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. 6,548,019

Case No. IPR2016-_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,548,019 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, U.S. Patent No. 6,548,019 (the "'019 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. [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 Branan Medical Corp.

[2] Petitioner is also filing a Petition for *Inter Partes* Review of U.S. Patent No. 8,623,291, which is also asserted in the same district court proceeding.

C. Counsel and Service Information

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II. CLAIM LISTING

1. A device for collecting and assaying a sample of biological fluid, the device comprising:

(a) a flow control channel defined by at least one liquid pervious side joined to liquid impervious sides, wherein the internal dimensions of the flow control channel are sufficient to permit placement therein of an assay test strip;

(b) an assay test strip within the flow control channel, wherein the assay test strip has a sample loading zone therein, and wherein further the assay test strip is disposed within the flow control channel so the

sample fluid contacts the sample loading zone at a liquid pervious side of the flow control channel; and,

(c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth;

wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container so that the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure, and wherein entry of fluid into the flow control channel creates an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel, thereby eliminating a pressure gradient along which excess sample fluid could flow into the flow control channel.

2. A device according to claim 1, wherein the sides of the flow control channel are loosely fitted around the assay test strip.

3. A device according to claim 1, wherein one of the liquid impervious sides of the flow control channel is formed as a portion of a liquid impervious backing; and wherein the device further comprises a holder

fittable inside the fluid sample container, the holder having at least one slot formed therein to receive the backing.

4. A device according to claim 3, wherein both the holder and the fluid sample container are curved in shape, and the curvature of the holder follows the curvature of the inner diameter of the fluid sample container.

5. A device according to claim 4, wherein the fluid sample container is a cup.

6. A device according to claim 5, further comprising a watertight cap fittable over the mouth of the cup.

9. A device according to claim 1, further comprising additional assay test strips, wherein the additional assay test strips detect the presence or absence of different analytes in a biological fluid.

10. A device according to claim 9, wherein all of the assay test strips are disposed in a single flow control channel.

11. A device according to claim 9, further comprising additional flow control channels, wherein each assay test strip is disposed in a separate flow control channel.

12. A device according to claim 9, wherein the different analytes are different narcotics.

13. A device according to claim 12, further comprising a sample integrity monitoring system, the system comprising one or more assay test strips into which reagents and labels are incorporated to provide a visually observable signal indicative of the presence of adulterants or contaminants in the biological fluid.

14. A device according to claim 9, wherein the biological fluid is urine.

15. A device according to claim 12, wherein the biological fluid is urine.

III. GROUNDS FOR STANDING

Petitioner certifies that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review on the grounds in this Petition. The petition is filed within one year of the March 24, 2016 service of the complaint.

IV. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1-6 and 9-15 of the ’019 patent based on the following references:

Ex.	Description		Type of Prior Art
1004	U.S. Patent No. 5,656,502 (“MacKay”)	Issued Aug. 12, 1997	§ 102(b)
1005	U.S. Patent No. 5,976,895 (“Cipkowski”)	Filed March 11, 1996	§ 102(e)

Ex.	Description		Type of Prior Art
1006	U.S. Patent No. 5,985,675 ("Charm")	Filed Dec. 31, 1997	§ 102(e)
1007	EPO Publication EP0860701 ("EP0860701") and certified English translation	Published August 26, 1998	§ 102(a)
1008	U.S. Patent No. 5,500,375 ("Lee-Own")	Issued March 19, 1996	§ 102(b)
1009	U.S. Patent No. 6,379,620 ("Tydings")	Filed Nov. 16, 1998	§ 102(e)[3]
1010	German Utility Model No. DE 297 02 825 ("DE") and certified English translation	Published May 22, 1997	§ 102(b)
1011	U.S. Patent No. 4,857,453 ("Ullman")	Issued Aug. 15, 1989	§ 102(b)
1012	U.S. Patent No. 5,602,040 ("May")	Issued Feb. 11, 1997	§ 102(b)

[3] The application leading to the issuance of the '019 patent was filed on August 18, 1999, and is a continuation-in-part of U.S. Appl. No. 09/192,969, which led to issuance of Tydings. The patent owner concedes that the priority date of the challenged claims is the date of the continuation-in-part, making Tydings prior art under section 102(e). Ex. 1013, at 4, ¶ (B).

Petitioner requests cancellation of claims 1-6 and 9-15 pursuant to the Grounds set forth in Section X. This petition, supported by the declaration of Dr. Robert Bohannon (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. OVERVIEW OF THE '019 PATENT

The invention claimed in the '019 Patent is a straightforward application of the basic principle that if one covers one end of a straw with a finger and inserts the other end in a liquid, the air trapped in the straw will prevent the liquid from rising in the straw. For claim 1, the sole independent claim, an assay test strip is mounted inside a covered-straw-like "flow-control channel" that is disposed, open side down, in a fluid sample container so that only the end of the test strip comes in direct contact with the test fluid. Ex. 1001, 8:42-9:2. Air trapped inside the channel prevents the uncontrolled flow of fluid up the channel, thereby preventing excessive wetting of the test strip. The test strip is "conventional in design." *Id.* at 5:31. Dependent claims add other conventional elements, such as a fluid container in the form of a cup with a lid, a holder with a slot for holding the test strip, placing multiple test strips in a single channel or in separate channels, multiple test strips for multiple narcotics, optionally sizing the channels so the strip fits inside loosely, and the fluid being urine.

The embodiments illustrated in the drawings show multiple test strips, each in a separate channel. *See* Ex. 1001, Fig. 3. One end 35 of each channel is sealed. The other end 37 is open. The fluid loading zone of the test strip 30 protrudes from the open end of the channel.

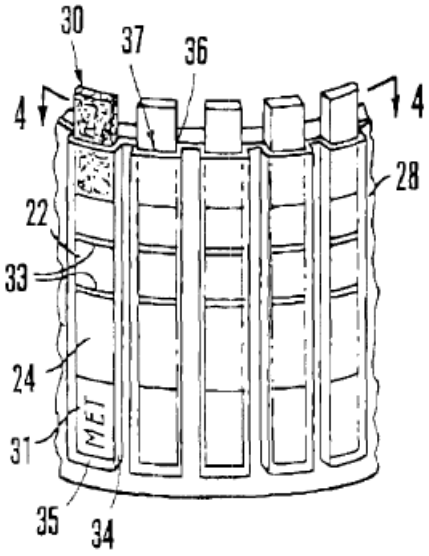


Fig. 3

Figure 4 shows a cross section of the five channels with five strips. Solid backing 28 forms one side of each of the five channels.

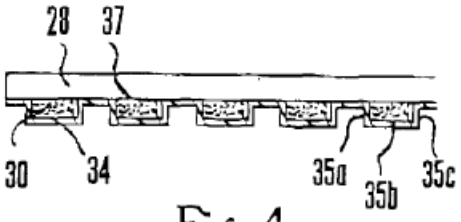


Fig. 4

The backing combined with the other sides of one or more flow control channels is referred to as a "flow control means."

In use, the flow control means containing test strips is placed with the open sides facing down in the cup, as shown in Figure 6, so that the fluid loading zone of the test strips are in the bottom of the cup.

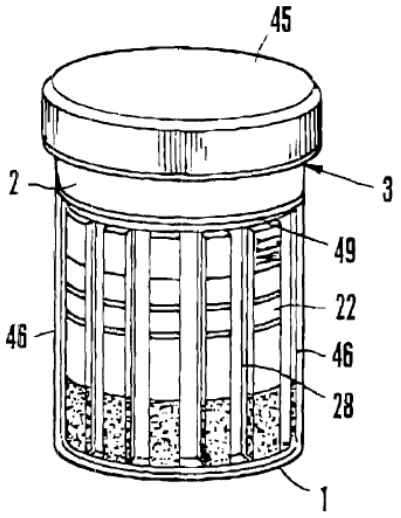


Fig. 6

Liquid is added to the cup; however, the liquid cannot rise above the bottom of the channels because the channels are sealed at the top.

Optionally, the flow control means may be placed in a "holder," which itself is placed inside the fluid collection container. In the embodiment of the holder shown in Figure 5, the holder is curved to follow the inside diameter of the collection cup.

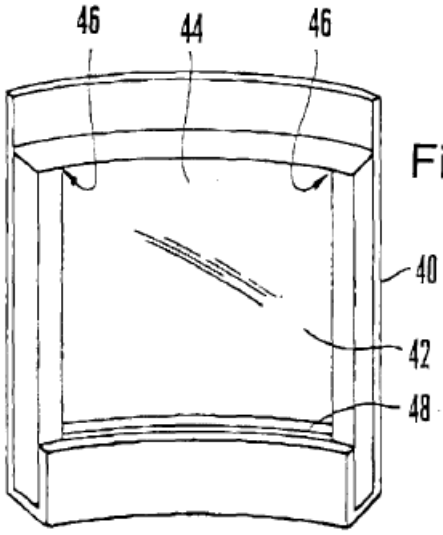


Fig. 5

In use, the backing 28 of the flow control means is inserted into slots 46 and 48.

