real party-in-interest.

B. Related Matters

As of the filing date of this petition for *inter partes* review (“IPR”), U.S. Patent No. 8,623,291 (“the ’291 patent”) is involved in litigation in the Southern District of California, captioned *Rembrandt Diagnostics, LP v. Alere Inc., et al.*, No. 3:16-cv-698-CAB-NLS (“the district court litigation”).¹ Petitioner is not aware of any other judicial or administrative matter that would affect or be affected by a decision in this IPR.²

¹ In addition to Alere Inc., the following subsidiaries were named as defendants in the district court litigation: Alere Toxicology Services, Inc., Amedica Biotech, Inc., Ameditech, Inc., Innovacon, Inc., Instant Technologies, Inc., Instant Tech Subsidiary Acquisition Inc. d/b/a US Diagnostics, and Branam Medical Corp.

² Petitioner is also filing a Petition for *Inter Partes* Review of U.S. Patent No. 6,548,019, also asserted in the same district court litigation.

C. Counsel and Service Information

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II. CLAIM LISTING

Independent Claim 1 of the '291 patent provides:

1. A device for assaying a fluid for the presence or absence of different analytes comprising:
 - (A) a base having adjacent slots therein of sufficient length for insertion of part of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (C) at least one open end,
 - (B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into

each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte; the protruding freestanding end of each test strip containing a sample addition pad for direct contact with the fluid to be analyzed;

(C) a cover attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of said base, wherein the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and

(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.

Ex. 1001, 11:10-12:2.

Claim 2 depends from Claim 1, and recites: “[t]he device according to claim 1 further comprising a second transparent window formed within the cover through which the test strips can be viewed.” *Id.*, 12:3-5.

Independent Claim 9 provides:

9. A method for detecting a multiplicity of analytes which comprises removing the cap from the device of claim 1 and inserting the protruding ends of the test strips into a sample to be analyzed and observing the effect of

the sample on the test and control zones of the test strips
contained in the device.

Id., 12:26-30.

III. GROUNDS FOR STANDING

Petitioner certifies that the patent for which review is sought is available for IPR and that Petitioner is not barred or estopped from requesting an IPR on the grounds in this Petition. This petition is timely under 35 U.S.C. § 315(b) because it was filed within one year of the March 24, 2017 service of the Complaint on Alere in the district court litigation.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges Claims 1, 2, and 9 of the '291 patent (Ex. 1001).

A. Prior Art Patents and Printed Publications

The '291 Patent was filed Jan. 5, 2007 and claims priority to an application filed July 14, 1998. The following references are pertinent prior art:

Ex.	Description	Filing, Pub., or Issue Date	Prior Art
1004	German Utility Model No. DE 297 02 825 (“DE”) and certified English translation	May 22, 1997	§ 102(b)
1005	U.S. Patent No. 5,602,040 (“May”)	Feb. 11, 1997	§ 102(b)

Ex.	Description	Filing, Pub., or Issue Date	Prior Art
1006	U.S. Patent No. 5,976,895 (“Cipkowski”)	March 11, 1996	§ 102(e)
1007	U.S. Patent No. 5,962,336 (“Sun”)	March 20, 1997	§ 102(e)
1008	U.S. Patent No. 5,985,675 (“Charm”)	Dec. 31, 1997	§ 102(e)
1009	U.S. Patent No. 4,943,522 (“Eisinger”)	July 24, 1990	§ 102(b)
1010	U.S. Patent No. 5,798,273 (“Shuler”)	Sept. 25, 1996	§ 102(e)
1011	U.S. Patent No. 5,622,871 (“May ’871”)	Apr. 22, 1997	§ 102(b)

B. Grounds for Challenge

Petitioner requests cancellation of claims 1, 2, and 9 of the ‘291 patent as unpatentable under 35 U.S.C. § 103, per the Grounds below.

Ground	Claims	Description - § 103(a) obviousness combination
I	1, 2, 9	DE in view of May
II	1, 9	DE in view of Charm and May ’871
III	2	DE in view of May, Shuler, and Eisinger
IV	1, 2, 9	Cipkowski in view of May
V	1, 9	Cipkowski in view of Charm and May ’871

VI	2	Cipkowski in view of May, Shuler, and Eisinger
VII	1, 2, 9	Sun in view of May
VIII	1, 9	Sun in view of Charm and May '871
IX	2	Sun in view of May, Shuler, and Eisinger

This petition, supported by Dr. Robert Bohannon's declaration (Ex. 1003)("Decl."), demonstrates a reasonable likelihood that Petitioner will prevail as to at least one challenged claim, and that each challenged claim is unpatentable. *See* 35 U.S.C. §314(a).

V. BACKGROUND

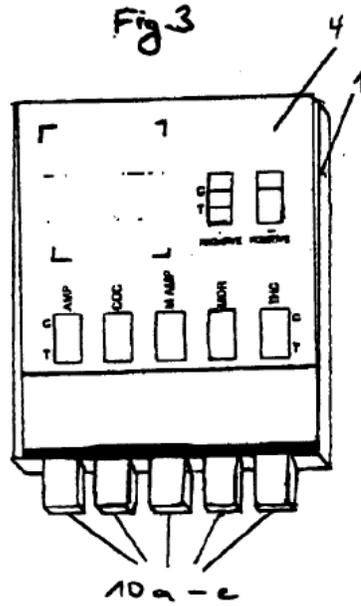
A. Overview of Technology

Systems and methods for detecting analytes, such as drugs, in biological fluid samples, such as urine, have long been known in the art. Decl. ¶¶ 16-43. Various commercial devices were known in the art long before the earliest effective filing date to which the '291 patent is entitled. *Id.* ¶¶ 24-25; Ex. 2012. The '291 patent discloses that the prior art includes single step assay devices that produce "visually observable assay results (such as... colored bars on [a] test strip)." Ex. 1001, 1:11-24. Assays known in the art included "competition" assays, wherein the *absence* of a line in a test zone indicates a positive result (presence of the analyte), and "sandwich" assays, wherein the *presence* of a line in a test zone indicates a positive result. *See id.*, 4:41-49 & 4:7-13; Decl. ¶ 18.

The '291 patent at 5:16-19 & 5:45-60 acknowledges that the test strips used in its claimed devices are “conventional in form,” that they are prepared using “means known in the art,” and use test binders and means for attaching the binders to porous test strips that are “well-known to those of ordinary skill in the art.” The '291 patent (Ex. 1001, 5:54-6:3) even refers the reader to prior art patents that “provide a representative sample of test strip designs known in the art,” including U.S. Patent No. 5,602,040 (“May,” Ex. 1005), discussed below.

Devices for simultaneously testing a single urine sample for multiple drugs of abuse were known in the art. Decl. ¶ 26. As discussed in more detail below, the primary prior art references relied upon in this petition, such as DE 297 02 825 (“DE”)(Ex. 1004), 1-2,³ U.S. Patent No. 5,976,895 (“Cipkowski”)(Ex. 1006), 1:63-2:10; U.S. Patent No. 5,962,336 (“Sun”)(Ex. 1007), 1:4-22, disclosed dipstick format multistrip devices for testing urine for drugs of abuse, each with test strips protruding from a housing, as shown in the following figures from these patents:

³ Citations to DE are to Petitioner’s certified English translation.



Ex. 1004, Fig. 3.

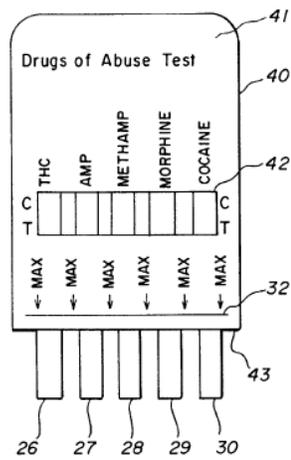
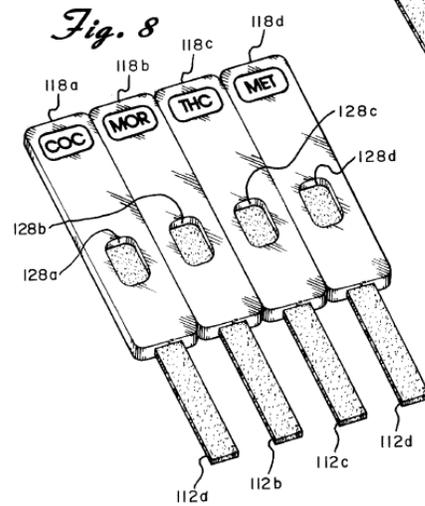


FIG. 9

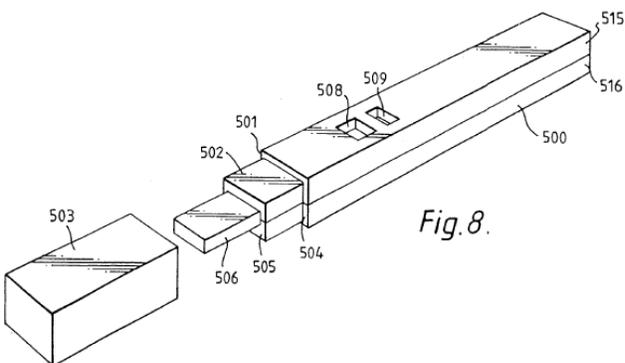
Ex. 1006, Fig. 9.



Ex. 1007, Fig. 8.

Such devices typically employed one or more windows/apertures for viewing parts of a test strip, including test and/or control zones. Decl. ¶¶ 36-39.

The use of a cap to cover the fluid-contacting open end of a dipstick device was also disclosed in the prior art. *Id.* ¶¶ 40-43. For example, U.S. Patent No. 5,602,040 (“May”) (Ex. 1005), which Applicant incorporated by reference in the ‘291 patent (Ex. 1001, 6:2-4), shows a removable cap 503 to cover the sample receiving end of the test strip contained within a casing.



Ex. 1005 at Fig. 8. In addition, U.S. Patent No. 5,985,675 (“Charm”), also discussed below, discloses capping a multi-strip device to prevent contamination, and incorporates by reference the capped device of U.S. Patent No. 5,622,871 (“May ’871,” which is in the same family as May)(Ex. 1011).⁴

B. The ’291 Patent And Its Prosecution History

The ’291 patent describes an assay device for testing multiple analytes, such as drugs, using individual test strips that are “conventional in form” for each analyte, plus assay methods. Ex. 1001, Abstract; 1:35-40 & 5:16-19; Decl. ¶¶ 56-61. “Each test strip provides binders and assay reagents for detection of a different analyte.” *Id.*, 1:54-55. The ’291 patent defines a “binder” as “a ligand for the analyte” (for “sandwich assay[s]”) or “a ligand for both the analyte and the tracer” (for “competitive assay[s]”). *Id.*, 3:1-6; *see also id.*, 4:5-57, 5:16-23. A “test zone” is defined as “an area in which a binder or the analyte is attached... to the test strip.” *Id.*, 3:7-9.

Fig. 2 depicts a top view:

⁴ Other prior art made similar disclosures. Decl. ¶¶ 40-43; U.S. Patent No. 6,808,682 (“Bates”)(Ex. 1013).

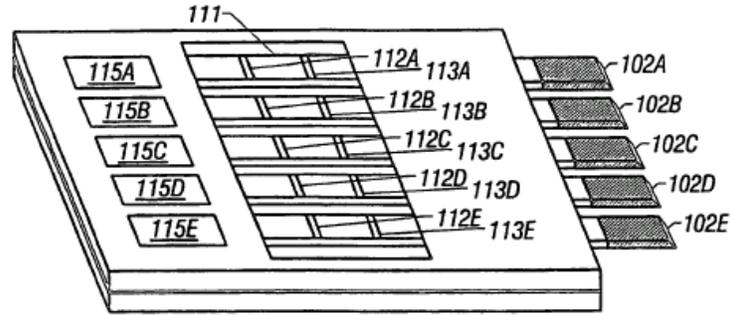


FIG. 2

Fig. 1 depicts an exploded view:

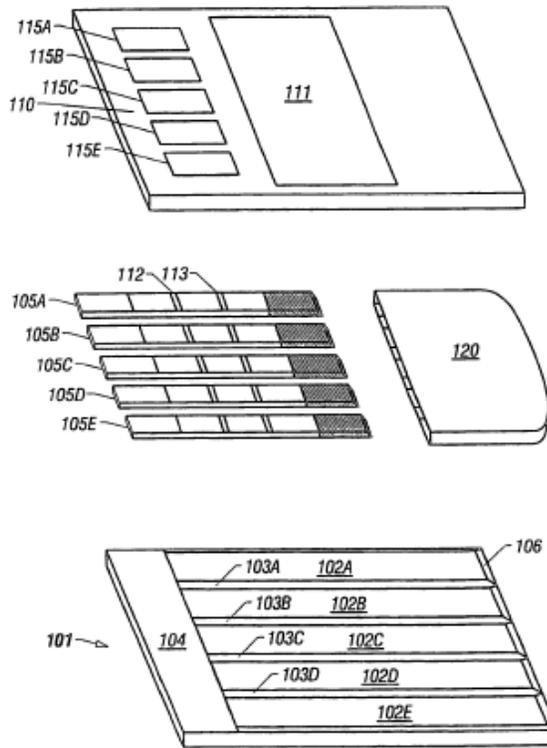


FIG. 1

In dipstick form, the assay device has a housing 100. *Id.*, Fig. 1; 4:61-63. Base 101 has a closed end 104 and an open end 106, with slots (102A-E) separated by rails (103A-D) for inserting test strips (105A-E), which extend from base 101. *Id.*, 4:67-5:9, 5:10-16, Fig. 2. Test and control zones are viewable through

transparent window portion 111 of cover 110. *Id.*, 6:9-12. The test strips are also viewable through additional transparent windows (115A-E). *Id.*, 6:20-25. Cap 120 protects protruding strip ends. *Id.*, 6:26-34.

The '291 patent also discloses a detection method. *Id.*, 8:31-35, 8:43-48. In dipstick devices, samples are applied to test strips by immersion. *Id.*, 9:59-63. Test results are viewed through window 111. *Id.*, 9:63-66. A color change in test zone 112 indicates analyte presence. *Id.*, 9:66-10:1.

During prosecution, the Examiner rejected the then-pending claims as obvious under 35 U.S.C. §103, based on DE (Ex. 1004) in view of U.S. Patent No. 5,770,458 (“Klimov”). Ex. 1002, 94-95; Decl. ¶¶ 62-65. DE’s Figures 1 & 3, which are discussed in more detail below, show a device for simultaneous testing of a urine sample for multiple drugs of abuse comprising, *inter alia*, a base with slots, with a test strip positioned in each slot, and a cover with transparent windows for viewing the test results on each strip. Ex. 1004, 1:8-19, 1:23-24, 2:15-25, 3:14-17, 4:21-5:7, 5:9-13, 7:5-19. Klimov was cited by the examiner as disclosing the claimed test strips and as teaching use of a seal for sealing or covering the sample pads. Ex. 1002, 49.⁵

In its Appeal Brief, Applicant stated as follows about DE:

⁵ Klimov is not relied upon here.

DE 297 02 825 is a German utility model patent which discloses a multiple analyte assay device in which the assay test strips extend beyond the housing for the test strips which are contained in channels in the housing ...

The patent does not disclose any kind of cap or cover for the exposed parts of the test strips.

Id., 98:3-7. Thus, the only limitation Applicant identified as missing from DE was the cap.