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"). Decl. ¶ 46. 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*. ¶ 47.

VII. CLAIM CONSTRUCTION

A. "an ambient pressure within the flow control channel equivalent to the ambient pressure outside of the flow control channel"

The broadest reasonable construction of this term requires that the pressure of air inside the flow control channel is equivalent to the combined ambient air pressure and fluid pressure immediately outside the flow control channel.

B. "the assay sample fluid, when added to the container, is delivered to the sample loading zone of the assay test strip by entry through a liquid pervious side of the flow control channel without migration through an intermediate structure"

The broadest reasonable construction of this term requires that some portion of the sample loading zone of the assay test strip must be disposed within the flow control channel. *See* Ex. 1001, 6:9-15 (sample loading zone protrudes through opening), 6:38-40 (same), Fig. 3 (showing sample loading zone partially inside channel and protruding from opening).

C. "loosely fitted"

Claim 2 requires that "the sides of the flow control channel are loosely fitted around the assay test strip." Ex. 1001, 9:3-5. The broadest reasonable construction of "loosely fitted" does not preclude the sides of the flow control channel from contacting the assay test strip. In the preferred embodiments, as illustrated in Figures 3 and 4 reproduced below, the sides of the flow control channels are in physical contact with the assay test strips. There is no indication of any space

between any part of the flow control channel and the surfaces of the assay test strips. Furthermore, opening 37 in Figures 3 and 4 is specifically described in the written description as "loosely fitted around test strip 22," *id.*, 6:38-40, and all four sides of opening 37 are depicted as being in contact with the assay test strip.

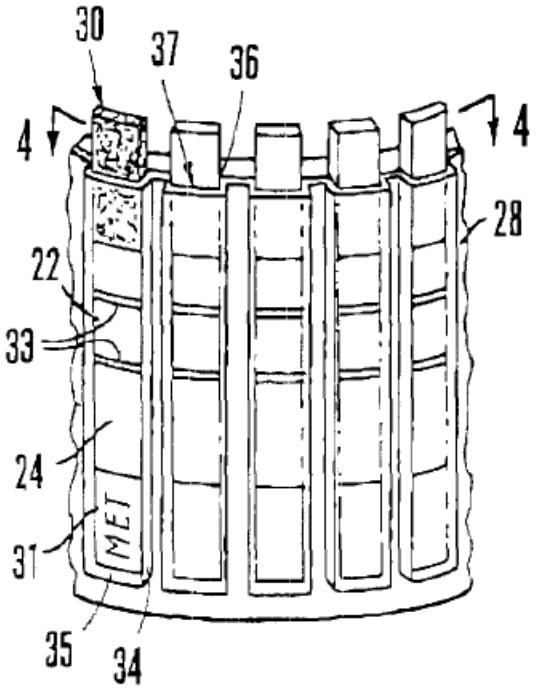


Fig. 3

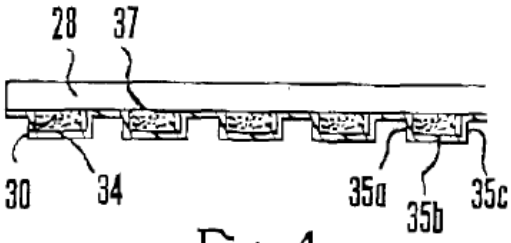


Fig. 4

VIII. SUMMARY OF THE PRIMARY PRIOR ART REFERENCES

There is nothing new or non-obvious in the '019 patent claims. Petitioner's Grounds are based on four primary references, each of which controls exposure of a test strip to fluid, thereby avoiding flooding, by using the covered straw principle discussed above.

A. MacKay

MacKay teaches positioning a test strip within an air-tight holder that is designed to ensure that when the open end of the holder is placed in liquid the liquid contacts and moves up the test strip only by capillary action, thus preventing flooding of the strip. *See* Ex. 1004, 1:6-9, 1:65-2:9. MacKay was disclosed in an IDS during prosecution; however, MacKay was never applied against the claims or even discussed, either individually or as part of a combination, and there is no evidence that the Examiner considered MacKay's disclosures cited herein in support of Petitioner's arguments. *See Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00486, Paper No. 10 at 15 (instituting IPR despite Patent Owner's objection that certain prior art references were submitted in IDS and initialed by Examiner).

In MacKay, the holder, shown below, is open at one end and otherwise sealingly and air-tightly closed, with a vent 42 positioned near the open end. Ex. 1004, 2:15-17, Figs. 8A-8C. The holder is immersed in liquid, open-end down; however, "[o]nce the liquid covers the at least one vent, the pressure of the air or ambient atmosphere in the elongated hollow member above the at least one vent prevents the liquid from further entering the elongated hollow member." *Id.*, 2:29-32.

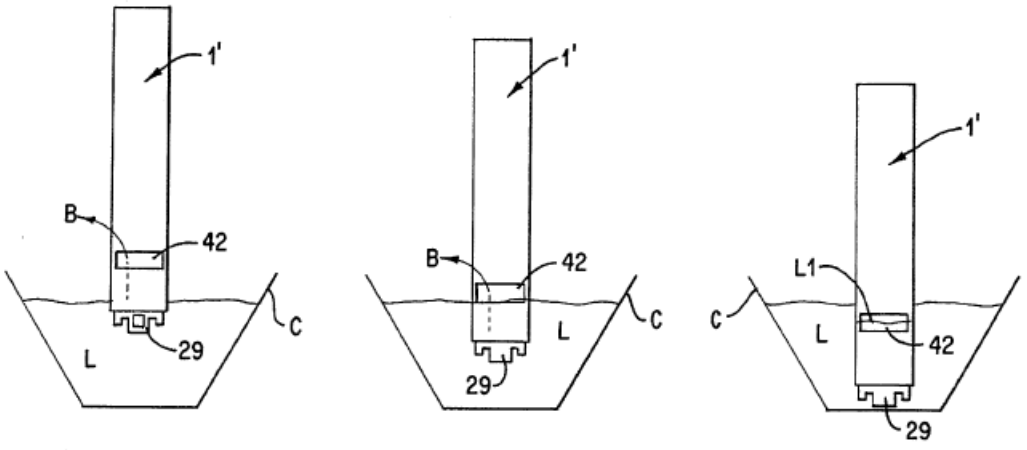


FIG.8A FIG.8B FIG.8C

As a result, the liquid enters the hollow member (flow control channel) at the open end 29 and contacts the test strip only in a predetermined designated area, designed for direct contact with the liquid, *i.e.*, a loading zone. *Id.,* 2:32-34.

B. Lee-Own

Lee-Own, which was not considered during prosecution of the '019 patent, teaches a "holder laminate" for dipstick immunochromatographic assays. Ex. 1008, 3:24-26. The holder laminate seals a test strip in a substantially air-tight and a substantially fluid-tight manner, which can subsequently be opened by cutting one end to expose the loading zone of the test strip. *See id.*, 3:26-34, 7:53-55. As shown in Fig. 5 below, the holder is attached to the inside wall of a collection vessel 30 (a cup shown with cap 32) by adhesive film or tape. *Id.*, 8:54-63. The holder can be pre-cut along the horizontal dashed line to expose the end of the test strip. *Id.*, 7:53-55, 8:61-62.

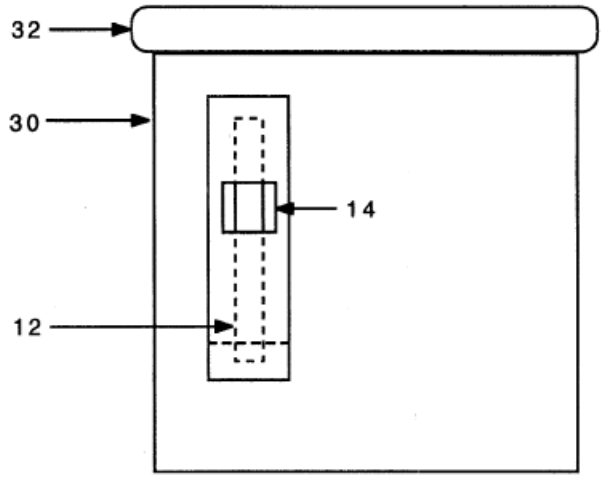


FIG. 5

When a sample is collected in the vessel above the level at which the test strip is exposed, the sample contacts the test strip at the opening and migrates up the test strip by capillary action to a detection zone. *Id.*, 5:25-30, 8:54-63, 9:1-4. The confinement of the test strip within the air- and liquid-tight holder laminate strictly controls the volume of sample that enters the holder. *Id.*, 8:24-31.

C. DE

DE, which was not considered during prosecution of the '019 patent, teaches a multiple strip test card for chromatography test strips. *See* Ex. 1010, 1:8.[4] DE discloses a holder 1 with multiple strip-shaped recesses 2 in a flat plastic plate. *Id.*, 2:15-25, 3:14-17, 4:21-5:7, 6:7-19.