In an effort to overcome Klimov, Applicant conceded that: (i) “Appellant admits that construction of the test strip itself is not novel” (*Id.*, 98:1-2); and (ii) “appellant does not rely on the construction of the test strip to support the patentability of the appealed claims” (*Id.*, 101:26-28).

Applicant further acknowledged: “The key feature of the claimed invention is that it minimizes any contamination of and damage to the various assay strips. With the cap on, the exposed strips are protected during transport and any contact between the operator of the test and the sample is further reduced.” *Id.*, 98:27-6:2.

The appeal of the §103 issue turned on whether Klimov disclosed the claimed cap. The Board reversed the obviousness rejection because “the Examiner [did] not explain how Klimov [which discloses an assay device with a rubber seal] would have rendered a removable cap prima facie obvious.” *See* Ex. 1002, 130-131. However, neither the Examiner nor the Board considered DE (or other primary references below) in view of either May (Ex. 1005) or U.S. Patent No.

5,985,675 (“Charm” or Ex. 1008), which both clearly disclose the claimed removable cap, as discussed below.

VI. PERSON OF ORDINARY SKILL IN THE ART

For purposes of this Petition, Petitioner adopts Dr. Bohannon’s opinion that the field of endeavor is *in vitro* device engineering, as well as his definition of a person of ordinary skill in the art (“POSITA”). *Id.* ¶¶ 52-55. Specifically, a POSITA would have a Bachelor of Science degree (or the equivalent) in a relevant scientific or engineering field, such as such as mechanical or biomechanical engineering, biology, biochemistry or immunology, with 3-5 years of experience in design, testing, and manufacturing of *in vitro* test devices. *Id.* ¶ 54.

VII. CLAIM CONSTRUCTION

A. “Sample Addition Pad”

Claim 1(B) recites: “a multiplicity of test strips... the protruding freestanding end of each test strip containing a *sample addition pad* for direct contact with the fluid to be analyzed.” *Id.*, 11:17-25 (emphasis added). A POSITA would understand that by July 14, 1998, it was known in the art that liquid samples could be added to a porous member that would absorb the sample, and the sample would then permeate a test strip in a housing. Decl. ¶ 67. For example, May (incorporated by reference in the ‘291 patent) discloses a “porous receiving member to which [a] liquid sample can be applied and from which the sample can permeate the porous solid phase material... [within a] housing.” Ex. 1005,

Abstract, 3:56-65, 4:46-5:7, 8:11-12, 12:14-37, 14:42-46, Figs. 8, 10. The porous receiving member provides “the sole route of access... to the strip within the housing, and can deliver the sample to the strip in a controlled manner.” *Id.*, 13:14-20.

Applying the broadest reasonable construction, “sample addition pad” should be construed to mean “pad that receives the sample.”

B. “Transparent Window”

Claims 1(C) and 2 both recite “transparent” windows. Ex. 1001, 11:26-31, 12:3-5. The ’291 patent discloses that “cover 110 is conveniently constructed of an opaque tape having at least one transparent window 111 formed therein for viewing of test results along test zone 112 and control zone 113” and “cover 110 is also provided with transparent windows 115[A-E] through which labels on test strips 102[A-E] can be viewed.” *Id.*, 6:9-25, Figs. 1-2; *see also id.*, 1:46-48. A transparent window is not an uncovered opening or aperture, but must be made of a solid transparent material; otherwise, the word “transparent” would add no meaning. Decl. ¶ 69. Moreover, a POSITA would understand that constructing a window with a solid transparent material (as opposed to an open aperture) is important in drug testing devices to avoid tampering or contamination of the test results. *Id.* Applying the broadest reasonable construction, “transparent window”

should be construed to mean “window consisting of a solid material that is transparent but whose boundaries may be defined by an opaque material.” *Id.*

C. “A First Transparent Window”

Claim 1(C) recites a cover attached to the base that “has a *first transparent window* formed therein through which the test zone and the control zone of the test strips can be viewed...” Ex. 1001, 11:26-31 (emphasis added). In “comprising” claims, “a” commonly means “one or more.” *See, e.g., Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008); *SanDisk Corp. v. Kingston Tech. Co., Inc.*, 695 F.3d 1348, 1360-61 (Fed. Cir. 2012). The ’291 patent teaches that test and control zones may be viewed through “at least one transparent window 111.” Ex. 1001, 6:20-25, Figs. 1-2. Applying the broadest reasonable construction, “a first transparent window” should be construed as “one or more first transparent windows.” Decl. ¶ 70.

D. “A Second Transparent Window”

Claim 2 recites: “The device according to claim 1 further comprising a *second transparent window* formed within the cover through which the test strips can be viewed.” *Id.*, 12:3-5 (emphasis added). The ’291 patent discloses “transparent windows 115A[-E]” as distinct from the “at least one transparent window 111.” *Id.*, 6:20-25. No specific purpose for the second transparent window, other than viewing the test strips, is recited in Claim 2. Applying the

broadest reasonable construction, “a second transparent window” should be construed as “one or more additional transparent windows in the cover through which the test strips can be viewed.” Decl. ¶ 71.

VIII. SUMMARY OF SELECT PRIOR ART

A. DE

DE is prior art under § 102(b) because it was published in the German Patent and Trade Mark Office’s Patent Gazette on May 22, 1997. Ex. 1004, 11; MPEP § 901.5 (IV)(Patent Gazette publication date is the “date published for public”).

As discussed briefly above, DE teaches a multiassay dipstick device for use in simultaneously testing a urine sample for multiple drugs of abuse. *See* Ex. 1004, 1:8-19; 2:18-25; Decl. ¶¶ 72-73. DE was considered during prosecution of the ’291 patent, but not in combination with the references herein. None of Petitioner’s Grounds relies solely on DE, and Petitioner presents different arguments and evidence not considered by the Patent Office, including Dr. Bohannon’s declaration. *See Chimei Innolux Corp. v. Semiconductor Energy Laboratory Co., Ltd.*, IPR2013-00038, Paper No. 9 at 6 (March 21, 2013) (instituting IPR although certain prior art references were considered during prosecution).

DE discloses a holder 1 with multiple strip-like recesses 2. Ex. 1004, 2:15-25, 3:14-17, 4:21-5:7, 7:7-19.

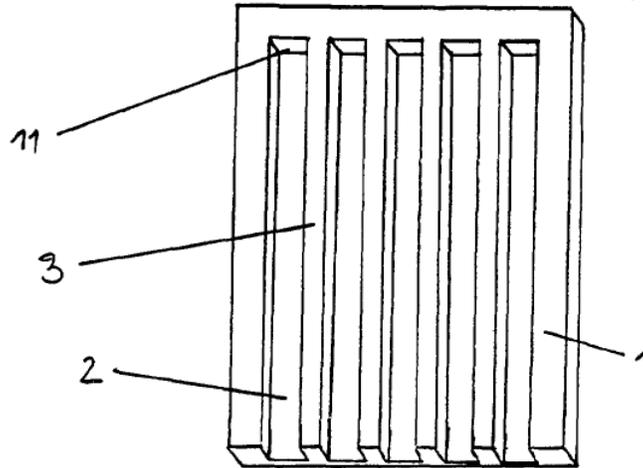
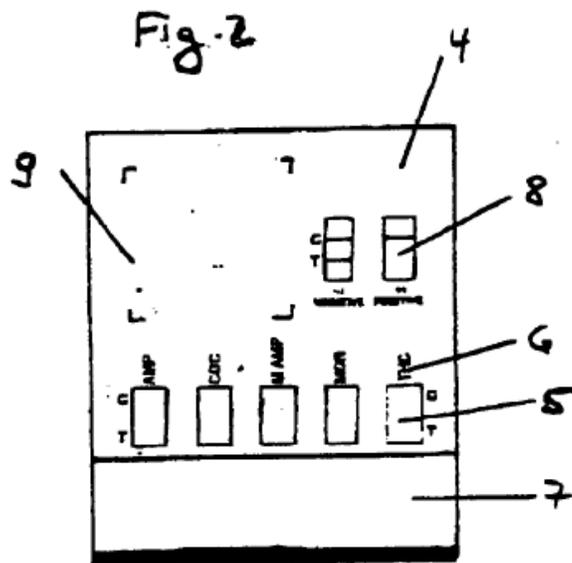
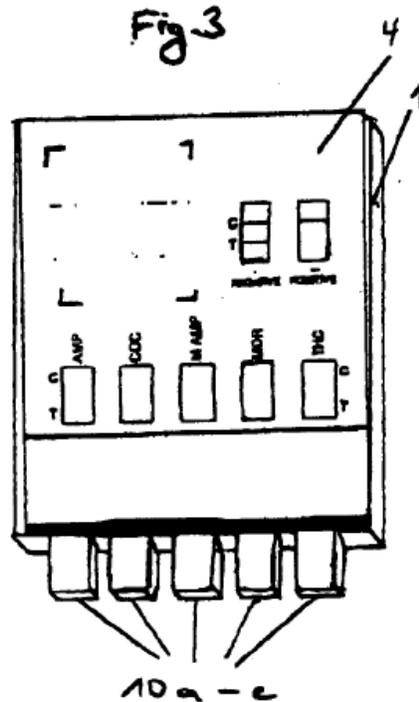


Fig. 1

Id., Fig. 1. Each test strip detects a different analyte, and is inserted into the recess so that the end to be dipped into the sample protrudes from the holder. *Id.*, 1:23-24, 2:15-25, 7:7-9, Figs. 2-3.



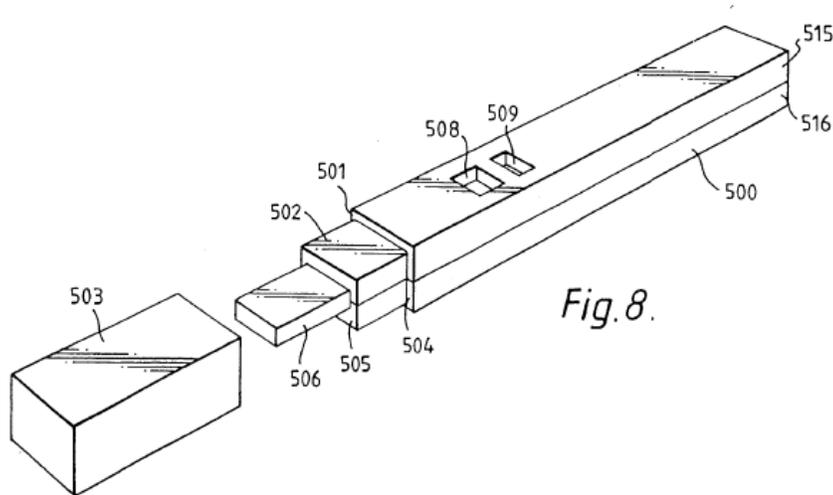
Id., Fig. 2.



Id., Fig. 3. The test strips are fixed in place with a self-bonding cover film 4 that is glued on the holder and secures the strips in their slots. *Id.*, Figs. 2-3, 5:9-11, 7:5-9. The cover film has transparent windows 5 for viewing test (T) and control (C) zones. *Id.*, Figs. 2, 3, 5:11-13, 7:11-12. The markings 6 on the cover in Figs. 2 & 3 indicate that each strip is testing for a different analyte.

B. May

May is prior art under § 102(b) because it issued Feb. 11, 1997. Ex. 1005. May was incorporated by reference into the '291 patent (Ex. 1001, 6:3-6), but was not addressed during prosecution of the '291 patent. May teaches a test device including a casing (500) with a porous carrier (510) and a sample receiving member (506). Ex. 1005, Abstract; Decl. ¶¶ 74-75.



Id., Fig. 8. May also discloses two or more strips arranged in parallel for simultaneously testing different samples or reagents. *Id.*, 6:26-39.

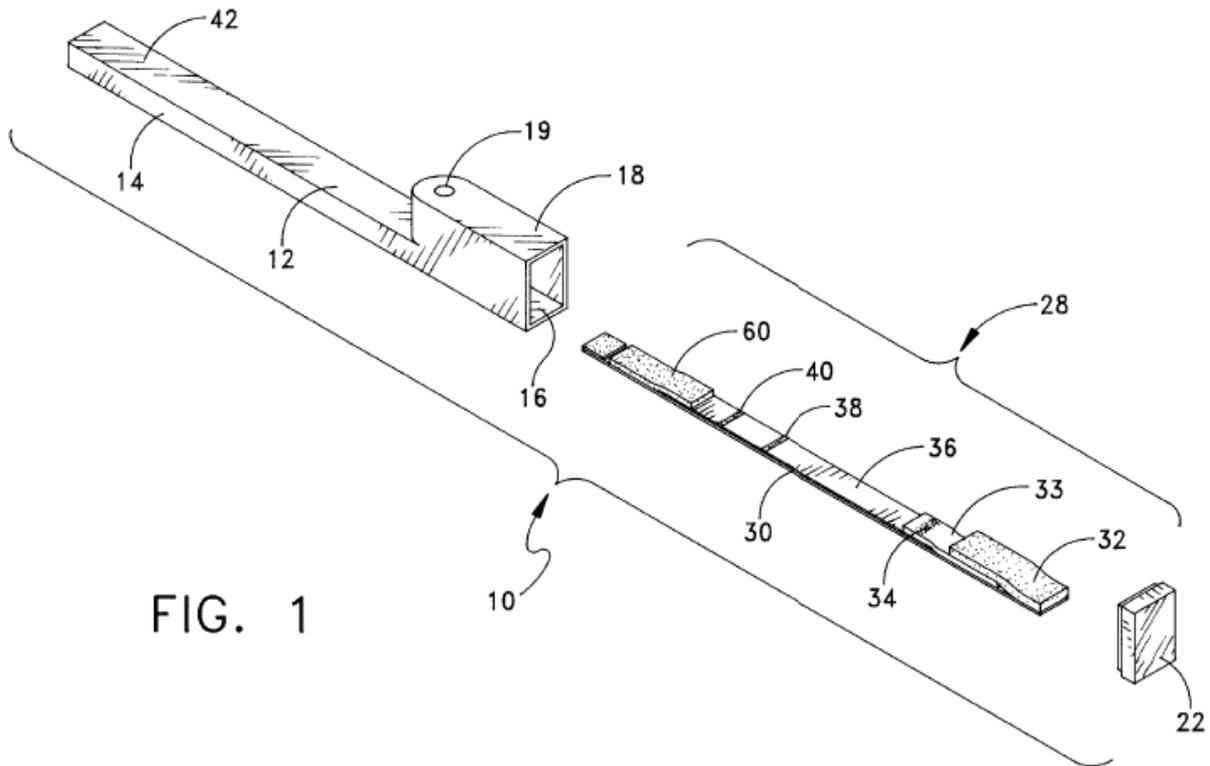
As discussed above, May also discloses a removable cap 503 that covers porous member 506. *Id.*, Abstract, 4:8-13; 12:9-15, 12:54-62, 13:27-30. “In operation, the protective cap 503 is removed from the holder and member 506 is exposed to a liquid sample;” then the cap “can be replaced.” *Id.*, 12:54-62. May also discloses apertures 508 and 509 for viewing test and control zones. *Id.*, 12:17-18, 12:62-67, 13:27-30. The apertures can be fitted with transparent inserts to protect against ingress of extraneous moisture from outside the housing. *Id.*, 13:11-14.

C. Charm

Charm is prior art under § 102(e) because it was filed Dec. 31, 1997. Ex.

1008

Charm teaches a device for testing liquid samples, such as urine, with “one or more test strips.” *Id.*, Abstract, 4:6-12; Decl. ¶ 76. Charm teaches a “protective cap to protect the test device from contamination” before and after use. Ex. 1008, 3:44-54. Cap 22 is “adapted to fit over the open application end 16.” *Id.*, 5:4-7.⁶ Charm was not of record during prosecution of the ‘291 patent.



Id., Fig. 1. As shown in Fig. 1, each test strip in Charm has “a test and a separate control line ... to detect the presence of analytes.” *Id.*, 1:63-67. The housing

⁶ Charm also states that prior art (U.S. Patent No. 5,622,871, which is in the same family as May) describes “a protective, removable cap.” Ex. 1008, 1:17-23; Decl. ¶ 118.

contains “a transparent top cover section” (*Id.*, 1:45-46)— or alternatively, “only a section of the top cover [is] transparent”— for “view[ing] the test results.” *Id.*, 3:38-40. Figures 6 and 13 show results based on control line 40 and reference line 38:

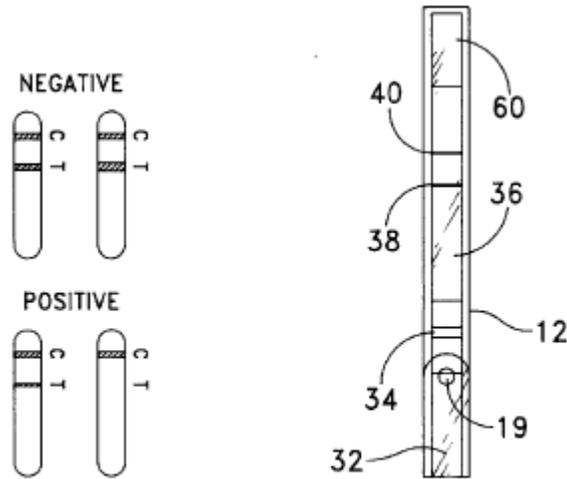


FIG. 6

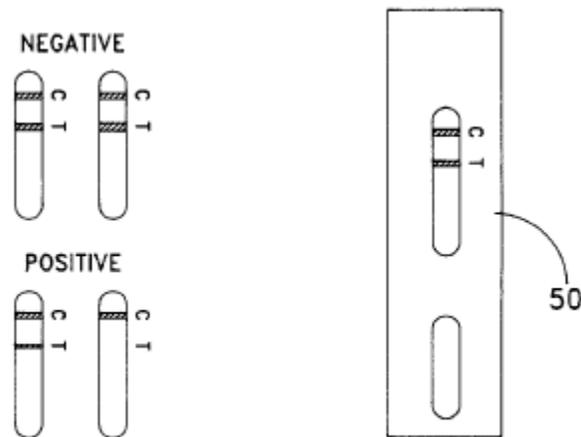


FIG. 13

Id., 4:46-48, 4:56-58, 5:52-56, 6:27-30, 6:48-53, 8:15-17.

D. Cipkowski

Cipkowski is prior art under § 102(e) because it was filed March 11, 1996.

Ex. 1006. Cipkowski teaches a drugs of abuse test kit with a “test card having a plurality of immunoassay test strips... with visual endpoints to indicate presence or absence of a particular drug.” *Id.*, Abstract, 1:3-8, 3:55-59; Decl. ¶¶ 77-81.

Cipkowski was not of record during prosecution of the '291 patent.

Fig. 9 shows a test card:

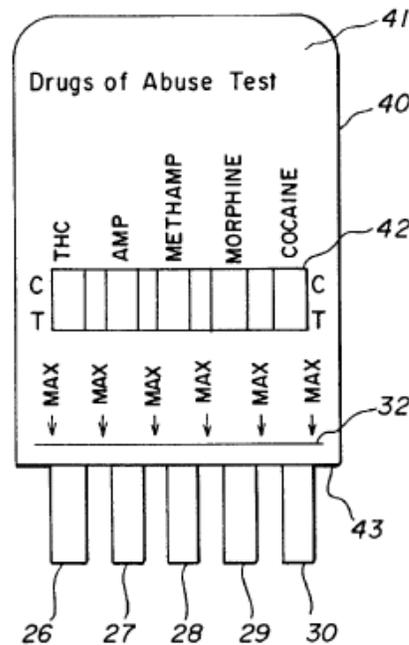
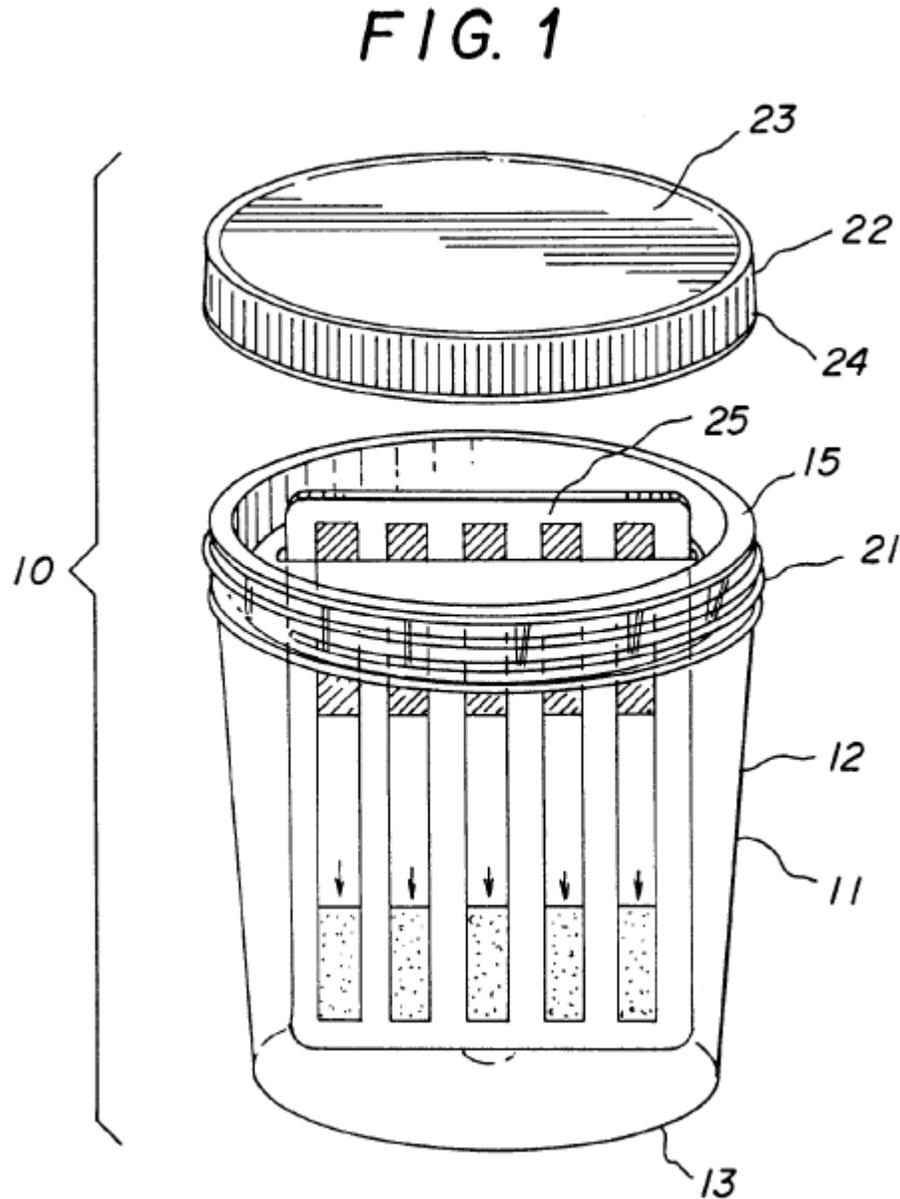


FIG. 9

In addition to the two plies that form the test card, a third ply 41 covers the strips and has an opening 42 for viewing test and control lines. *Id.*, 4:66-5:4. Test strips 26-30 project beyond end 43. *Id.*, 5:4-8. The test card is inserted into a urine sample. *Id.*, 2:20-26. If the result is positive, the test card is removed and the

container is shipped to a laboratory for more “complete analysis.” Decl. ¶ 77; Ex. 1006, 1:12-17, 2:26-34.

Fig. 1 shows a container, another test card embodiment, and a cover:



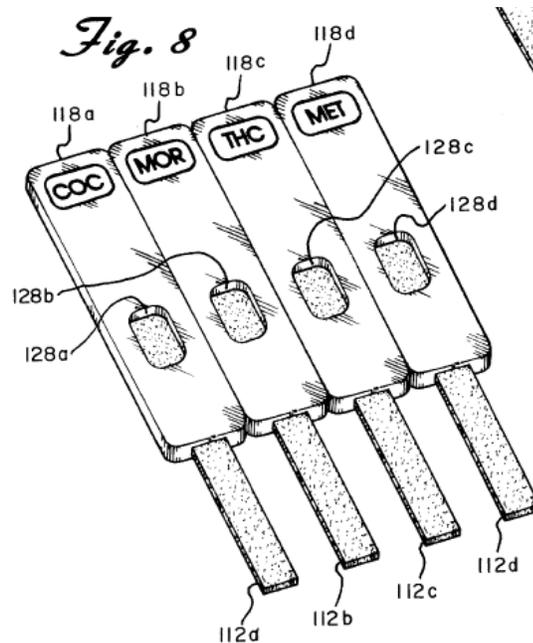
Decl. ¶ 78. Cipkowski teaches a variety of test card configurations. *Id.* ¶¶ 79-81.

E. Sun

Sun is prior art under § 102(e) because it was filed March 20, 1997. Ex.

1007. Sun teaches a multi-test panel with several test strips. *Id.*, Abstract; Decl. ¶¶ 82-84. Sun was not of record during prosecution of the '291 patent.

In one embodiment, shown in Fig. 8, multiple test strips 112a-d are joined together in a multi-test panel for detecting drugs of abuse, with each strip in a separate slot in separate housings 118a-d with windows 128a-d, and at least one open end. Ex. 1007, 4:11-35.



The end of each strip 112a-d extends from housing 118a-d. *Id.* Test results are viewable through windows 128a-d. *Id.*

IX. STATEMENT OF NON-REDUNDANCY

Each Ground raised in this Petition is meaningfully distinct (non-redundant).

The Petition proposes Grounds based on three primary references: DE (Grounds I-III), Cipkowski (Grounds IV-VI), and Sun (Grounds VII-IX). The Grounds are not redundant because each of DE, Cipkowski, and Sun disclose significantly different structures. For example, DE teaches a dipstick device, Cipkowski teaches a test card used with a container, and Sun teaches a panel formed of multiple connected housings where each test strip is in a slot of a separate housing. Each primary reference also discloses certain features in more detail than the others. For example, DE teaches that each window for viewing test and control zones of each test strip is covered with a transparent film for protecting the strips against physical manipulation and destruction. Ex. 1004, 7:11-12, 3:14-21, 5:11-13, Figs. 2-3. Cipkowski clearly teaches a “sample receiving portion” that a POSITA would understand constitutes a sample addition pad for direct contact with the fluid to be analyzed. Ex. 1006, 6:20-25; Decl. ¶ 135. Sun, on the other hand, explicitly teaches viewing any part of a test strip a user might wish to view through a first transparent window that may extend up to the entire length of a housing. Ex. 1007, 3:14-20, 4:23-26.

Within each set of Grounds based upon DE, Cipkowski, or Sun, the secondary references are not vertically redundant. Each secondary reference, for example, provides different motivations to combine. May teaches a dipstick test device with a removable cap. Ex. 1005, Abstract, 4:8-13; 12:9-15, 12:54-62,

13:27-30, Fig. 8. Charm too teaches a capped device, but also explicitly explains that the “protect[ion]” offered by a cap is protection against contamination (Ex. 1008, 3:44-54). Shuler and Eisinger, likewise, both teach a second transparent window to view additional parts of a strip, for describe different reasons for including such a feature: to view additional test or control zones (Eisinger), or to view the end of the assay; an area distinct from a control zone (Shuler).

X. SPECIFIC GROUNDS FOR PETITION

Pursuant to Rule 42.104(b)(4)-(5), the below sections, and the Bohannon Declaration, demonstrate how the prior art discloses each and every limitation of '291 patent claims 1, 2, and 9, and how those claims would have been obvious. Decl. ¶¶ 85-196. Petitioner is unaware of any evidence of secondary considerations of non-obviousness. *Id.* ¶ 86.

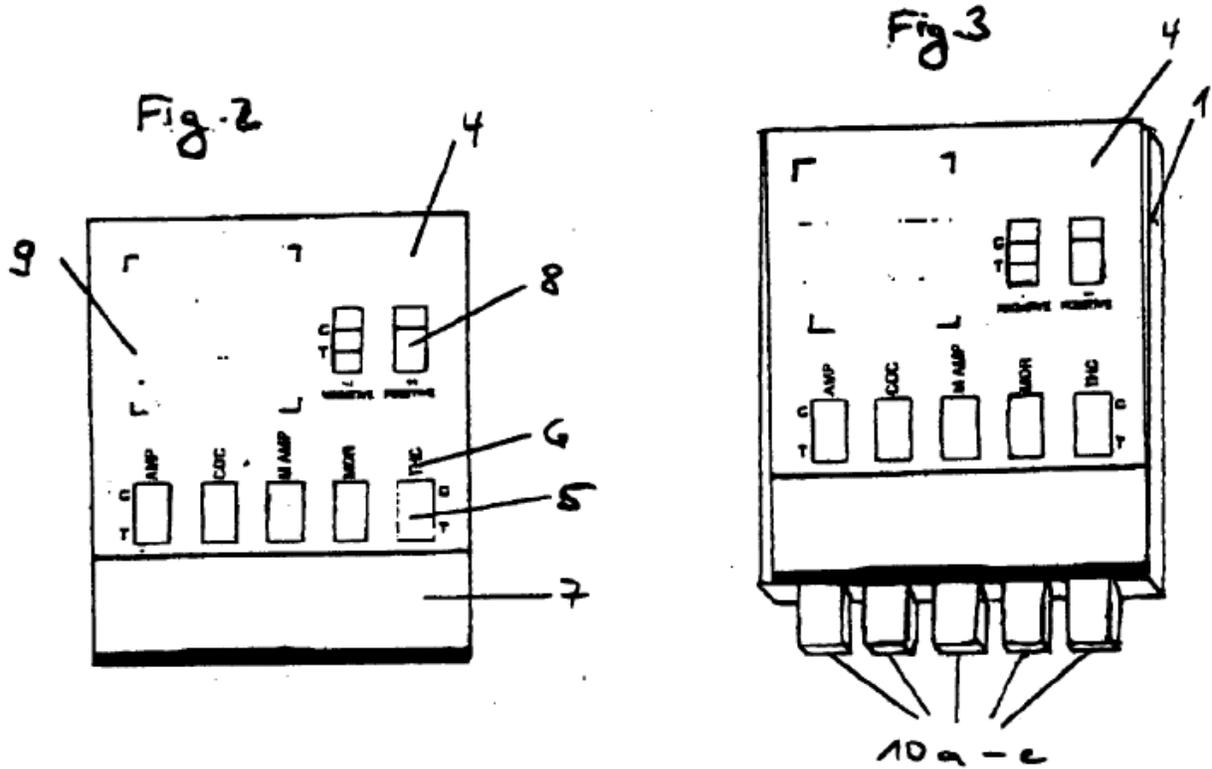
A. Ground I: Claims 1, 2, and 9 Are Obvious Over DE In View of May

1. Claim 1

a) *Preamble: “A device for assaying a fluid...”*

DE teaches a device for assaying a fluid for the presence or absence of different analytes. Specifically, DE discloses that “a plurality of strips may... be placed into [a] holder and then immersed in [a] sample at the same time” to “detect a plurality of substances” in body fluids such as urine. Ex. 1004, 1:10-14, 2:18-25.