[4] Citations to DE are to Petitioner's certified English translation.

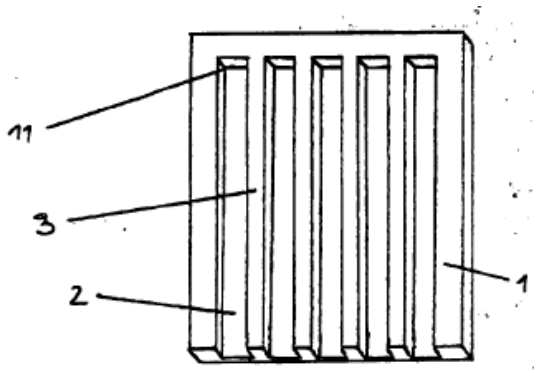
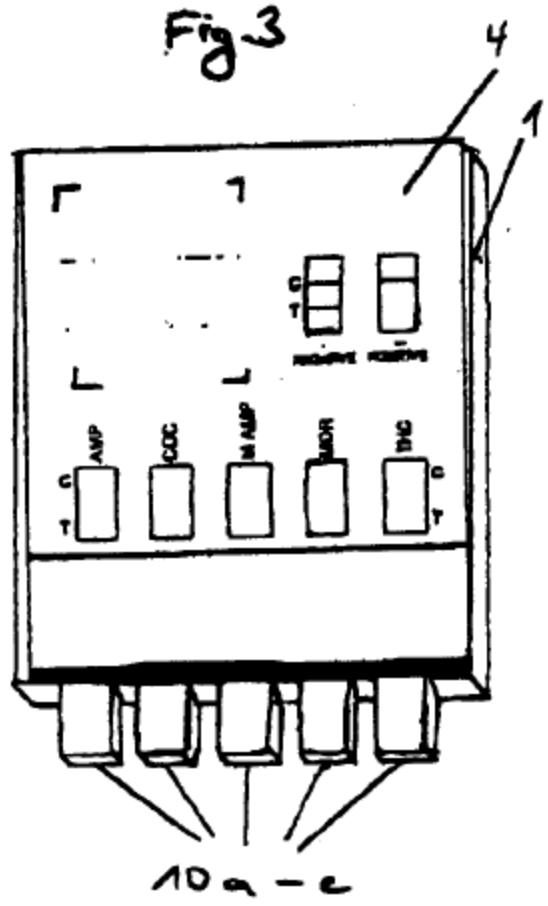


Fig. 1

After the strips are placed in the recesses, an adhesive plastic cover film 4 is placed over the top of the recesses sealing the strips into air-tight and fluid-tight channels. *See id.*, Fig. 3, 5:9-11.



The holder is then dipped or immersed in a sample fluid. *Id.*, 2:22-25. The ends of the test strips contact the liquid; however, the sealed recesses (flow control channels) prevent liquid from entering the recesses and flooding the strips. Decl. ¶ 64.

D. Tydings

During prosecution, the examiner considered Tydings and applied it to the claims under examination. The examiner did not, however, discuss Tydings in view of MacKay or Lee-Own, which combinations are asserted by Petitioner.

Tydings teaches an assay device for field urine testing. Ex. 1009, Abstract. A laminated assay means comprises a liquid impermeable backing 8, with assay strips provided on the front surface of the backing. *Id.*, Fig. 4, 2:37-40, 2:46-47. The front surface of the backing is covered by a front cover which seals the assay strips at the bottom and both sides of the assay strips to isolate each assay strip from each other and prevent contamination from either the urine or another assay strip. *Id.*, 2:59-63.

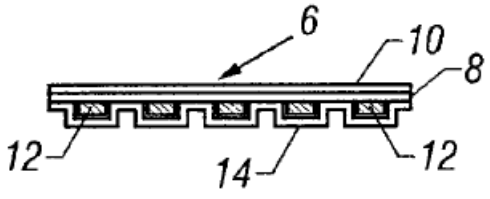


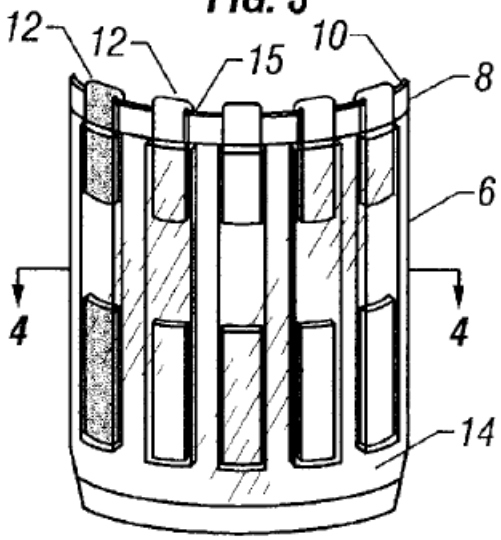
FIG. 4

The front and back covers may be made from plastic and the front cover sealed to the backing by a suitable adhesive or other means such as ultrasonic or heat welding. *Id.*, 2:37-40, 2:63-65, 3:15-17.

As so sealed, the backing and front cover of Tydings define five liquid impervious sides of a flow control channel as claimed: (a) a back, defined by the backing and (b) a front, bottom, and both sides, defined by the front cover. The backing and front cover also define a liquid pervious side through which an end of an assay test strip protrudes. *Id.*, Fig. 3; 2:37-40, 2:46-47, 2:59-65.

The assay means also includes a wicking material 10 attached to the rear side of backing 8. *Id.*, 2:40-41. As shown in Fig. 3, the top portions of the test strips 12 are bent over the top edge 15 of backing 8 and overlapped onto the wicking material 10. *Id.*, 2:65-67.

FIG. 3



Alternatively, the wicking material 10 can be folded over the top edge of the backing and overlapped onto the top portions of the test strip. *Id.*, 3:1-2. The assay means is then assembled into the collection container, either using tabs formed on the inside of the container or a separate holder with slots, which itself is then placed inside the container. *Id.*, 3:2-10, 3:36-60.

In use, a urine sample is introduced into the container, the urine wicks up the wicking material until it reaches the assay test strips, and the urine then wicks down the test strip to react with the chemical agents on the strip to indicate a result. *Id.*, 3:19-31, 3:61-4:2.

IX. STATEMENT OF NON-REDUNDANCY

Each Ground raised in this Petition is meaningfully distinct (non-redundant). As noted just above, the Petition relies on four different primary references—MacKay, Lee-Own, DE and Tydings. The four references are asserted against different sets of claims in different combinations with various secondary references. Differences among the references include:

MacKay expressly teaches the principle of pressure equilibrium, which was touted as a patentably-distinct feature during prosecution.

Lee-Own discloses a holder-laminate mounted on the inside wall of a cup and also that flooding of the strip or strips inside such a holder is prevented.

DE is based a card with multiple sealed closed-end recessed slots containing test strips that are dipped together in a urine sample.

Tydings discloses a holder-laminate structure that is virtually identical to the claims at issue but has the channel for the test strips oriented toward the *top* of the cup. The supposed deficiency of Tydings discussed in the specification of the '019 patent—the flooding of test strips if the strips' orientation is reversed–is resolved by the teachings of MacKay and Lee-Own.

The MacKay and Lee-Own Grounds are also distinct from the DE and Tydings Grounds because MacKay and Lee-Own anticipate some of the challenged claims whereas the DE and Tydings Grounds are based entirely on obviousness. The MacKay and Tydings Grounds are also distinct from the Lee-Own and DE Grounds because they address claim 10 (multiple strips in a single flow control channel), whereas the Lee-Own and DE Grounds address claim 11 (multiple strips in separate flow control channels), but not claim 10.

X. SPECIFIC GROUNDS FOR PETITION

Pursuant to Rule 42.104(b)(4)-(5), the below sections, as confirmed in the Bohannon Declaration, demonstrate in detail how the prior art discloses, teaches, and/or suggests each and every limitation of the '019 patent claims, and how those claims would have been anticipated or obvious in view of the prior art. Petitioner

is unaware of any evidence of secondary considerations of non-obviousness. Decl. ¶ 72.

A. Ground I: Claims 1 and 2 are Anticipated by MacKay

1. Independent Claim 1

a) *Preamble: "A device for collecting and assaying a sample of biological fluid, the device comprising:"*

MacKay, *e.g.*, Figs. 8A-8C, discloses a container C for collecting and holding a liquid to be tested. Ex. 1004, Figs. 3A-3C, Figs. 8A-8C, 5:21-23, 7:54-55. The liquid is tested using test strips such as pregnancy test strips; immunoassay test strips; antigen, antibody and polynucleotide test strips; or test strips of analytes, such as drugs and metabolites. *Id.*, 7:39-48. A POSITA would have understood these types of test strips to be used with samples of biological fluid. Decl. ¶ 73.

b) *"(a) a flow control channel …"*

The test strip holder or case of MacKay includes a "flow control channel" in the form of an elongated hollow member that is open at one end and sealingly and air-tightly closed at the other end. Ex. 1004, 2:15-17. A test strip holder 1' includes an elongate hollow member 20, formed from a test strip receiving part 21 and a test strip covering part 22, which are connected by a hinge 23, shown in an open position in Fig. 4. *Id.*, Figs. 4 & 6, 5:56-62. When the test strip covering part 22 is closed over the test strip receiving part 21, the protrusions 25 of the covering

part enter into and form a seal with the peripheral groove of the receiving part, forming an airtight seal. *Id.*, 6:4-11. Optionally, adhesive sealant or welding may be used to enhance the seal. *Id.*, 6:14-16, 22-27.