Figures 2 and 3 show a line next to the “T” in the “negative” window, but no equivalent line in the “positive” window:



A POSITA would understand that DE discloses a competition assay, where the appearance of the line (a color change) signals a negative result and the absence of a line indicates a positive result, and thus that DE assays for both the presence and absence of analytes. Decl. ¶ 87.

b) “(A) a base having adjacent slots...”

DE teaches a base (“holder 1”) having adjacent slots (“recesses 2”), as shown in Fig. 1:

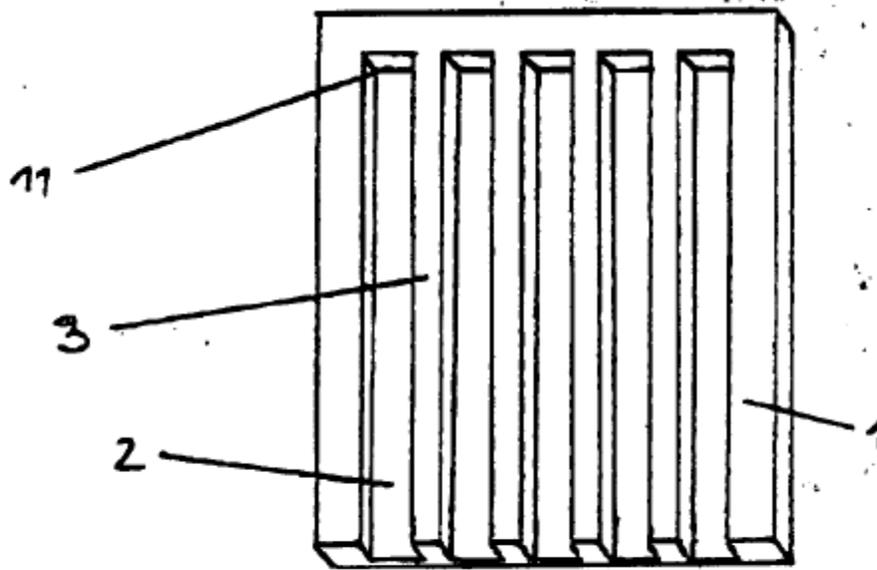


Fig. 1

Ex. 1004, Fig. 1, 4:21-5:7, 6:7-9. The slots are of sufficient length for insertion of part of a test strip therein (“The recesses in the holder are selected in such a way that the end of the test strip... projects out of the holder.”). *Id.*, 4:25-26, 6:15-16. Each slot is defined by a floor (*see* Fig. 1), and raised walls depending upwardly from the floor to separate each adjacent slot from the next (“The recesses are spaced apart from each other by... webs 3.”)(*Id.*, 4:27-5:5), and at least one open end (*see* Fig. 1). Decl. ¶ 88.

c) “(B) a multiplicity of test strips...”

DE teaches a multiplicity of test strips (“one or more test strips can be inserted into matching recesses”). Ex. 1004, 2:18-20. Each “test strip projects out of the holder with the end that is to be immersed in the sample.” *Id.* A POSITA

would understand that the test strips have an upstream end (the end inserted into the holder) and a downstream end (the end that protrudes from the holder for dipping into the sample). Decl. ¶ 89. Each test strip protrudes out of the open end of each slot (recess). Ex. 1004, 2:18-20.

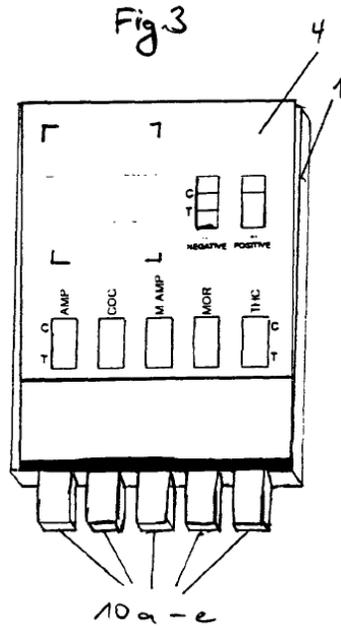


Fig. 3 discloses zones labeled “T” and “C,” which a POSITA would understand to mean “test zone” and “control zone,” respectively. Decl. ¶ 90. Fig. 3 discloses fields “AMP,” “COC,” “M AMP,” “MOR,” and “THC.” A POSITA would understand that each test strip contains a binder specific for a different analyte. *Id.* Indeed, DE discloses testing persons who have “consume[d] a variety of narcotics,” by providing a holder for multiple test strips, to test for “a plurality of substances.” Ex. 1004, 1:21-24, 2:22-25. The protruding freestanding end of each test strip contains a portion that is to be placed in direct contact with the fluid

to be analyzed (“the end of the test strip, which has to be immersed in the sample, projects out of the holder”). Ex. 1004, 4:25-26.

A POSITA would understand that this test strip of DE contains a sample addition pad—*i.e.*, the portion of the test strip that contacts the sample. Decl. ¶ 90. Such sample application pads were conventional. *Id.* ¶ 92. Indeed, the ‘291 patent at 5:16-19 describes the purported invention’s test strips as “conventional in form,” and Fig. 2 depicts such conventional test strips with sample addition pads (shaded areas at the end of each strip).

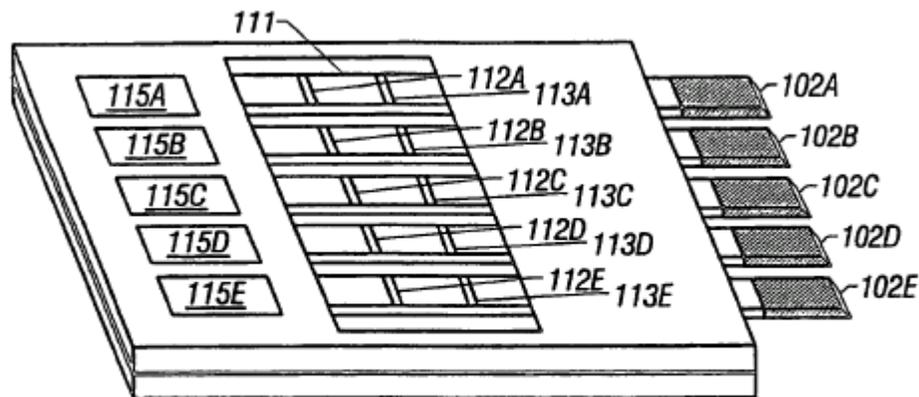


FIG. 2

Ex. 1001, Fig. 2. Thus, DE discloses limitation (B).

Furthermore, sample addition pads were known in the art by July 14, 1998. Decl. ¶ 92. May – which is incorporated by reference into the ‘291 patent – discloses “a porous receiving member to which the liquid sample can be applied and from which the sample can permeate into the porous solid phase material.” Ex. 1005, 3:56-65, 12:20-27. To the extent DE does not disclose a sample addition

pad, a POSITA would be motivated to add May's porous receiving member to efficiently absorb a liquid sample and transport the analyte into the test strip in the housing. Decl. ¶ 92. Success would be expected because May's sample addition pad would fit onto DE's test strips and function as intended. *Id.* This change would simply involve adding one known component (May's sample addition pad) to another (DE's strips). *Id.*; *KSR International Co. v. Teleflex Inc.* ("KSR"), 550 U.S. 398, 417 (2007); MPEP § 2141(I). Thus, limitation (B) is disclosed by DE and/or DE and May. Decl. ¶¶ 89-93.

d) “(C) a cover... has a first transparent window... through which the test zone and the control zone... can be viewed...”

DE teaches a cover (“cover film 4”/ “adhesive film (4)”) attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of the base. Ex. 1004, Figs. 1-2, 5:9-13, 5:19-20, 7:5-6 (the “holder (1) can be covered with a one-sided adhesive film (4)”). For example, whereas Figure 1 shows an uncovered plate with recesses 2 separated by raised webs 3, Figure 3 shows the plate covered by adhesive film. Decl. ¶ 94. The cover retains the test strips within the slots (“adhesive film (4) is used to fix the test strips (10) on the holder (1)”). Ex. 1004, Figs. 1-2, 5:9-11, 7:8-9.

As discussed in Section VI, “a first transparent window” should be construed as “one or more first transparent windows.” DE discloses that “a film

may be “glued... over the holder” and “the adhesive film (4) is transparent at least in the region (5) of the detection fields of the strips (10).” Ex. 1004, 7:11-12, 3:14-21. DE also refers to the film as a “cover film,” stating that “[t]he cover film has transparent windows 5 in the region of the indicator fields of the test strips.” Ex. 1004, 5:11-12, Figs. 2-3. A POSITA would understand that the disclosed transparent windows are a feature of the film itself; *i.e.*, that the transparent windows are sealed film rather than open spaces. Decl. ¶ 95. Moreover, the adhesive/cover film is described as “protect[ing]” the detection fields “against physical manipulation and destruction.” Ex. 1004, 3:19-21, 5:12-13. A POSITA would understand that transparent film windows reduce the risk of tampering because manipulation or destruction of the test strip would likely involve manipulation or destruction of the film windows, which may be easier to detect. Decl. ¶ 96.

As shown in Figs. 2-3, DE discloses a parallel row of transparent windows, for viewing the test (“T”) and control (“C”) zones of each test strip. *Id.* ¶ 97. A POSITA would understand that DE discloses that the cover has a first transparent window formed therein through which the test and control zone of each of the test strips can be viewed. *Id.* ¶¶ 94-97.

e) “(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.”

As described above, on appeal, the only limitation of Claim 1 Applicant identified as missing from DE was the cap limitation. Although DE does not expressly teach a cap, caps were known in the art by July 14, 1998. *See* Section VI(A), *supra*; Decl. ¶ 98.

May teaches a cap 503 that encloses the protruding end of a test strip (porous member 506, which extends beyond end 505 of portion 502 of the housing 500), as depicted in Figure 8:

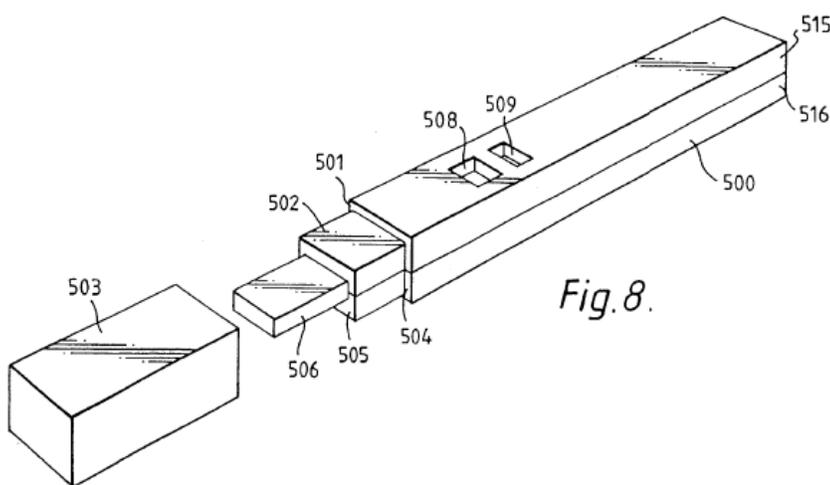


Fig. 8.

Ex. 1005, Fig. 8, 12:12-15; *see also id.*, 4:8-13 (“[T]he housing [has] a removable cap or shroud which can protect the protruding porous receiving member during storage before use ... [T]he cap or shroud can be replaced ... after sample application, while the assay procedure is being performed.”); *id.*, 12:54-62.

May also discloses two or more strips arranged in parallel for simultaneously testing different samples or reagents. Ex. 1005, Abstract, 6:26-39. A POSITA would understand May as disclosing a cap enclosing protruding ends of multiple test strips. Decl. ¶ 99. May also teaches that the cap is removably attached to the open end of the base (“In operation, the protective cap 503 is removed from the holder and member 506 is exposed to a liquid sample” after which “the cap 503 can be replaced”). Ex. 1005, 12:54-62, 13:27-30.

A POSITA would have been motivated to combine DE and May’s teachings. Decl. ¶ 101. Both references relate to devices for testing analytes via multiple test strips protruding from a housing and test for the same types of substances (*e.g.*, drug, diabetes, or pregnancy tests). Ex. 1004, 1:23-24, 2:18-20, Fig. 3; Ex. 1005, Abstract, Fig. 8, 1:36-43, 6:26-39, 9:19-37. A POSITA would naturally consider enhancing DE’s test strip holder by adding May’s cap to better protect the strips. Decl. ¶ 101. As May teaches, a cap can “protect the protruding porous receiving member” during storage. Ex. 1005, 4:9-12.

A cap would reduce the risk of damage, alteration, or tampering. *Id.* ¶ 102. Success would be expected because a cap like May’s could be readily configured to fit over and protect DE’s strips. *Id.* Further, there would have been an expectation of success in combining the teachings of DE and May because May teaches that “the general shape of the housing and cap, both in terms of their

length, cross-section and other physical features, can be the subject of considerable variation.” Ex. 1005, 13:38-41.

Combining those references would have involved the predictable use of known elements (May’s cap, and DE’s test strip holder) according to their established functions (protecting test strips, and assaying for analytes, respectively). Decl. ¶ 103; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

An assay device having a cap that removably covers test strips, for better protection, would have been an obvious matter of design choice that would have been fast and inexpensive to implement. Decl. ¶ 104; *In re Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975)(“manner [of making] electrical contract... would be an obvious matter of design choice.”); *Rexnord Indust., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013)(“[claimed] dimension [of space between modules in a conveyor belt is] a design choice.”).

Thus, DE in view of May renders Claim 1 obvious. *Id.* ¶¶ 87-105.

2. Claim 2: “...a second transparent window formed within the cover through which the test strips can be viewed.”

DE does not expressly disclose a second transparent window as claimed. May, however, discloses using more than one window to view the test strip(s) contained within the cover. First, May discloses at least two windows – apertures 508 and 509, in the “[u]pper face 507 of housing 500.” Ex. 1005, 12:17-18; *see also id.*, 21:20-22. A user “can ascertain whether the assay has been completed by

observing the control zone through aperture 509, and can ascertain the result of the assay by observing the second zone through aperture 508.” Ex. 1005, 12:62-67; *see also id.*, 12:47-53, 13:27-30. “[A]pertures 508 and 509 [may have] transparent inserts [to] insure greater security against ingress of extraneous moisture.” Ex. 1005, 13:11-14. Transparent windows would also protect against tampering, a common challenge in drug testing. Decl. ¶ 106.

Second, May also discloses testing multiple analytes in one strip. Ex. 1005, 9:30-10:44. May discloses that determining “the presence (if any) of more than one analyte in [a] sample can have significant clinical utility.” *Id.*, 9:31-45. For example, multi-analyte tests could “measure two steroids simultaneously, e.g. E-3G and P-3-G.” *Id.*, 9:37-39. May discloses that a ratio of two different apolipoproteins in the same sample could be determined by using two different zones and analyzing the “visible signal” in each zone. *Id.*, 9:31-10:17. A POSITA would understand that such multi-analyte assays require multiple test lines on a single strip. Decl. ¶ 108. A POSITA would have been motivated to provide a window for each test zone, to enable individual observation of each test result, and a POSITA could have easily implemented this configuration using one or more additional transparent windows.

In addition, May discloses that two or more separate strips may be arranged in parallel within the casing for simultaneously testing different samples or

reagents. Ex. 1005, Abstract, 6:26-39. And, May discloses flexibility in designing the housings for the strips: “[T]he general shape of the housing and cap, both in terms of their length, cross-section and other physical features, can be the subject of considerable variation.” *Id.*, 13:38-41.

May’s disclosures of a housing having two transparent windows to view different portions of a test strip, with multiple test strips in such housings, where each test strip could be used to provide test results for more than one analyte, teach a POSITA to use a housing with multiple transparent windows, each for viewing a different test result portion of the test strips. Decl. ¶ 110. A POSITA would have been motivated to provide such additional windows to clearly show test results. *Id.* Adding a second transparent window formed within the cover through which the test strips can be viewed would have been easy for a POSITA to implement. *Id.*

As discussed above (Claim 1), a POSITA would have been motivated to combine DE and May. Decl. ¶¶ 101-102. A POSITA would have further understood that the benefits of testing for multiple analytes on a single strip, such as those disclosed in May, would also have been desirable in DE’s assay device. *Id.* ¶ 111. May discloses testing various analytes, including “drugs.” Ex. 1005, 9:21-23. DE also discloses the desirability of testing for “a variety of narcotics.” Ex. 1004, 1:23-24. Including more than one assay on a strip could reduce the number of strips needed in a single test unit. *Id.* And if there were more than one

test line, those test lines would have to be viewable through the casing so the results could be easily read. *Id.* A POSITA would have been motivated to apply May's teaching of more than two windows (to observe test strips with multiple test lines, and a control line) to DE's assay device. *Id.* Combining May and DE would have involved a simple substitution of known elements (May's multiple first transparent windows for viewing May's test strips each with multiple test zones) for other known elements (DE's first transparent window and DE's strips). Decl. ¶ 111; *KSR*, 550 U.S. at 417; MPEP § 2141(I). Adding a strip with another test zone and another transparent window for viewing each zone of each strip to DE's holder would have been a straightforward design change, that would have been fast and inexpensive to implement. *Id.* Thus, DE and May render claim 2 obvious. *Id.*

3. **Claim 9: “A method for detecting a multiplicity of analytes which comprises removing the cap from the device of claim 1 and inserting the protruding ends of the test strips into a sample to be analyzed and observing the effect of the sample on the test and control zones of the test strips contained in the device.”**

As noted above in this Ground (Claim 1), DE in view of May renders claim 1 obvious. Thus, it further renders obvious the method for detecting a multiplicity of analytes via the device of claim 1. Decl. ¶ 112; Ex. 1004, 1:10-14, 2:22-25, 3:26-4:5, 6:7-9, Figs. 2-3.

As discussed above (Claim 1), it would have been obvious to combine DE's device with May's cap. Similarly, it would have been obvious to remove May's

cap when following DE's detection method. Decl. ¶ 113. May teaches that "protective cap 503 is removed from the holder and member 506 is exposed to a liquid sample," after which the cap "can be replaced." Ex. 1005, 12:54-62; *see also id.*, 4:9-13. Cap removal is necessary for successful testing; *i.e.*, strips must be uncapped during insertion, to make contact with the samples. Decl. ¶ 113. A POSITA would have combined DE's detection method with May's cap removal to collect a sample with an undamaged test strip, and this combination would have been fast and inexpensive to implement, rendering Claim 9 obvious. *Id.*

B. Ground II: Claims 1 and 9 Are Obvious Over DE in View of Charm and May '871

1. Claim 1

As discussed above (Ground I), DE discloses Claim 1's preamble and limitations (A), (B), and (C).

In addition, Charm teaches a device wherein each test strip has a sample application pad (pad 32) that is "liquid-sample absorbent" and "extend[s] generally to about or slightly beyond the plane of the open application end" of each strip. *Id.*, 5:12-17, 5:32-37. Sample is applied directly to pad 32 (including by dipping) and is absorbed and laterally flows through test strip 28. *Id.*, 5:42-45, 7:5-7, 8:62-65.

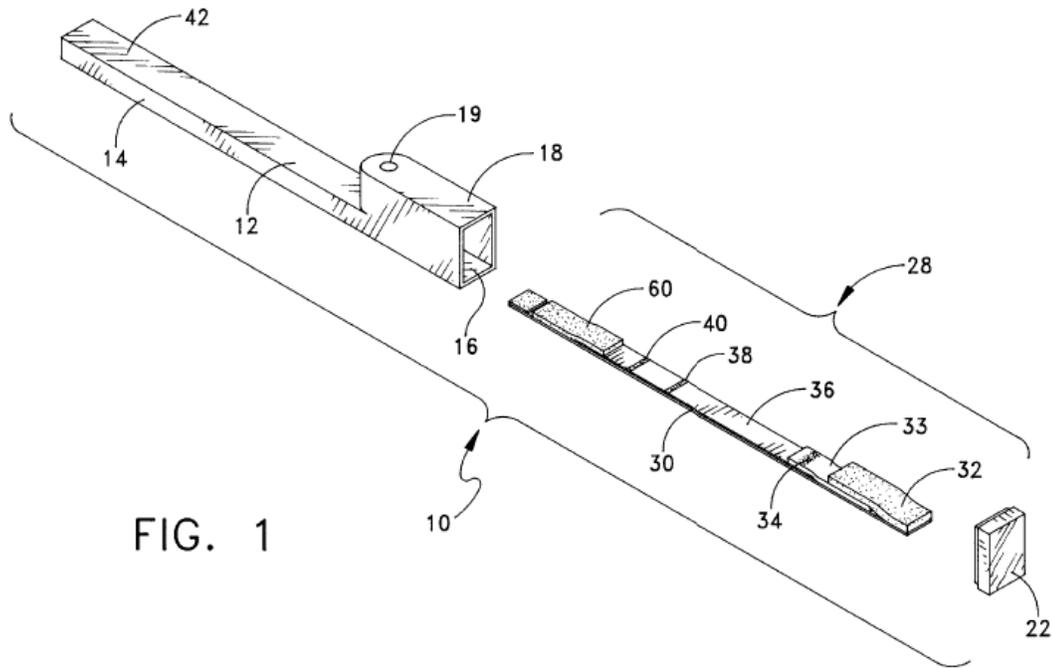


FIG. 1

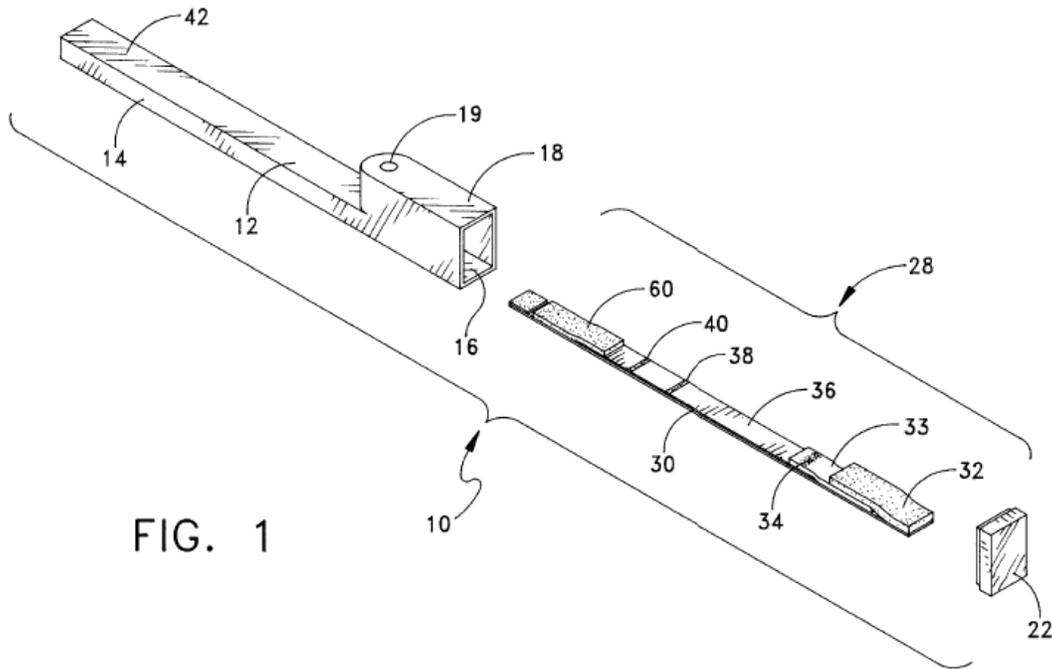
Id., Fig. 1. To the extent DE does not itself disclose a sample addition pad, DE in view of Charm does. Decl. ¶ 115. A POSITA would have been motivated to combine DE and Charm's teachings. Both references relate to devices for testing analytes in urine via test strips in a slot-shaped housing. *Id.*; Ex. 1004, 1:10-11, 2:18-20, Fig. 3; Ex. 1008, Abstract, 4:6-12.

A POSITA would understand that a sample addition pad provides the benefit of controlled delivery of sample to the test strips. Decl. ¶ 116. A POSITA would naturally consider enhancing DE's test strips by adding Charm's sample addition pad to achieve the same benefit, and would expect success because Charm's sample addition pad could readily be fitted onto and would perform the same function if attached to DE's strips. *Id.*

Combining DE and Charm would have involved the predictable use of prior art elements (Charm's sample addition pad, and DE's test strips) according to their established functions (protecting test strips, and assaying for analytes). Decl. ¶ 117; *KSR*, 550 U.S. at 417; MPEP § 2141(I). Indeed, both in the '291 patent and during prosecution, the Applicant acknowledged that test strip construction was conventional. Ex. 1002, 98:1-2;101:26-28; Ex. 1001, 5:16-19, Fig. 2. Charm is an example of a conventional test strip used for the exact same purpose as DE. Decl. ¶ 117. Combining DE and Charm is an obvious design choice that would have been fast and inexpensive to implement. *Id.*; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust., LLC*, 705 F.3d at 1356.

Regarding limitation (D), as discussed above, on appeal the only feature of Claim 1 Applicant identified as missing from DE was the cap. Caps were known in the art by July 14, 1998. *See* Section V(A), *supra*; Decl. ¶¶ 39-42. Charm teaches a cap for covering the end of the strip to be dipped into the sample. Charm states that prior art (May '871, which is in the same family as May) describes "a protective, removable cap to protect and enclose the application end of [a] casing." Ex. 1008, 1:17-23; Decl. ¶ 118. In May '871, the removable cap that is referred to by Charm covers the protruding end of the test strip and sample pad. Decl. ¶ 118; Ex. 1011, Abstract, Fig. 8. Moreover, Charm itself discloses a casing with "one or more test strips" that may employ a "protective cap at the application end, to

protect the test device from contamination prior to use and to protect the test device after contact with the liquid sample and... to protect against cross-contamination.” Ex. 1008, 3:44-54, 4:7-12, 5:45-46. Fig. 1 of Charm shows “protective... cap 22 adapted to fit over the open application end 16.” *Id.*, 5:4-7, 5:32-37.



Id., Fig. 1. “In operation, [the] cap [is] removed and the application end contacted with a liquid to be tested, such as by immersion.” *Id.*, 4:21-23, 3:49-54.

As discussed immediately above, a POSITA would have been motivated to combine DE and Charm’s teachings. *Id.* ¶ 120; Ex. 1004, 1:10-11, 2:18-20, Fig. 3; Ex. 1008, Abstract, 4:6-12. A POSITA would naturally consider enhancing DE’s test strip holder disclosed by adding the cap of May ’871 as disclosed in Charm

itself, or by using a cap like Charm's to better protect the strips. Decl. ¶ 120.

Charm recognized that there already existed in the art a motivation to provide a cap, as disclosed in May '871, for protective purposes. Charm teaches the above benefits of caps, and also confirms that caps may be used in multi-strip devices.

Id. A POSITA would be motivated to use a similar cap with the DE test card and would expect success because such a cap would be compatible with DE's device.

Id. Moreover, a POSITA would understand that capping DE's device would provide the protective benefits of reduced risk of damage, alteration, or tampering.

Id.

Combining DE and Charm would have involved the predictable use of prior art elements (the caps disclosed in May '871 and Charm, and DE's holder with test strips) according to their established functions (protecting test strips, and assaying for analytes, respectively). Decl. ¶ 121; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

This obvious design choice would have been fast and inexpensive to implement.

Id.; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust., LLC*, 705 F.3d at 1356.

Thus, DE in view of Charm and May '871 renders Claim 1 obvious. *Id.* ¶¶ 114-121.

2. Claim 9

As discussed above (Ground I), DE discloses every element of Claim 9 except that DE does not expressly teach a cap. Decl. ¶¶ 112-113; Ex. 1004, 2:22-

25, 6:7-9, 1:10-14, 3:26-4:5, Figs. 2-3. As discussed immediately above in this Ground, it would have been obvious to combine DE's device with Charm's teachings concerning caps. Similarly, Charm discloses removing a cap (Ex. 1008, 3:49-54, 4:21-23) and it would have been obvious to do so when following DE's detection method because successful testing requires cap removal. Decl. ¶ 122. A POSITA would have combined DE's detection method with Charm's cap removal to collect a sample with an undamaged test strip, and this combination would have been fast and inexpensive to implement, rendering Claim 9 obvious. *Id.*

C. Ground III: Claim 2 Is Obvious Over DE In View of May, Shuler, and Eisinger

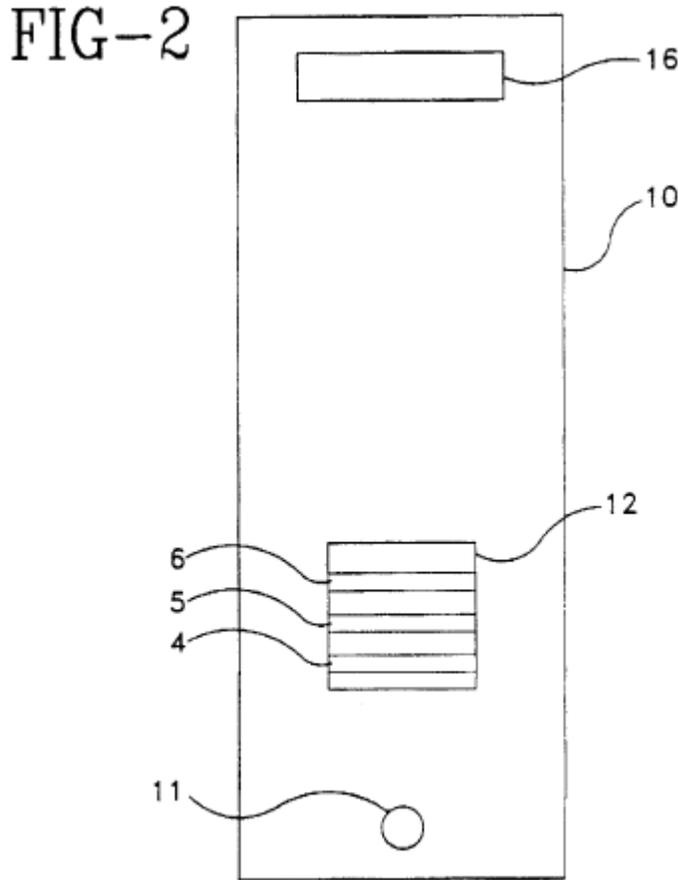
As discussed above (Ground I), DE in view of May renders Claim 1 obvious. Decl. ¶¶ 87-105. To the extent DE in view of May does not disclose Claim 2's second transparent window, DE in view of May, Shuler, and Eisinger would. *Id.* ¶¶ 123-129. Schuler and Eisinger provide additional motivation for a second transparent window.⁷ *Id.*

Shuler teaches a lateral flow device for detecting, *e.g.*, drugs of abuse, with a window 12 for viewing test and control zones, and a second window 16 at the distal end of a housing for viewing the "end of the assay"—*i.e.*, to confirm that the

⁷ Shuler is prior art under § 102(e) because it was filed Sept. 25, 1996. Ex. 1010.