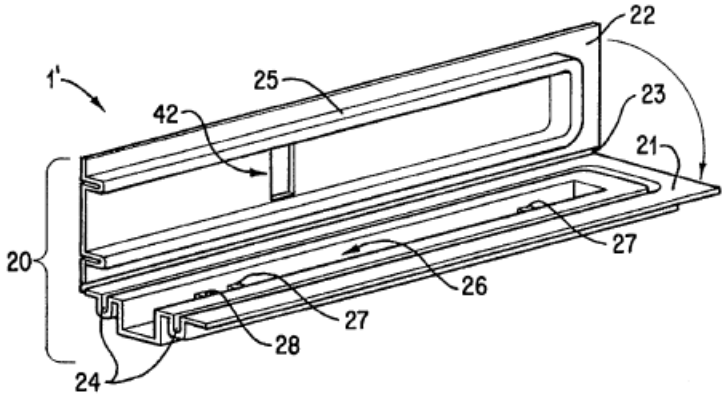


FIG. 4

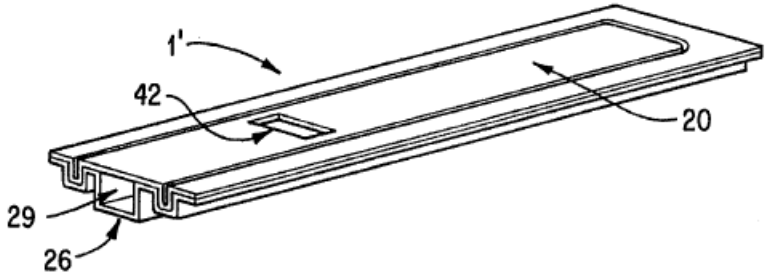


FIG. 6

The test strip receiving channel 26 of the test strip holder of MacKay is a flow control channel defined by five liquid impervious sides: (a) a back, two sides, and an end defined by the test strip receiving part 21 and (b) a front defined by the test strip covering part 22 and a liquid pervious side: the opening 29 through which liquid enters. *Id.*, Fig. 7, 4:22-24 (hollow member may be made from any non-reactive material, such as plastic or glass). Figure 9 discloses the same sealed flow control channel, except that the grooves and protrusions are replaced by flat surfaces, which are welded together or sealed with adhesive. Ex. 1004, 8:30-53.

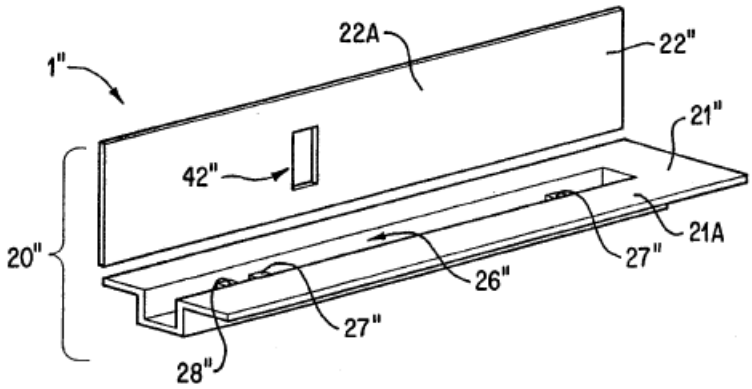


FIG. 9

c) *"(b) an assay test strip within the flow control channel …"*

In MacKay, a test strip is positioned within a test strip receiving channel 26 having an opening through which liquid enters. Ex. 1004, Abstract, 2:62-63, 5:56–58, 6:47-48, 6:56-57, 8:1-6, 8:10-13, Fig. 4 (labeling opening 29). The test strip includes a sample pad 34, which is a sample loading zone. *Id.*, 7:19-21, 8:54-59. Vent 42 is positioned over the sample pad 34, as shown in Figure 7.

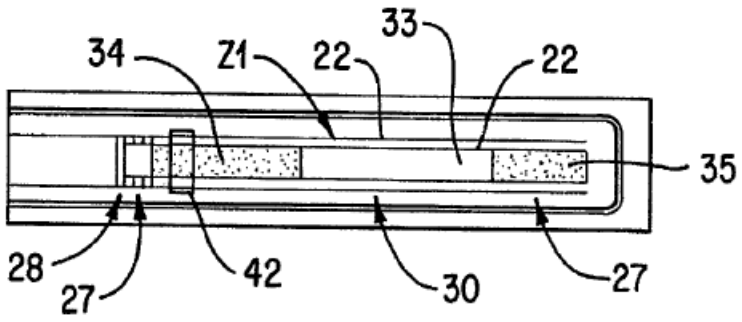


FIG. 7

Vent 42 allows the fluid to rise high enough in the flow control channel to contact the sample pad 34 but prevents the fluid from rising beyond the sample pad, as shown in Figure 8C. *Id.*, 8:14-18. Liquid enters the open end of channel and contacts the test strip only a predetermined designated area designed for direct contact with the liquid. *Id.*, 7:55-57, 8:1-3, 8:54-59.

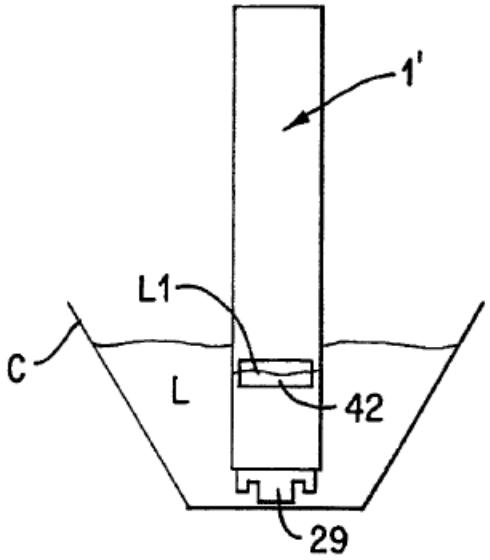


FIG. 8C

d) *"(c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth"*

MacKay discloses a sample container C having a base, open mouth, and walls connecting the base to the mouth. Ex. 1004, Figs. 8A-8C, 7:54-55; *see also id.*, Figs. 3A-3C, 5:20-23.

e) *"wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container …"*

MacKay discloses a test strip holder disposed inside the sample container C with the open end 29 oriented toward the base of the container. Ex. 1004, Figs. 8A-8C (reproduced below and showing holder in fluid with opening 29 oriented downward). As discussed above, liquid enters the open end of test strip receiving channel 29 and contacts the test strip in a predetermined designated area designed for direct contact with the liquid. *Id.*, 7:55-57, 8:1-3, 8:54-59; *see also id.*, 5:21-26. As the test strip holder is inserted farther into the liquid, the liquid level rises until it reaches the top of vent 42. *Id.*, 7:57-61; *see also id.*, 5:30-32. After the liquid rises above the vent 42, air can no longer escape through the vent and air pressure within the remaining portion of the test strip receiving channel 26 opposes the pressure exerted by the ambient pressure outside the channel, as exerted by the rising fluid, and prevents liquid L from rising farther into the channel. *See, e.g., id.*, 7:61-67; *see also id.*, 2:29-32, 5:32-38, 9:11-17.

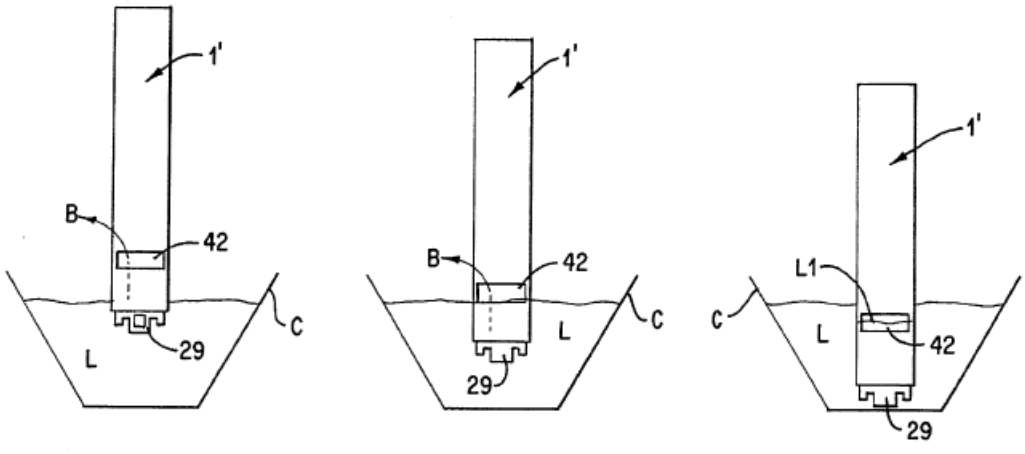


FIG.8A FIG.8B FIG.8C

2. <u>Dependent Claim 2: "… loosely fitted …"</u>

MacKay discloses support structures that maintain the test strip spaced from the inner walls of the test strip holder, which prevents the test strip zones from being contacted by any liquid on the sidewalls of the test strip holder. Ex. 1004, 6:47-52, 8:10-13; *see also id.*, 3:19-37, 9:5-7. The spacing of the test strip from the side walls of the elongated hollow member ensures that liquid, under normal atmospheric conditions, flows up the test strip by capillary action. *Id.*, 3:38-42.