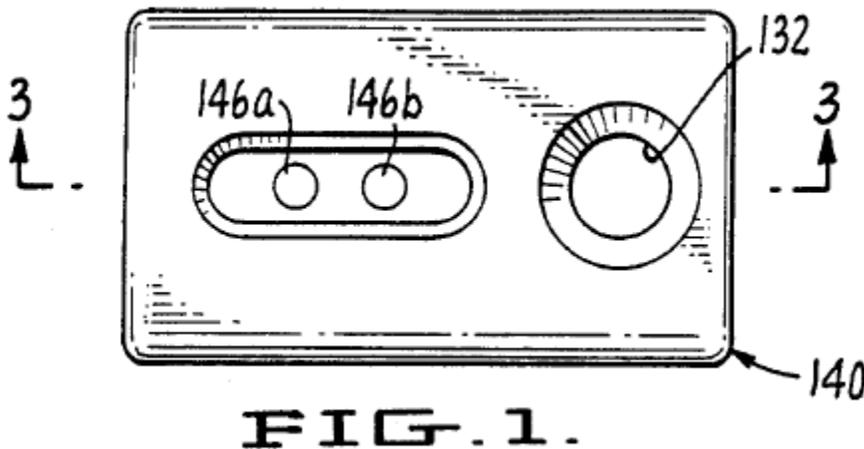
Eisinger is prior art under § 102(b) because it issued July 24, 1990. Ex. 1009.

assay has finished. *Id.* ¶ 124; Ex. 1010, Abstract, Figs. 1, 2, 1:6-19, 2:37-44, 3:3-19, 8:60-65. Shuler thus discloses the additional limitations of Claim 2. Decl. ¶ 124.



Id., Fig. 2. Eisinger—incorporated by reference into the '291 patent (Ex. 1001, 6:1-4)— teaches a device with a “porous membrane” having “more than one indicator zone.” The multiple indicator zones can be used for “detect[ing] different analytes,” in addition to “control and reference zones.” Ex. 1009, 5:12-18; *see also id.*, 11:45-48, 16:60-63, 17:51-53, 19:30-34. In one embodiment, “[o]ne or more ‘indicator’ apertures 146, e.g., 146a and 146b ... [permit] viewing of the

‘indicator’ zone(s).” *Id.*, 12:23-26. “These apertures may be formed of or covered with thin, clear or translucent coverings” for signal detection. *Id.*, 12:26-31. Fig. 1 of Eisinger shows two different transparent windows on a single strip.



For the reasons stated above (Ground 1, Claim 2), a POSITA would already know from May that there were various reasons to provide a second transparent window to the casing, as claimed in claim 2, and such a window could allow viewing of any part of a test strip that a user might desire to view. Decl. ¶ 127.

Shuler’s first and second windows, and Eisinger and May’s multiple windows, would motivate a POSITA to include a second transparent window as in claim 2 to view the far end of the test strip to confirm the completion of the assay, or use separate viewing windows for different analytes on each strip. Decl. ¶ 128. Further, success would be expected because DE already discloses windows to view test strips, so adding more windows would be straightforward, and Shuler’s or Eisinger’s test strips would be compatible with DE’s and May’s devices because

they were designed to house similar strips. *Id.* ¶ 129. As discussed above, combining DE and May would involve a simple substitution of known components. *Id.* So would using Shuler’s or Eisinger’s windows and strips. *Id.* Thus, DE in view of May, Shuler, and Eisinger renders claim 2 obvious. *Id.* ¶¶ 123-129.

D. Ground IV: Claims 1, 2 and 9 Are Obvious Over Cipkowski In View of May

1. Claim 1

a) *Preamble: “A device for assaying a fluid...”*

Cipkowski teaches a device for assaying a fluid for the presence or absence of different analytes (a “multiple drug test card having a plurality of immunoassay test strips thereon with visual endpoints to indicate presence or absence of a particular drug.”). Ex. 1006, Abstract, *see also id.*, 3:55-59; Decl. ¶ 130.

b) “(A) a base having adjacent slots...”

Cipkowski teaches a base (test card “preferably formed of two plys 34 and 35...”). Ex. 1006, Figs. 3, 7, and 9, 4:7-10, 4:66-5:2. The base has adjacent slots therein of sufficient length for insertion of part of a test strip therein (“ply 35 is formed within a plurality of dye [sic] cut slots 37 which are shaped and sized to receive each of the test strips” and in one embodiment, “test strips 26-30 project beyond the end 43.”). *Id.*, 4:10-14, 5:4-7. Each slot is defined by a floor (defined

by an adhered face of the second ply), and raised walls depending upwardly from the floor (defined by interior walls of the first ply's slots), as shown in Figure 7:

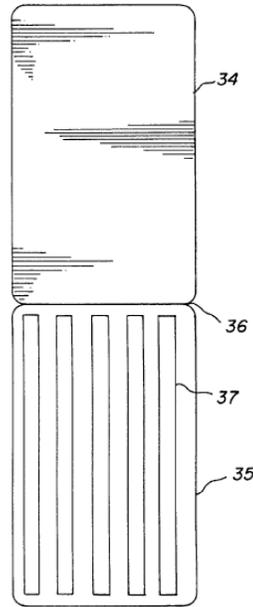


FIG. 7

Decl. ¶ 131. In the Figure 9 embodiment, each slot has at least one open end (“test strips 26-30 project beyond the end 43.”). Ex. 1006, 5:4-7.

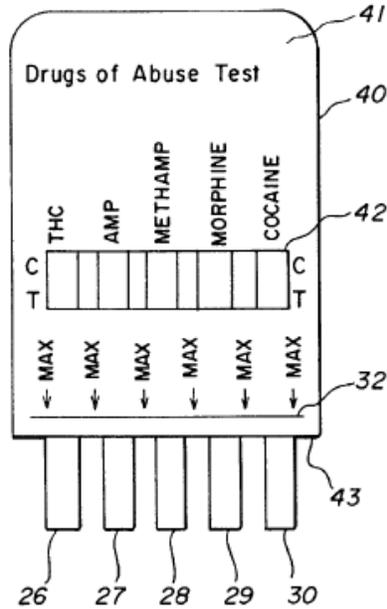


FIG. 9

Id., Fig. 9; Decl. ¶ 132.

c) **“(B) a multiplicity of test strips...”**

Cipkowski teaches a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip protrudes out of the open end of each slot (“test strips 26-30 project beyond the end 43 of the shortened test card”).

Ex. 1006, 4:66-5:7, Fig. 9; *see also id.*, 4:14-17; Decl. ¶ 133. Each test strip has a test zone and a control zone (“[T]hird ply 41 is provided with an opening 42 through which the test and control lines may be seen.”). Ex. 1006, 4:66-5:7; *see also id.*, Fig. 9 (showing test zone “T” and control zone “C”).

Cipkowski discloses that the test card has multiple test strips and “each strip is responsive or indicative to a particular drug of abuse.” Ex. 1006, 5:51-54, 3:61-

67. Thus, each test strip contains a binder specific for a different analyte. Decl. ¶ 134.

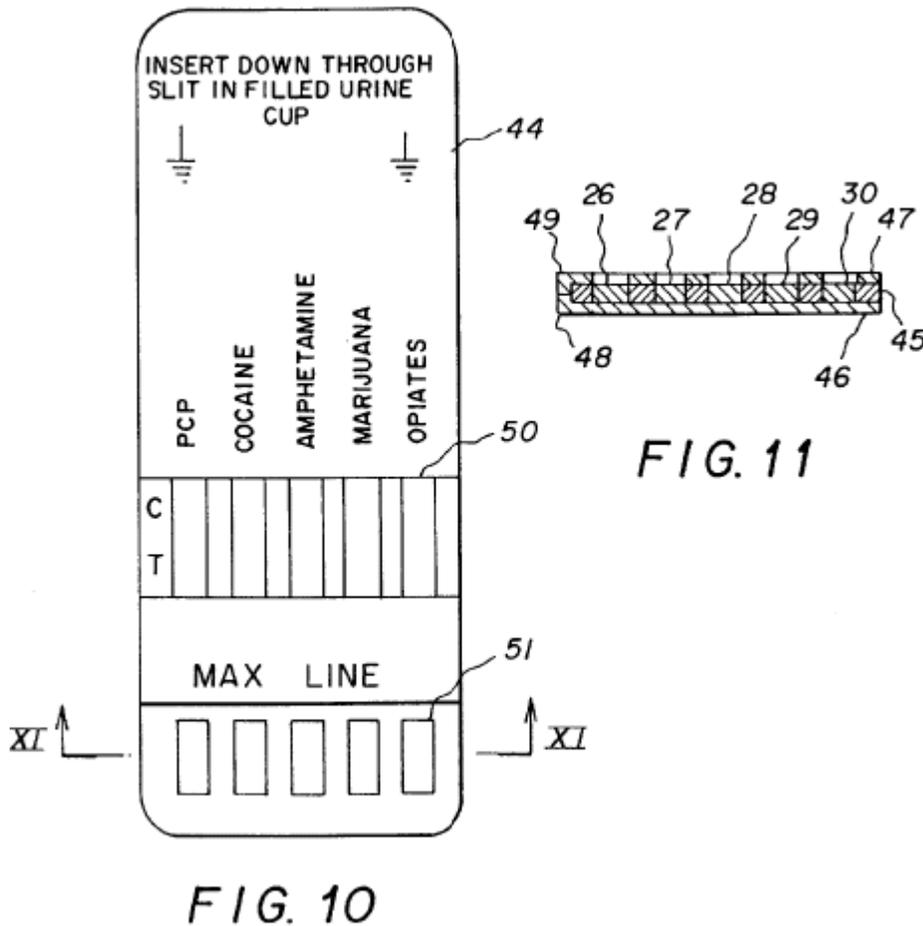
Cipkowski also discloses that “[t]he test card is insertable through the slit so as to have one end immersed in the urine sample to a predetermined depth whereby the visual results of each test strip can be seen through the transparent wall of the container without removing the test card from the container so as to indicate the presence or absence of a particular drug of abuse.” Ex. 1006, 2:20-27; *see also id.*, 4:22-27, 5:7-8, 5:30-38. Each strip has “a bottom end defining a sample receiving portion and a test portion ... wherein, in use, the presence or absence of the selected drug of abuse ... is visually indicated...” Ex. 1006, 6:20-25. A POSITA would understand that Cipkowski’s “sample receiving portion” constitutes a sample addition pad for direct contact with the fluid to be analyzed. Decl. ¶ 135.

d) “(C) a cover... has a first transparent window... through which the test zone and the control zone... can be viewed...”

In the embodiment of Fig. 9, Cipkowski teaches a cover (third ply 41). Ex. 1006, 4:66-5:2 (Figure 9 embodiment is “constructed with two plys” plus “a third ply 41 which covers the test strips.”). Each strip “is adhered to the surface of the first portion 34 upon which the second portion 35 has been folded.” *Id.*, 4:14-17. A POSITA would understand that the third ply is attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of

the base—*i.e.*, the third ply is attached to the surface of the first ply 34, which defines the slots retaining the test strips. Decl. ¶ 136; Ex. 1006, 4:14-17, 4:66-5:7. And “third ply 41 is provided with an opening 42 through which the test and control lines may be seen.” Ex. 1006, 5:2-4.

Alternatively, in the embodiment of Figs. 10-11, Cipkowski discloses that test card 44 comprises central ply 45 sandwiched between bottom ply 46, and top ply 47, which has a plurality of test windows 50 through which test results can be seen. *Id.*, 5:12-22, 5:28-29, 6:52-61; Decl. ¶ 137.



Ex. 1006, Figs. 10, 11. Central ply 45 defines slots with upstanding walls extending from the base defined by the face of the second ply. *Id.*, 5:12-19, 6:52-61, Fig. 11. This modification discloses a cover (top ply 47) attached to the upwardmost surface of each raised wall of the slots of the base, wherein the cover retains the test strips within the slots and has a first transparent window (test windows 50) through which the test and control (“T” and “C”) zone of each of the strips can be viewed. Decl. ¶ 138. Although there is no express disclosure that the test strips could project through an open end of the base beyond the end of Figure 10’s test card, a POSITA would have understood that configuring Figure 10’s central ply embodiment with Figure 9’s projecting test strips, so that the cover extends to the open end of the base, requires no more than substituting one known test strip configuration for another. *Id.*; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

Although Cipkowski’s embodiments do not expressly disclose that the openings/windows are transparent, covers having transparent windows were known by July 14, 1998. Decl. ¶ 139. For example, May discloses a cover (upper face 507) that incorporates windows (apertures 508 and 509) for viewing test and control zones on each strip, and that the windows may be transparent (“[A]pertures 508 and 509 [may have] transparent inserts [to] insure greater security against ingress of extraneous moisture.”). Ex. 1005, 12:17-18, 12:62-67, 13:11-14, 21:20-22, 12:47-53, 13:27-30. May also discloses that “porous member 506 is firmly

retained in the housing,” which is “hollow,” and that the device may contain multiple strips arranged in parallel. *Id.*, 12:20-37, 6:26-39. May thus discloses a cover that retains test strips within slots, and that has a first transparent window through which the test zone and the control zone of each of the test strips can be viewed. Decl. ¶ 139.

A POSITA would have been motivated to combine Cipkowski and May’s teachings to arrive at Claim 1’s limitation (C). Both patents relate to devices for testing analytes via multiple test strips that protrude from a housing, and test for the same types of substances. *Id.* ¶ 140; Ex. 1006, Abstract, 3:55-59, 5:4-7, Fig. 9; Ex. 1005, Abstract, Fig. 8, 1:36-43, 6:26-39, 9:19-37. A POSITA would naturally consider enhancing Cipkowski’s test card device by adding May’s transparent inserts. Decl. ¶ 140. Adding transparent windows to Cipkowski’s test card would provide similar benefits by protecting the strips against manipulation or ingress of moisture. *Id.*; Ex. 1006, Abstract, Fig. 9, 5:4-7; Ex. 1005, Abstract, Fig. 8, 1:36-43, 9:19-37. Success would be expected because these configurations perform the same function of providing windows for viewing test strips, so the combination would result in the claimed first transparent window. Decl. ¶ 140. This combination would have involved a simple substitution of one known element (May’s transparent window) for another (Cipkowski’s windows/openings). *Id.* ¶ 141; *KSR*, 550 U.S. at 417; MPEP § 2141(I). This obvious design choice would

have been fast and inexpensive to implement. Decl. ¶ 141; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust.*, 705 F.3d at 1356. Thus, Cipkowski in view of May renders Claim 1's limitation (C) obvious. *Id.* ¶ 141.

e) “(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.”

Cipkowski discloses a dip-strip embodiment (Fig. 9) that includes suspending the dip-strip into a urine sample in a cup, using a slotted holder within the cup. Ex. 1006, 2:11-26, Fig. 9. Cipkowski also teaches removing the test card, and then sealing the cup for shipment and further analysis. *Id.*, 2:31-34. A POSITA would understand, in the context of tests for drugs of abuse, that preserving evidence of the original test is important. Decl. ¶ 142. A POSITA would be motivated to provide a cap for the dip-strip embodiment, applying May's teaching of preserving and protecting protruding ends of test strips and preventing contamination. *Id.*; Ex. 1005, 4:9-13, 13:11-14.

Caps protecting protruding ends of test strips were known in the art by July 14, 1998. Decl. ¶¶ 39-42, 139. As discussed above (Ground I, Claim 1, limitation (D)), May discloses a cap. As discussed above in this Ground (Claim 1, limitation (C)), a POSITA would have been motivated to combine Cipkowski and May's teachings. *Id.* ¶ 144. A POSITA would naturally consider enhancing Cipkowski's device by applying May's cap to better protect Cipkowski's strips before and after testing inside Cipkowski's cup-like container. *Id.*

As May discloses, a cap can “protect the protruding porous receiving member” during storage. Ex. 1005, 4:9-12. Such protection would reduce the risk of damaging or altering the test strips, such as through tampering. Decl. ¶ 145. Success would be expected because both references disclose similar protruding strip configurations, so May’s cap could easily be fitted over and protect Cipkowski’s strips and test card. *Id.*

Combining references would have involved the predictable use of known elements (May’s cap, and Cipkowski’s card with test strips) according to their established functions (protecting test strips, and assaying for analytes) that were well known in the art. *Id.* ¶ 146; *KSR*, 550 U.S. at 417; MPEP § 2141(I). This combination would have been an obvious matter of design choice that would have been fast and inexpensive to implement. *Id.*; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust.*, 705 F.3d at 1356.

Thus, Cipkowski in view of May renders Claim 1 obvious. *Id.* ¶ 147.

2. Claim 2

As discussed above in this Ground (Claim 1, limitation (C)), Cipkowski discloses openings/windows in the cover through which the control and test zones of test strips can be viewed. Ex. 1006, 5:2-4, 5:12-22, 5:28-29, 6:52-61. May further teaches a transparent material forming the window for viewing test strips.

Ex. 1005, 13:11-14. Cipkowski and May thus render obvious the claimed first transparent window. Decl. ¶ 148; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

Claim 2 further requires a “second transparent window” formed in the cover through which the test strips can be viewed. No specific purpose for such a window, other than viewing test strips, is claimed in Claim 2. Using one or more transparent windows in a cover to provide an additional view of the test strip was known in the art by July 14, 1998. Decl. ¶ 149. As discussed above (Ground I, Claim 2), a POSITA would have understood that May discloses the claimed second transparent window to see separate results for each of multiple analytes tested on each strip. *Id.* As discussed above in this Ground (Claim 1, limitation (C)), a POSITA would have been motivated to combine Cipkowski and May. *Id.* A POSITA would have understood that the benefits of testing for multiple analytes on a single strip taught in May would have been desirable in Cipkowski’s device. *Id.* A POSITA would have been motivated to apply May’s teaching of having more than two windows (to observe multiple test lines, and a control line) to Cipkowski’s device. *Id.* Combining May and Cipkowski would have involved a simple addition of known elements (May’s multiple first transparent windows for viewing May’s test strips, each with multiple test zones) to other known elements (Cipkowski’s first window and test strips); their functions were well known in the art. *Id.*; *KSR*, 550 U.S. at 417; MPEP § 2141(I). Adding one or more second

transparent windows to Cipkowski's device would have been a straightforward design change, that would have been fast and inexpensive to implement. Decl. ¶ 149. Thus, Cipkowski in view of May renders claim 2 obvious. *Id.*

3. **Claim 9**

As noted above in this Ground (Claim 1), Cipkowski in view of May renders obvious the device of claim 1. Thus, it further renders obvious the method for detecting a multiplicity of analytes via the device of claim 1. Decl. ¶ 150.

As discussed above in this Ground (Claim 1, limitation (D)), a POSITA would have been motivated to combine Cipkowski with May and would expect success in creating the claimed cap. *Id.* ¶ 151. Similarly, it would have been obvious to remove May's cap when following Cipkowski's detection method because successful testing requires cap removal. Decl. ¶ 152; Ex. 1005, 12:54-62, 4:9-13. A POSITA would have combined Cipkowski's method with May's cap removal to obtain the benefit of collecting a sample with an undamaged test strip, and this combination would have been fast and inexpensive for a POSITA to implement. *Id.* ¶ 151.

Furthermore, following Cipkowski's and May's explicit teachings, discussed above, after removing the cap, it would have been obvious to insert the protruding test strip ends into a sample to be analyzed and observe the effect of the sample on the test and control zones of the test strips contained in the device. *See* Ground IV

(Claim 1). Those steps are the normal basic functionality of the housing, test card, and test strips described in Cipkowski and May. Decl. ¶ 152. Thus, Cipkowski in view of May renders Claim 9 obvious. *Id.*

E. Ground V: Claims 1 and 9 Are Obvious Over Cipkowski in View of Charm and May '871

1. Claim 1

As discussed above (Ground IV), Cipkowski alone discloses Claim 1's preamble, limitations (A) and (B), and limitation (C)'s requirement of "a cover attached to the upwardmost surface of each raised wall of the slots of the base and extending to the open end of said base, wherein the cover retains the test strips within the slots." Regarding limitation (C)'s requirement of a "first transparent window" in the cover, Charm teaches a device with a "housing cavity 14" with a "bottom surface [having] a lateral-flow test strip 28 adapted to detect the presence of an analyte in a liquid sample." Ex. 1008, 5:10-12, 5:30-37, Fig. 1. Charm's device, which may hold more than one test strip (*Id.*, 4:10-12), has a top cover that may be "fully transparent," "have an aperture," or have "***only a section... [that is] transparent***" –*i.e.*, a transparent window. *Id.*, 3:36-43, 1:45-46 (emphasis added); Decl. ¶ 154. "[T]ransparent cover 42 [permits] visual observation of the reference line 38 and control line 40." *Id.*, 5:30-32. A POSITA would understand Charm as disclosing the claimed cover and first transparent window. Decl. ¶ 154.

A POSITA would have been motivated to combine Cipkowski and Charm's teachings because both patents relate to devices for testing analytes via multiple test strips contained in a housing, and viewing test results from outside the casing. Decl. ¶ 155; Ex. 1006, Abstract, 3:55-59, 5:4-7, Fig. 9; Ex. 1008, Abstract, 4:6-12. A POSITA would naturally consider enhancing Cipkowski's test card by adding Charm's transparent cover, because it would provide benefits such as protecting test strips from damage, manipulation, or ingress of moisture. Decl. ¶ 155. Cipkowski's test strips would benefit similarly from Charm's transparent cover. *Id.* Success would be expected because Cipkowski's apertures/windows and Charm's transparent cover perform the same function of providing one or more transparent windows for viewing test and control lines of test strips contained within the test device. *Id.*

Combining those references would have involved a simple substitution of one known element (Charm's partially or fully transparent cover) to another (Cipkowski's windows/openings). Decl. ¶ 156; *KSR*, 550 U.S. at 417; MPEP § 2141(I). This obvious design choice would have been fast and inexpensive to implement. Decl. ¶ 156; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust.*, 705 F.3d at 1356.

Regarding limitation (D), as discussed above, a POSITA would have been motivated to provide a cap for Cipkowski's dip-strip embodiment. Decl. ¶ 157;

Ex. 1006, 2:11-26, 2:31-34, Fig. 9. As discussed above (Ground II, Claim 1), Charm references the protective cap disclosed in May '871 and itself teaches a protective removable cap. Ex. 1008, 1:15-23, 3:49-54, 4:21-23, 5:32-37.

A POSITA would naturally consider enhancing Cipkowski's device by applying a protective cap as taught in Charm to better protect Cipkowski's strips before and after testing. *Id.* ¶ 158. Success would be expected because it would readily be within the skill of a POSITA to design and implement a cap that would readily fit over the protruding ends of Cipkowski's strips. *Id.*

Combining the references would have involved the predictable use of known elements (the protective cap and windows taught in Charm, and Cipkowski's card with test strips) according to their established functions (protecting test strips, and assaying for analytes), which were well known in the art. *Id.* ¶ 159; *KSR*, 550 U.S. at 417; MPEP § 2141(I). This obvious design choice would have been fast and inexpensive to implement. Decl. ¶ 159; *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust.*, 705 F.3d at 1356.

Thus, Cipkowski in view of Charm and May '871 renders Claim 1 obvious. *Id.* ¶ 159.

2. Claim 9

As discussed immediately above in this Ground, Cipkowski in view of Charm renders obvious claim 1. Thus, it renders obvious the method for detecting a multiplicity of analytes via the device of claim 1. *Id.* ¶ 160.

As discussed above in this Ground (Claim 1, limitation (D)), it would have been obvious to combine a cap as taught in Charm with Cipkowski's device. *Id.* ¶ 161. Charm also discloses cap removal. Ex. 1008, 3:49-54, 4:21-23. It would have been obvious to remove a protective cap when following Cipkowski's detection method. Decl. ¶ 161. Cap removal is necessary for successful testing. *Id.* A POSITA would have combined Cipkowski's method with removal of a protective cap as taught in Charm to obtain the benefit of collecting a sample with an undamaged test strip, and this combination would have been fast and inexpensive for a POSITA to implement. *Id.*

Furthermore, following Cipkowski and Charm's teachings above, after cap removal, it would have been obvious to insert the protruding test strip ends into a sample to be analyzed and observe the effect of the sample on the strips' test and control zones. *Id.* ¶ 162. Those steps are the normal basic functionality of the housing, test card, and test strips of Cipkowski and Charm. *Id.* Thus, Cipkowski in view of Charm renders Claim 9 obvious. *Id.*

F. Ground VI: Claim 2 Is Obvious Over Cipkowski in View of May, Shuler, and Eisinger

As discussed above (Ground IV), Cipkowski in view of May renders Claim 1 obvious. To the extent Cipkowski and May do not disclose Claim 2, Cipkowski in view of May, Shuler, and Eisinger would. Decl. ¶ 163. Shuler and Eisinger provide additional motivations for a second transparent window.

As discussed above (Ground III), Shuler and Eisinger both teach a second transparent window to view additional parts of a strip, for different reasons: to view additional test or control zones, or to view the end of the assay to determine when the assay is complete. *Id.* ¶¶ 124-125.

Success would be expected because Cipkowski already discloses openings/windows to view test strips, so adding more windows would be straightforward, and Shuler's or Eisinger's test strips would be compatible with Cipkowski and May's devices because they were designed to house similar strips. *Id.* ¶ 164. As discussed above, combining Cipkowski and May would have involved a simple substitution of known components. *Id.* Shuler's or Eisinger's aforementioned disclosures would add to the motivation described above to combine Cipkowski and May to view parts of test strips through a second transparent window. *Id.*

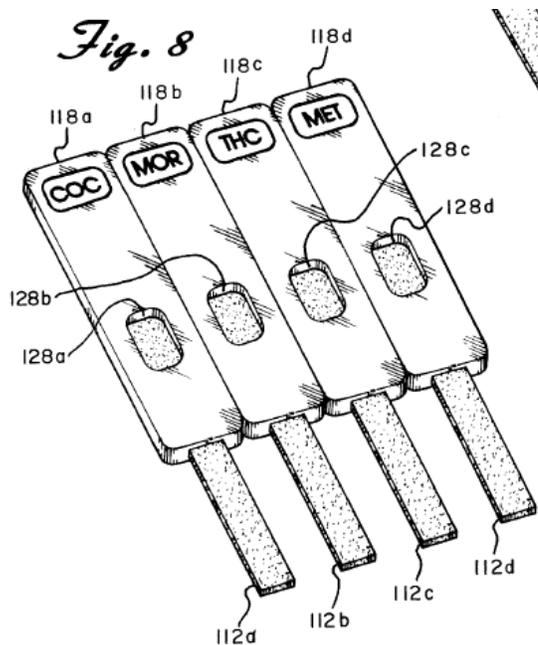
Cipkowski in view of May, Eisinger, and Shuler thus renders claim 2 obvious. *Id.* ¶ 165.

G. Ground VII: Claims 1, 2, and 9 Are Obvious Over Sun in View of May

1. Claim 1

a) *Preamble: “A device for assaying a fluid...”*

Sun teaches a device for assaying a fluid (“analytical test device for analyzing body fluids”) for the presence or absence of different analytes (a “way of testing a bodily fluid sample for various drugs” simultaneously in a “multi-test panel structure”). Ex. 1007, 1:4-7, 1:9-19, 2:7-17; *see also* Ex. 1001, 1:12-14 (claimed device detects “analytes, such as drugs.”); Decl. ¶ 166.



Ex. 1007, Fig. 8.

b) “(A) a base having adjacent slots...”

Sun teaches a base (housings 18, 20, 22, or 118a-d) having adjacent slots (“each strip is contained in a separate housing” as shown by insertion of test strips

12, 14, and 16 into housings 18, 20, 22 or of test strips 112a-d into housings 118a-d). Ex. 1007, 2:66-3:3, 4:32-36, Figs. 5, 6, 8; Decl. ¶ 167. The slots are of sufficient length for insertion of part of a test strip therein (“[D]ip strip 112a may be used in the multi-test panel... [A]n end of the strip extends from the housing 118a...”). Ex. 1007, 4:11-17. Each slot is defined by a floor (bottom half 26). *Id.*, Fig. 1, 1:14-15, 1:57-62, 4:32-36. Each slot is also defined by raised walls depending upwardly from the floor to separate each adjacent slot from the next (e.g., “spaced apart walls 46a and 48a... extend upwardly from the bottom inside surface of the bottom half 26.”). *Id.*, Fig. 6, 3:57-59. Finally, each slot is defined by at least one open end (“[w]ith the dip strip type of test strip an end of the strip extends from the housing 118a.”). *Id.*, 4:15-17.

c) “(B) a multiplicity of test strips...”

Sun teaches a multiplicity of test strips (112a-d). Ex. 1007, Figs. 7-8, 4:10-12, 4:27-29; Decl. ¶168. Sun discloses that “each dip strip contains a different antibody” and “[t]he sample on the strip migrates toward the antibody.” *Id.*, 4:17-20. A POSITA would understand that Sun discloses that each strip has an upstream end (the end dipped in the sample) and a downstream end (*i.e.*, the end towards which the sample migrates). Decl. ¶ 168. Sun discloses that a single test strip protrudes out of each slot’s open end. Ex. 1007, Figs. 6-8.

Sun discloses that the strip yields a visual indicator if the sample contains the antigen which conjugates with the antibody. *Id.*, 3:38-45. A POSITA would understand that Sun discloses that each test strip has a test zone. Decl. ¶ 169. Each test strip contains a binder specific for a different analyte (“[e]ach test strip contains a different immunochromatographic system so that a different test may be conducted on each strip.”). *Id.* ¶¶ 169-170; Ex. 1007, 3:36-39.