B. Ground II: Claims 3-6, 9, 12, 14, 15 are Rendered Obvious by MacKay in view of Cipkowski

1. <u>Dependent Claim 3: "… liquid impervious backing; and … a holder …"</u>

MacKay does not disclose the holder of claim 3; however, Cipkowski does disclose the claimed holder. It would have been obvious to a POSITA to combine the holder of Cipkowski with the flow control channel containing the test strip disclosed in MacKay. Decl. ¶ 81-86.

As discussed above, MacKay teaches that one of the liquid impervious sides of the flow control channel serves as a liquid impervious backing for the test strip. MacKay discloses a test strip holder 1' having a test strip receiving channel 26 with an opening 29 through which liquid enters. Ex. 1004, Fig. 6, 2:62-63, 5:66-6:1, 7:55-57. A test strip is positioned within the test strip receiving channel 26. *Id.*, 8:10-12. The bottom of MacKay's test strip holder, constitutes an impervious backing. *See id.*, 4:22-24 (holder may be made of plastic or glass).

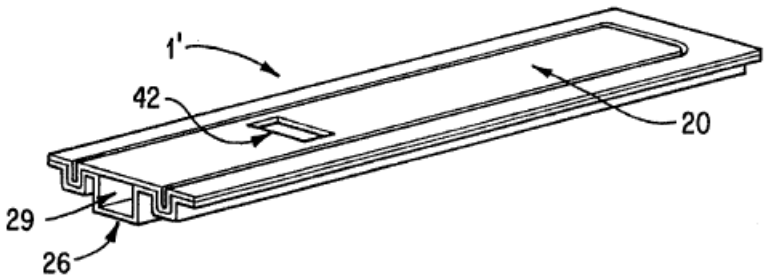


FIG. 6

Cipkowski teaches a test strip card with a liquid impervious side that is formed as a portion of a liquid impervious backing. The test card includes a plurality of test strips each disposed in a channel defined by an impervious backing (bottom ply 46), cover (top ply 47), and side walls (central ply 45). Ex. 1005, Fig. 11, 5:9-19, 5:44-45, 5:54-56 (test card may be made of a plastic material, plastic coated cardboard, or thin sheets of plastic which are laminated together).

Cipkowski also discloses the holder required by claim 3. Cipkowski discloses a cup-like container 11 having a side wall 12, a closed bottom 13, an

open top 14, and an outer cover 22. *Id.*, Fig. 2, 3:28-33. A holder, inner closure insert 15, fits within the cup and includes a diametrical slot 19 shaped to accommodate a test card 25. *Id.*, 3:33-40, 4:29-31.

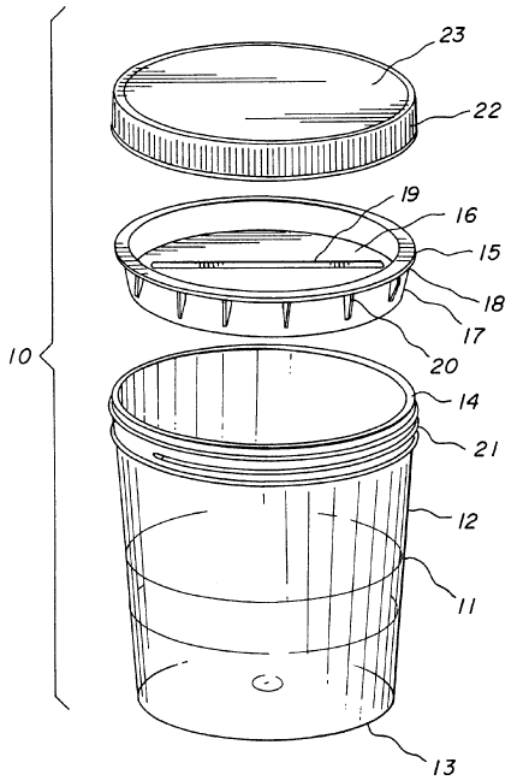
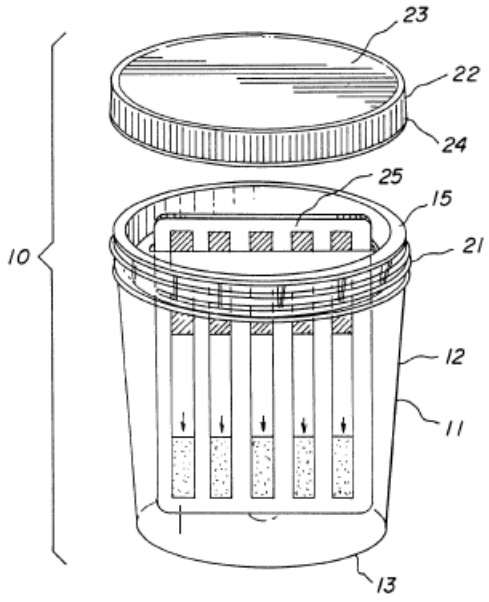


FIG. 2

The test card 25 is inserted into the slot 19 in the holder (insert 15) with the impervious backing (bottom ply 46) located in slot 19. Ex. 1005, Fig. 1, 3:55-57, 4:33-38.

FIG. 1



A POSITA at the time of the alleged invention would have been motivated to combine the test strip case/flow control channel of MacKay with the cup and holder/insert of Cipkowski to supply the limitations of Claim 3. Decl. ¶ 86. Both patents relate to devices for dipping or immersing test strips in a container with a sample fluid. *E.g.*, Ex. 1004, Figs. 3A-3C; Ex. 1005, 2:20-26. A POSITA would naturally consider using MacKay's sealed test strip case with Cipkowski's cup and insert by inserting such a test strip case into the slot in the top of Cipkowski's insert. Decl. ¶ 86. Use of such a sealed case would provide the benefit of preventing flooding of the test strip as taught in MacKay. Ex. 1004, 7:61-67. And, Cipkowski's insert also provides benefits, such as allowing testing personnel to avoid contact with the fluid specimen, that are directly applicable to MacKay's sealed test strip case. Ex. 1005, 1:22-25; Decl. ¶ 86. There would have been an

expectation of success because the rectangular slit in the closure insert in Cipkowski could easily be made to accommodate the test strip holder/case in MacKay. Decl. ¶ 86.

2. Dependent Claim 4: "… holder and … container are curved …"

Cipkowski discloses that the holder (insert 15) and fluid sample container (cup-like container 11) are curved in shape and that the curvature of the holder follows the curvature of the inner diameter of the inside of the cup. Ex. 1005, Figs. 1 & 2. For reasons stated above with respect to claim 3, it would have been obvious to combine MacKay with the curved holder and cup of Cipkowski.

3. Dependent Claim 5: "… cup …"

Cipkowski discloses a cup-like container 11 having a side wall 12, a closed bottom 13, an open top 14, and an outer cover 22. Ex. 1005, Figs. 1 & 2.

4. Dependent Claim 6: "… watertight cap ..."

Cipkowski discloses a drug testing cup with a threaded cover 22 to seal the container against leakage from the fluid specimen. Ex. 1005, Fig. 1, 3:48-54, 4:60-65 (describing cover 22 as sealing container against leakage).

5. Dependent Claim 9: "… additional strips ..."

MacKay does not expressly disclose additional assay test strips. However, the use of multiple assay strips to detect different analytes was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 90-91.

For example, Cipkowski discloses a "screen test card for drugs of abuse … . A plurality of immunoassay test strips are fastened side-by-side … . Each test strip is reactive to provide a visual indication in response to a particular drug of abuse. This test card thus provides for the simultaneous detection of multiple analytes." Ex. 1005, 2:45-52.

A POSITA at the time of the alleged invention would have been motivated to use additional test strips in MacKay's holder or to use more than one of MacKay's holders with the cup and insert of Cipkowski to supply the limitations of Claim 9. Decl. ¶ 92. A POSITA would have found it obvious to equip the holder and container of MacKay with additional test strips to achieve the benefits expected from detecting the presence or absence of different analytes as taught by Cipkowski. *Id.* MacKay teaches that suitable test strips include test strips of analytes for drugs. Ex. 1004, 7:39-48. Cipkowski teaches that field testing for drugs must be simple, reliable and hygienic, and provides these benefits by providing a multi-strip test card for use with its insert to provide for simultaneous detection of multiple analytes. Ex. 1005, 1:9-61, 2:45-52. Cipkowski's teachings of the benefits of simultaneous detection of multiple analytes for drugs of abuse apply equally to drug testing with the device in MacKay. Decl. ¶ 92.

6. Dependent Claim 12: "… different narcotics ..."

Cipkowski discloses multiple assay test strips that detect different analytes, where the different analytes are different narcotics, such as PCP, cocaine, amphetamines, marijuana and opiates, which are the same five drugs listed as narcotics in the '019 patent specification. *Compare* Ex. 1005, Fig. 10 *with* Ex. 1001, 7:64-8:3. "It is a further object of the present invention to provide a test card having a plurality of immunoassay test strips thereon with each strip being responsive to a particular drug of abuse." Ex. 1005, 2:6-9; *see also id.,* 2:49-52. As discussed above with respect to claim 9, Cipkowski's teachings of the benefits of simultaneous detection of multiple analytes for drugs of abuse apply equally to drug testing with the device in MacKay. Decl. ¶ 93.

7. Dependent Claims 14 and 15: "… urine"

Both MacKay and Cipkowski disclose testing urine. MacKay's test strips can be pregnancy test strips or tests strips for analytes such as drugs. Ex. 1004, 7:39-47. At the time of the priority date of the '019 patent, urine was a liquid commonly tested for pregnancy or drugs using test strips and sample containers. Decl. ¶ 94. Furthermore, MacKay cites U.S. Patent No. 4,857,453 ("Ullman"), which is incorporated in its entirety by reference, as discussing examples of suitable test strips. *Id.*, 7:50-53. Ullman discloses test strips for use with urine. Ex. 1011, 17:11-15, 21:49-55. The invention in Cipkowski specifically "relates to

a test kit for the collection and testing of urine samples for drugs of abuse." Ex. 1005, 1:4-5 ; *see also id.,* 1:63-66.

C. Ground III: Claim 13 is Rendered Obvious by MacKay in view of Cipkowski and EP0860701

Neither MacKay nor Cipkowski expressly discloses a sample integrity monitoring system for detecting the presence of adulterants or contaminants; however, the use of a sample integrity monitoring system in devices for testing biological fluid for multiple narcotics was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 95-96.

For example, EP0860701 discloses a test strip holder, constructed according to DE, with multiple test strips for detecting narcotics and an additional test strip for indicating whether the bodily fluid being analyzed has been altered or tampered with. Ex. 1007, 1:50-53, 2:85-89, 3:9-20, 3:23-30.

A POSITA would have considered it obvious to use one of the multiple test strips of Cipkowski for sample integrity monitoring, as taught by EP0860701. Decl. ¶ 97. EP0860701 provides a suggestion and motivation to combine a multiple strip holder, as taught by Cipkowski, with a sample integrity monitoring strip. EP0860701 teaches that drug addicts try to conceal their drug consumption by tampering with the urine analysis. *Id.*, 1:28-31, 36-38, 41-43. EP0860701 expressly identifies a need for test strip combinations, *i.e.,* multi-strip devices that detect of foreign substances in urine and identifying tampering. *Id.*, 1:44-48. It

would have been easy to add an integrity monitoring strip to a multi-strip version of MacKay, and a POSITA would have had a reasonable expectation such a combination would have succeeded. Decl. ¶ 97.

D. Ground IV: Claims 9, 10 and 14 are Rendered Obvious by MacKay in view of Charm or May

1. Dependent Claim 9: "… additional strips ..."

MacKay does not expressly disclose additional assay test strips. However, the use of multiple assay strips to detect different analytes was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 98-102.

For example, Charm discloses an analyte test device comprising a one-piece, molded housing 12, formed of an injection-molded transparent styrene polymer, defining an elongated housing cavity 14 with open end 16, and a test strip 28 disposed within the cavity of the housing. Ex. 1006, Fig. 1, 4:64-5:2, 5:10-12. The housing comprises five liquid impervious sides and a liquid pervious side (open end 16).

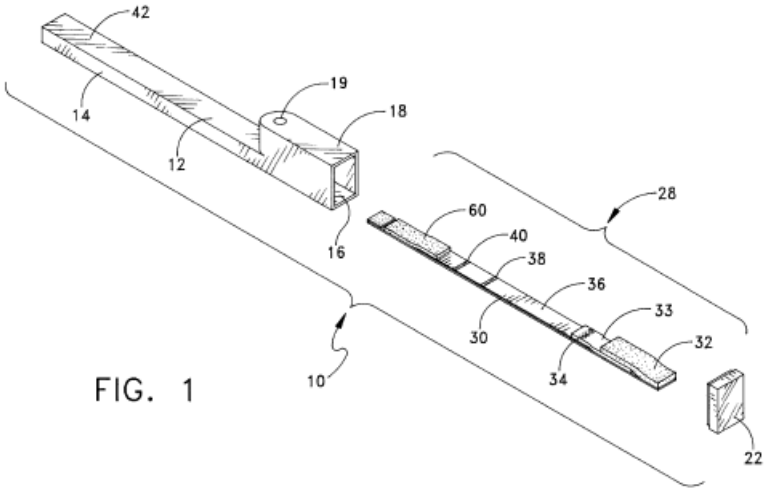


FIG. 1

Although the figures in Charm illustrate only a single test strip, Charm teaches that "the test device may employ one or more test strips directed to a variety of tests." *Id.*, 4:10-12. Accordingly, Charm teaches additional assay test strips that detect the presence or absence of different analytes in a biological fluid.

May also discloses an analytical test device comprising a hollow casing constructed of moisture-impervious material containing a test strip. Ex. 1012, 2:3-8, 10:45-60, Figs. 3 & 4.

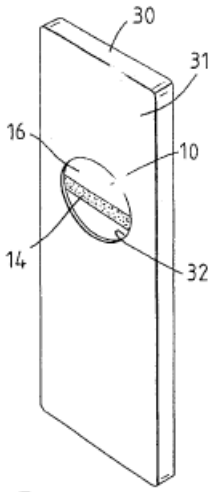


Fig.3.

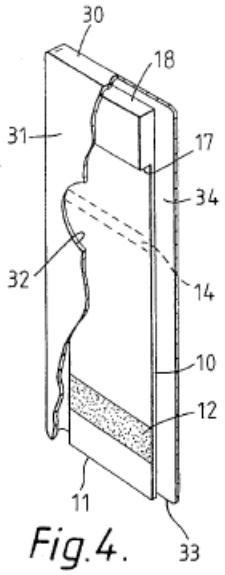


Fig.4.

May further discloses that the device can incorporate two or more separate strips, each with different reagents, to allow for simultaneous determination of a plurality of analytes from a single sample. *Id.*, 6:26-36.

A POSITA would have found it obvious to equip the holder and container of MacKay with additional test strips to achieve the benefits expected from detecting the presence or absence of different analytes in a single step as taught by Charm and May. Decl. ¶ 103. The holder of MacKay is similar in structure to the holders in Charm and May, and a POSITA would have understood that placing multiple strips in a single housing as taught by Charm and May would have increased the efficiency of the MacKay device by allowing multiple tests to be conducted simultaneously in the same manner as they improve the efficiency of the devices in Charm and May. *Id.* ¶ 103. Combining those references would have involved the

predictable use of prior art elements (similar test strip holders, and holders with multiple test strips) according to their established functions (protecting test strips, and simultaneously assaying for multiple analytes, respectively). *Id.* ¶ 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); MPEP § 2141(I).

2. Dependent Claim 10: "… single flow control channel"

As discussed above, Charm and May disclose multiple assay test strips disposed in a single flow control channel. Because Charm and May, like MacKay, disclose only a single flow control channel, a POSITA would have understood the multiple assay test strips of Charm and May to be disposed in a single flow control channel, and it would have been obvious to modify MacKay such that multiple assay test strips would be located in the single flow control channel of MacKay. Decl. ¶ 104.

3. Dependent Claim 14: "… urine"

MacKay, Charm and May all disclose testing urine. MacKay's test strips can be pregnancy test strips or tests strips for analytes such as drugs. Ex. 1004, 7:39-47. At the time of the priority date of the '019 patent, urine was a liquid commonly tested for pregnancy or drugs using test strips and sample containers. Decl. ¶ 105. Furthermore, MacKay cites Ullman, which is incorporated in its entirety by reference, as discussing examples of suitable test strips. Ex. 1004, 7:50-53. Ullman discloses test strips for use with urine. Ex. 1011, 17:11-15,

21:49-55. The test device taught in Charm "is particularly useful in connection with the liquid sample comprising a biological fluid; for example, urine … ." Ex. 1006, 4:6-8. May discloses that the device may be used by immersing a bottom end of the device in a liquid sample (e.g., urine). Ex. 1012, 11:4-8.