Sun discloses that “an end of [each dip-strip] extends from the housing 118a and is dipped into a sample.” Ex. 1007, 4:15-17. Thus, Sun discloses a sample addition pad. Decl. ¶ 171.

Alternatively, May discloses (Figs. 8-9 and 12:5-26) that porous member 506 extends outside the housing, receives the liquid sample, and transports the sample to the test strip; thus serving as a sample addition pad. Decl. ¶ 172. “Porous member 506 and strip 510 overlap to ensure that there is adequate contact between those two materials and that a liquid sample applied to member 506 can permeate member 506 and progress into strip 510.” Ex. 1005, 12:23-26. It would have been obvious to a POSITA to use a strip design, such as taught in May, that includes a sample receiving pad that receives and transports the liquid sample to the test strip. Decl. ¶ 172.

Sun does not expressly teach a “control zone.” *Id.* ¶ 173. However, test strips having both test and control zones were commonly used by July 14, 1998.

Id. Indeed, on appeal, Appellant conceded that: “the construction of the test strip itself is not novel” and “appellant does not rely on the construction of the test strip” for patentability. Ex. 1002, 98, 101. Moreover, May discloses a porous carrier with a first zone containing a mobile, labelled specific binding reagent, and a second zone containing an immobilized, unlabeled specific binding reagent for the same analyte, “the two zones being arranged such that liquid sample applied to the porous carrier can permeate via the first zone into the second zone.” Ex. 1005, Abstract. May also discloses several “control zone” options, such as a design that “merely [conveys] an unrelated signal to the user that the device has worked,” a design that “contain[s] an anhydrous reagent that, when moistened, produces a colour change or colour formation,” and a design that “contain[s] immobilised analyte which will react with excess labelled reagent from the first zone.” *Id.*, 5:8-26, 11:54-12:2, 13:51-58, 14:37-41. May discloses that a user “can ascertain whether the assay has been completed by observing the control zone through aperture 509, and can ascertain the result of the assay by observing the second zone through aperture 508.” *Id.*, 12:62-67, 12:47-53, 13:27-30. May also discloses two or more separate strips arranged in parallel for simultaneously testing different samples or reagents. *Id.*, Abstract, 6:26-39. A POSITA would understand that May discloses a multiplicity of test strips, wherein each strip has a test zone and a control zone. Decl. ¶ 173.

A POSITA would have been motivated to combine Sun and May’s teachings to arrive at the test strips of Claim 1, including the limitation that “each test strip has a test zone and a control zone therein.” *Id.* ¶ 174. Both references relate to devices for testing analytes via multiple test strips that protrude from a housing. *Id.* A POSITA would naturally consider enhancing the test strips disclosed by Sun by adding May’s control zone to enhance the accuracy and ease of use of the test strips. *Id.* Success would be expected because Sun and May each disclose the same type of strips—immunoassay test strips using antibody detection, so May’s cap could readily be fitted over and protect Sun’s strips. *Id.* ¶ 174.

Combining those references would have involved a simple substitution of one known element (Sun’s strip with a test zone) for another (May’s strip with a test zone and a control zone), whose functions were well known in the art. *Id.* ¶ 175; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

This obvious design choice would have been fast and inexpensive to implement. Decl. ¶ 175, *In re Kuhle*, 526 F.2d at 555; *Rexnord Indust.*, 705 F.3d at 1356. Thus, Sun in view of May renders Claim 1’s limitation (B) obvious. Decl. ¶ 175.

d) “(C) a cover... has a first transparent window... through which the test zone and the control zone... can be viewed...”

Sun teaches a cover (*e.g.*, top half 24 or 124, connected to the top half of other housings) attached to the upwardmost surface of each raised wall of the slots of the base and extending to the base’s open end (“the projection of one of the top halves is friction fitted into the groove of the bottom half of another housing” such that the housings are “in alignment.”). Ex. 1007, Fig. 6, 3:4-6, 3:14-19, 3:66- 4:10, 4:12-15; Decl. ¶ 176. Sun teaches that the cover retains the test strips within the slots (“top half 24 also has teeth 38a-c and protrusions 40a-d in the center... to hold the strip in place” within the first embodiment’s housings, and each second embodiment housing is “similar to the housings of the first embodiment”). Ex. 1007, Figs. 4, 8, 3:32-35, 4:32-35.

Sun teaches that the cover has a first transparent window formed therein through which each of the test strips can be viewed (the plastic of top half 24 “may be clear” and “test strip 12 resting within the housing 18 may be seen through... window 28”). *Id.*, 3:14-20; *see also id.*, 4:23-24 (in second embodiment, “[t]he result of the test may be seen through window 128a”). A POSITA would understand that seeing test results through the window means seeing the test zone through the window. Decl. ¶¶ 36, 177. Sun also discloses that the entire top half 124 “may be clear,” and that “window 128a may extend the entire length of the top

half 124 of the housing 118a.” Ex. 1007, 3:14-20, 4:25-26. A POSITA would understand that an entire housing/casing/enclosure could be transparent. Decl. ¶¶ 36, 177.

As discussed above, it would have been obvious to use May’s strips, with both a test and a control zone, in Sun’s assay device. Similarly, it would have been obvious to combine Sun and May such that both the test and the control zones would have been visible through Sun’s transparent windows. *Id.* ¶ 178. A POSITA would have understood that viewing the test and control zones through one or more first transparent windows would have improved the accuracy and ease of use of Sun’s assay device, and this feature would have been fast and inexpensive to implement. *Id.* Thus, it would have been obvious.

e) “(D) a cap enclosing the protruding ends of the test strips and removably attached to the open end of said base.”

Sun does not expressly disclose a cap. However, caps were known in the art by July 14, 1998. Decl. ¶ 179. For example, as discussed above (Ground I: Claim 1, limitation (D)), May teaches a cap. *Id.* ¶ 180.

A POSITA would have been further motivated to combine Sun and May because the protruding ends of Sun’s test strips (Ex. 1007, 4:15-23) would have benefited from adding May’s removable cap to protect the strips during storage, reducing the risk of damage or alteration. Ex. 1005, 4:9-12; Decl. ¶ 180.

Combining Sun and May would have involved the predictable use of prior art

elements (May’s cap, and Sun’s device) according to their established functions (protecting test strips, and assaying for analytes)— a fast and inexpensive solution to implement. *Id.* ¶ 180; *KSR*, 550 U.S. at 417; MPEP §2141(I).

Thus, Sun in view of May renders Claim 1 obvious. *Id.* ¶ 181.

2. Claim 2

Sun teaches that the housing’s plastic may be “clear” (Ex. 1007, 3:14-20). Sun also teaches that “window 128a may extend the entire length of the top half 124 of the housing 118a.” Ex. 1007, 4:24-26. Sun does not expressly disclose the claimed second transparent window. However, covers having two transparent windows were known by July 14, 1998. Decl. ¶ 182. As discussed above (Ground I, Claim 2), a POSITA would have understood that May discloses a second transparent window. *Id.* As discussed above in this Ground (Claim 1, limitations (B) and (C)), a POSITA would have been motivated to combine Sun and May.

A POSITA would have understood that the benefits of testing for multiple analytes taught in May would have been desirable in Sun’s device. *Id.* ¶ 183. A POSITA would have been motivated to apply May’s teaching of more than two windows (to observe multiple test lines, and a control line) to Sun’s device. *Id.* Indeed, Sun’s disclosure of a clear window that may extend the entire length of the housing indicates the desirability of viewing multiple zones or the entire strip. *Id.* Combining May and Sun would have involved a simple substitution of one known

element (May's cover with multiple transparent windows for each strip) for another (Sun's top half with clear window) whose functions were well known in the art. *Id.* ¶ 183; *KSR*, 550 U.S. at 417; MPEP § 2141(I). Adding one or more second transparent windows to Sun's device would have been a straightforward design change, that would have been fast and inexpensive to implement. Decl. ¶ 183. Thus, Sun and May render claim 2 obvious. *Id.*

3. Claim 9

Sun teaches a method for detecting a multiplicity of analytes (“a dip strip 112a type test strip may be used in the multi-test panel”). Ex. 1007, 4:11-13; Decl. ¶ 184. Sun teaches inserting the protruding ends of the test strips into a sample to be analyzed (“an end of the strip extends from the housing 118a and is dipped into a sample.”). Ex. 1007, 4:13-17.

As discussed above (Claim 1), it would have been obvious to combine Sun's multi-test panel with May's cap. For similar reasons, it would have been obvious to remove a cap from Sun's device during testing. Decl. ¶ 185. May teaches that “protective cap 503 is removed from the holder” during testing, then “can be replaced.” Ex. 1005, 12:54-62; *see also id.*, 4:9-13. Cap removal is necessary for successful testing. Decl. ¶ 185. A POSITA would have combined Sun's detection method with May's cap removal to expose the test strip to a sample to obtain the benefit of collecting a sample with an undamaged strip, and this combination

would have been straightforward, fast, and inexpensive for a POSITA to implement. *Id.*

Sun also teaches observing the effect of the sample on the test strips contained in the device (“colored particles contained within the strip serve as a visual indicator”). Ex. 1007, 4:20-24. As discussed above, Sun discloses viewing a test result in a test zone, and it would have been obvious to combine May’s control zone with Sun’s test strips. Decl. ¶ 186. May discloses “observing the control zone through aperture 509” and “observing the [test] zone through aperture 508.” Ex. 1005, 12:62-67; *see also id.*, 12:47-53, 13:27-30. A POSITA would have combined May’s disclosure of observing the effect of the sample on the test and control zones of the test strips contained in the device with Sun’s disclosure of observing the strips to obtain the benefits of quickly and easily verifying that the strips worked and seeing the results, and this combination would have been straightforward, fast, and inexpensive to implement. Decl. ¶ 186.

H. Ground VIII: Claims 1 and 9 Are Obvious Over Sun in View of Charm and May ’871

1. Claim 1

As discussed above (Ground VI), Sun discloses Claim 1’s preamble, and limitation (A). Regarding limitation (B), to extent Sun does not expressly teach a sample addition pad, Charm does. *See* Ground II, *supra*; Ex. 1008, 5:32-37, 5:42-45, Fig. 1. Regarding limitation (C), Charm teaches test strips with both a test and

control zone. Ex. 1008, 3:59-61, 5:25-32, 6:48-53, 8:14-17, 8:46-51. It would have been obvious to use Charm's strips—with a sample addition pad, and a test and control zone—in Sun's assay device. Decl. ¶ 187. Similarly, it would have been obvious to combine Sun and Charm such that both the test zone and the control zone would have been visible through Sun's transparent windows. *Id.* Using a sample addition pad in Sun's assay device (to the extent not disclosed in Sun) would be beneficial to control sample delivery to the test strip in the housing. *Id.* Viewing test and control zones through one or more first transparent windows would have improved the accuracy and ease of use of Sun's assay device. *Id.* Adding the sample addition pad, and configuring a test strip with both test and control zones viewable through a first transparent window would have been straightforward and inexpensive to implement. *Id.* Thus, it would have been obvious.

Regarding limitation (D), as discussed above (Ground II: Claim 1, limitation (D)), Charm teaches a cap. Decl. ¶ 188. A POSITA would have been motivated to protect the protruding ends of Sun's strips with a cap. *Id.* Combining Sun and Charm would have involved the predictable use of prior art elements (a protective cap as taught in Charm, and Sun's device) according to their established functions (protecting test strips, and assaying for analytes)— a fast and inexpensive solution to implement. *Id.*; *KSR*, 550 U.S. at 417; MPEP § 2141(I).

Thus, Sun in view of Charm renders Claim 1 obvious. *Id.* ¶ 189.

2. Claim 9

As discussed immediately above in this Ground, Sun in view of Charm renders obvious Claim 1. Thus, it renders obvious the method for detecting a multiplicity of analytes via the device of claim 1. *Id.* ¶ 190.

As discussed above in this Ground (Claim 1, limitation (D)), a POSITA would have been motivated to combine Sun with Charm and would expect success in achieving the claimed cap. *Id.* ¶ 191. Charm discloses cap removal during testing. Ex. 1008, 3:49-54, 4:21-23. It would have been obvious to remove a protective cap when following Sun's detection method. Decl. ¶ 191. Cap removal is necessary for successful testing. *Id.* A POSITA would have combined Sun's method with the teaching of cap removal in Charm to obtain the benefit of collecting a sample with an undamaged test strip, and this combination would have been fast and inexpensive for a POSITA to implement. *Id.*

Thus, Sun in view of Charm renders Claim 9 obvious. *Id.*

I. Ground IX: Claim 2 Is Obvious Over Sun in View of May, Shuler, and Eisinger

As discussed above in Ground VIII, Sun in view of May renders Claim 1 obvious. To the extent that Sun in view of May does not disclose Claim 2, Sun in view of May, Shuler, and Eisinger would. Decl. ¶ 192. As discussed above (Ground III), Shuler and Eisinger both teach a second transparent window to view

additional parts of a strip, for different reasons: to view additional test or control zones, or to view the end of the assay. *Id.* ¶¶ 124-125.

Success would be expected because Sun already discloses windows to view test strips, so adding more windows would be straightforward, and Shuler's or Eisinger's test strips would be compatible with Sun and May's devices because they were designed to house similar strips. *Id.* ¶ 193. As discussed above, combining Sun and May would have involved a simple substitution of known components. *Id.* Shuler's and/or Eisinger's aforementioned disclosures would add to the motivation to combine Sun and May to view parts of test strips through a second transparent window. *Id.*

Sun in view of May, Shuler, and Eisinger thus renders claim 2 obvious. *Id.*

XI. CONCLUSION

Petitioner requests IPR of claims 1, 2, and 9 of the '291 patent to cancel the claims.

Respectfully Submitted,

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ADDENDUM: LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 8,263,291
1002	Prosecution History for U.S. Patent No. 8,263,291
1003	Declaration of Robert Bohannon, Ph.D.
1004	German Utility Model No. DE 297 02 825 (“DE”), and certified English Translation
1005	U.S. Patent No. 5,602,040 (“May”)
1006	U.S. Patent No. 5,976,895 (“Cipkowski”)
1007	U.S. Patent No. 5,962,336 (“Sun”)
1008	U.S. Patent No. 5,985,675 (“Charm”)
1009	U.S. Patent No. 4,943,522 (“Eisinger”)
1010	U.S. Patent No. 5,798,273 (“Shuler”)
1011	U.S. Patent No. 5,622,871 (“May ’871”)
1012	Brown E R S, Jarvie D R, Simpson D, Evaluation of Bionike one-step tests for the detection of drugs of abuse in urine, 34 ANN. CLIN. BIOCHEM. 1997, at 74-80 (“Brown”)
1013	U.S. Patent No. 6,808,682 (“Bates”)

CERTIFICATE OF WORD COUNT

The undersigned certifies that the attached Petition for *Inter Partes* Review of U.S. Patent No. 8,623,291 contains 13,990 words (as calculated by the word processing system used to prepare this Petition), excluding the parts of the Petition exempted by 37 C.F.R. §42.24(a)(1).

Dated: July 27, 2016

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that on July 27, 2016, I that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 8,623,291 and all Exhibits and other documents filed together with this Petition were served via FEDERAL EXPRESS overnight delivery, on July 27, 2016 on the official correspondence address for U.S. Patent No. 8,623,291 shown in PAIR and Patent Owner's current litigation counsel:

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