E. Ground V: Claims 1-6, 9, 12, 14 and 15 are Anticipated by Lee-Own

1. Independent Claim 1

a) *Preamble: "A device for collecting and assaying a sample of biological fluid, the device comprising:"*

Lee-Own discloses an integrated packaging holder laminate for dipstick immunochromatographic assays, which can be incorporated into a sample collection vessel such as a urine collection vessel, thus allowing immediate specimen testing in the urine container. Ex. 1008, 3:24-26, 8:54-57. The immunochromatographic assay is preferably a "membrane strip." Ex. 1008, 5:52-54.

b) *"(a) a flow control channel …"*

Lee-Own discloses a laminate having one or more membrane strips sealed in a substantially air-tight and substantially liquid-tight manner. Ex. 1008, Figs. 1 & 2, 6:48-54, 7:21-23, 8:9-20. Initially, the membrane strip 12 is totally enclosed. *Id.*, 7:49-52. An assay is carried out by exposing an end of the membrane strip by cutting the laminate along cut marks 16. *Id.*, Fig. 1, 7:53-62. A liquid sample

"will enter through the exposed end of the membrane (the only channel of access available) and migrate up" the strip. *Id.*, 7:60-62.

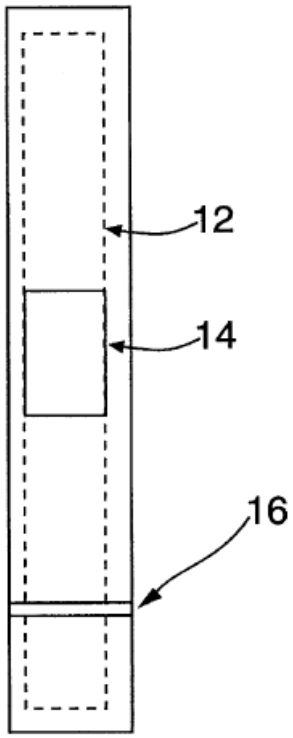


FIG. 1

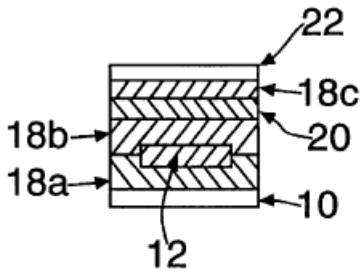


FIG. 2

The laminate is created either by directly attaching the plastic sealing member 10 and transparent plastic sheet 20 by, e.g., sonic welding, or by indirectly attaching them using double-sided tape or adhesive film 18a and 18b. Ex. 1008, 7:27-39. In either case, the laminate surrounds a test strip in a substantially air- and fluid-tight manner to create a flow control channel defined by five liquid impervious sides (the back, front, sides and top of the laminate) and at least one

liquid pervious side (the cut end of the laminate). *Id.*, Figs. 1-3, 3:28-39, 7:28-39, 7:53-62.

c) *"(b) an assay test strip within the flow control channel …"*

The membrane strip of Lee-Own is enclosed within a flow control channel defined by the laminate. An assay is carried out by exposing an end of the membrane strip, e.g., by cutting the laminate or by peeling off a protective cover. Ex. 1008, 6:48-54, 7:21-23, 7:53-55, 8:9-20. The membrane strip has a loading zone, which is the portion of the strip that is exposed at the pervious side of the flow control channel, i.e., the opening in the laminate created by a cut along cut lines 16 or the opening created by peeling off the a protective cover. For example, Figure 6 shows a strip 62 of blue latex on the test strip, the laminate is cut just below the blue latex, and the portion of the strip at the cut lines 16 (not shown in Fig. 6) is a sample loading zone that at which fluid is applied for migration to the test zone. *Id.*, 11:15-20.

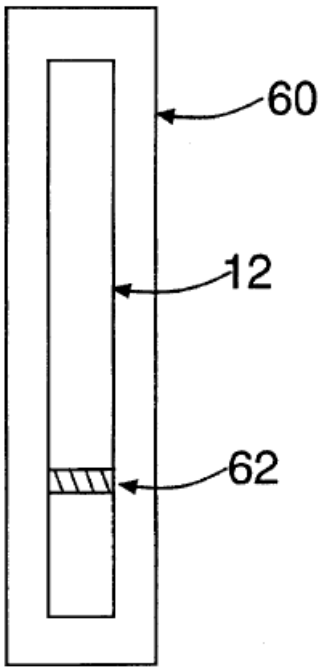


FIG. 6

The laminate with strip can be immersed in the sample (for example, a full urine collection vessel) and the sample contacts the end of the strip at the opening in the laminate (the only channel of access available). Ex. 1008, 7:58-62.

d) *"(c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth"*

A collection vessel 30 has a base, mouth, walls for connecting the base to the mouth, and a cap 32, which can be screwed on to seal the container. Ex. 1008, Fig. 5, 8:54-57, 8:63-64.

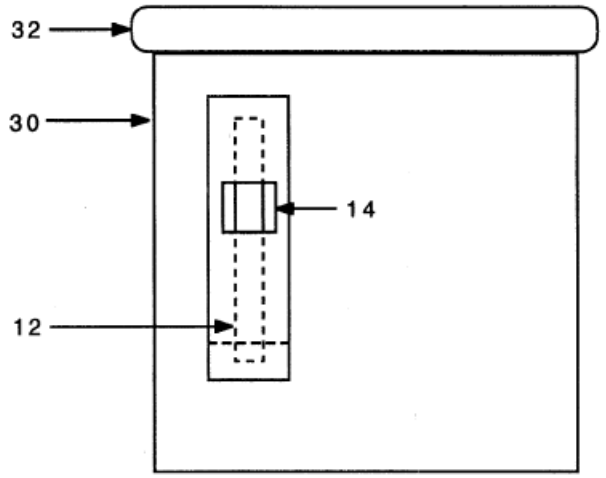


FIG. 5

e) *"wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container …"*

The laminate with membrane strip is secured to the inside wall of the collection vessel allowing immediate specimen testing in the collection vessel. *Id.*, Fig. 5, 3:24-26, 8:54-61, 13:55-58. The laminate can be "pre-cut with the test-strip membrane exposed (*i.e.*, as if the test is ready to run)." *Id.*, 8:61-63. The laminate with membrane strip is attached to the wall of the container with the pervious side of the flow control channel oriented toward the base of the container. *Id.*, Fig. 5, 8:59-61. When the sample in the container rises above to the cut in the laminate (the liquid pervious side of the flow control channel), the liquid is delivered to the sample loading zone of the membrane strip through that liquid pervious side. *Id.*, 9:1-4.

As discussed above, the laminate seals the one or more membrane strips in a substantially air-tight and substantially liquid-tight manner. *Id.*, 6:48-54, 7:21-23, 8:9-20. The membrane strips in Lee-Own allow migration of the sample liquid via capillary action. *Id.*, 5:26-30. When the device is immersed in a full collection vessel, the sample enters through the liquid pervious side of the flow control channel (*e.g.*, the opening created by the cut in the laminate) and migrates up the strip. *Id.*, 7:58-62. Because the flow control channel is closed on all sides other than the bottom, air pressure inside the flow control chamber prevents the liquid from rising into the flow control chamber in an uncontrolled manner. Decl. ¶ 113. "The migration of the sample is strictly controlled by the physical limitations imposed by the confinement of the test-strip membrane in the laminate." Ex. 1008, 8:28-32. The equilibrium between the air pressure inside the flow control channel and the pressure outside the flow control channel prevents excess liquid from entering the flow control channel. Decl. ¶ 113.

2. Dependent Claim 2: "… loosely fitted …"

Lee-Own discloses that "sealing with an adhesive confers non-rigidity to the device, allowing migration of air into interstitial spaces of the adhesive or slight separation of the sealing means to allow for the movement of liquid in the solid phase support." Ex. 1008, 6:60-65. Examples of "sealing means" include adhesive tape, plastic and mylar. *Id.*, 6:56-58. Accordingly, sealing with an

adhesive, separates the tape, plastic or mylar layers of the laminate from each other, creating a looser fit between the claimed sides of the flow control channel and the assay test strip. Decl. ¶ 114.

3. Dependent Claim 3: "… liquid impervious backing; and … a holder …"

As discussed above, Lee-Own discloses a laminate that seals one or more membrane strips in a substantially air-tight and substantially liquid-tight manner. Ex. 1008, 6:48-53, 7:21-23, 8:9-20. The laminate defines the claimed flow control channel. The membrane strip 12 of the laminate is attached to a sealing member 10 (plastic, mylar or other suitable material). *Id.*, Fig. 3, 7:28-32. The sealing member 10 constitutes a liquid impervious backing as claimed.

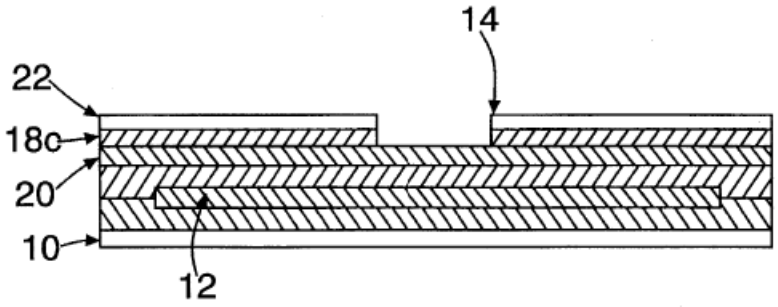


FIG. 3

Also as discussed above, Lee-Own discloses that the laminate with membrane strip may be attached to the inside wall of the collection vessel by adhesive film. Ex. 1008, Fig. 5, 8:59-63. The adhesive film, attaching the laminate with membrane strip to the inside wall of the collection vessel, constitutes a holder fittable inside the fluid sample container. Decl. ¶ 116. The holder, *i.e.*,

the adhesive film, forms a slot between the inner wall of the container with the laminate, and backing 10, received therein. *Id.*

4. Dependent Claim 4: "… holder and … container are curved …"

In Lee-Own, the laminate with membrane strip is attached to the inside wall of the collection vessel, *e.g.*, with an adhesive film. Ex. 1008, Fig. 5, 8:59-64. A POSITA would understand that inside wall of the collection vessel of Lee-Own is curved in shape. *See id.*, Fig. 5, 8:63-65 (cap 32 screws on to collection vessel 30); Decl. ¶ 117. One would also understand that the holder, *e.g.*, the adhesive film, which is attached to the inside wall of the collection vessel, would follow the curvature of the inner diameter thereof. *Id.* ¶ 117.

5. Dependent Claim 5: "… cup …"

The collection vessel 30 of Lee-Own is a cup, as claimed, having a base, mouth, walls for connecting the base to the mouth, and a cap 32, which can be screwed on to seal the container. Ex. 1008, Fig. 5, 8:63-64; Decl. ¶ 118.

6. Dependent Claim 6: "… watertight cap ..."

The collection vessel 30 has a cap 32, which can be screwed on to seal the container to provide package integrity. Ex. 1008, Fig. 5, 8:63-64. A POSITA would have understood "package integrity" to mean at least that the cap is watertight. Decl. ¶ 119.

7. Dependent Claim 9: "… additional strips ..."

Lee-Own discloses that the laminate may include more than one membrane strip whereby more than one analyte can be detected in a sample. Ex. 1008, 3:40-42, 7:20-22, 13:64-65 (claiming assay means for more than one analyte), 15:8-10 (claiming multiple strips capable of detecting more than one analyte); Decl. ¶ 120.

8. Dependent Claim 12: "… different narcotics ..."

Lee-Own discloses that the membrane strips may be used in assays for drugs of abuse such as illicit drugs and metabolites thereof and that drugs of abuse include cocaine, cannabinoid, amphetamines, opiates and PCP. Ex. 1008, 1:42-54, 5:9-12, 8:9-15. A POSITA would have understood that these drugs of abuse are narcotics, and that different strips could test for different narcotics. Decl. ¶ 121.

9. Dependent Claims 14 and 15: "… urine"

The sample collection vessel of Lee-Own may be a urine collection vessel, thus allowing immediate specimen testing of urine. Ex. 1008, 3:24-26, 8:54-57.

F. Ground VI: Claims 3-6 are Rendered Obvious by Lee-Own in view of Tydings

1. Dependent Claim 3: "… liquid impervious backing; and … a holder …"

As discussed above, Lee-Own discloses each element of claim 1 from which claim 3 depends. To the extent Lee-Own does not disclose the holder in claim 3, it would have been obvious to combine the holder in Tydings with the cup and assay test device of Lee-Own. Decl. ¶¶ 123-28.

As discussed above, Lee-Own discloses a laminate that seals one or more membrane strips in a substantially air-tight and substantially liquid-tight manner. Ex. 1008, 6:48-54, 7:21-23, 8:9-20. The laminate defines the claimed flow control channel. Decl. ¶ 124. The membrane strip 12 of the laminate is attached to "a sealing member 10 (plastic, mylar or other suitable material)." *Id.*, Fig. 3, 7:28-32. The sealing member 10 constitutes a liquid impervious backing as claimed.

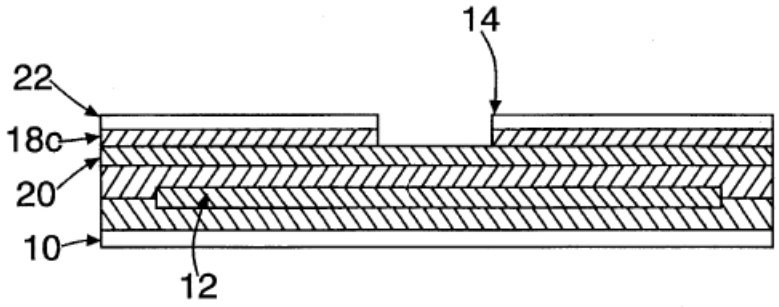


FIG. 3

Tydings teaches a test strip card similar to the test strip card of Lee-Own. Tydings discloses an assay device for field urine testing including a container for collecting a urine sample and an assay assembly for chemically analyzing the urine sample. Ex. 1009, Abstract, 4:16-25, 5:1-7, 5:29-36, 6:14-19. The test strips are enclosed in channels defined by a liquid impermeable backing 8 and a transparent plastic front cover 14 which seals the assays strips at the bottom and sides preventing contamination by urine or another assay strip. *Id.*, Fig. 4, 2:46-3:2, 3:15-17, 4:37-41, 4:57-60, 5:19-22, 6:21-32.

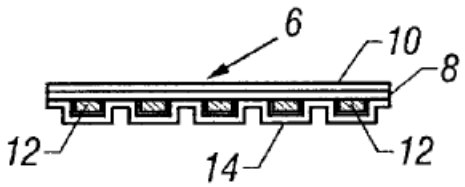


FIG. 4

Tydings discloses alternative holders fittable inside the container with slots for holding the backing 8, strips 12, and front cover 14 (the "assay means") in the urine cup. In Figure 2, the assay means are held in place by a rear cover 16 and tabs 18 that hold the assay means in a slot against the inner wall of the cup. *Id.*, 3:2-6, 4:42-45, 4:61-67.

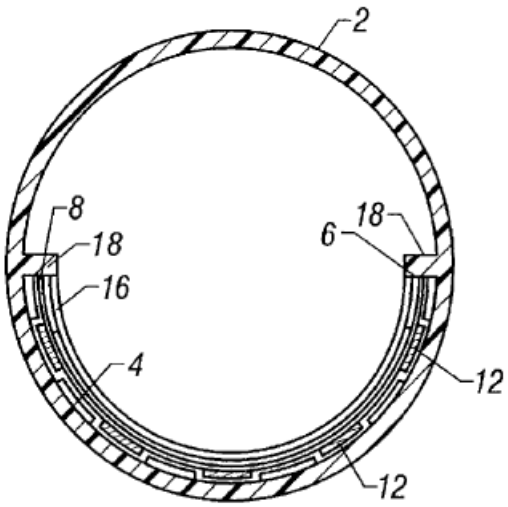


FIG. 2

In the embodiment of Fig. 9, the assay means are held in place by an injection molded rear cover 30 having slots 36 that retain the back and front cover of the assay means. *Id.*, Fig. 7, 3:36-48, 4:42-45, 4:61-67. The assay means 6 is inserted

into the vertical slots 36 and the assembled holder and assay means is placed inside the container. *Id.*, Fig. 9, 3:52-55, 4:42-45, 4:61-67.

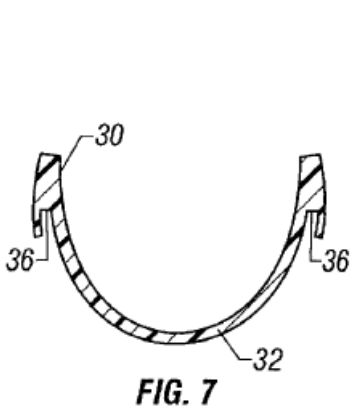


FIG. 7

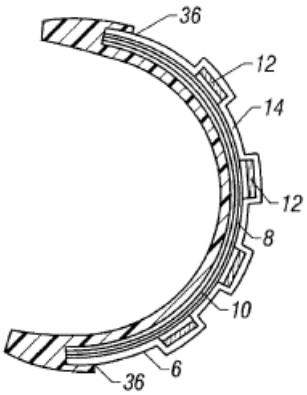


FIG. 9

A POSITA would have found it obvious to employ an assay means holder of Tydings (*e.g.*, the rear cover and tabs of Fig. 2 or the slotted holder of Figs. 7 and 9) to retain the laminate of Lee-Own in a sample container to achieve the benefits expected from a combination sample fluid container/assay device that permits the assay results to be read through a window of the container. Decl. ¶ 128. There would have been an expectation of success because the holders of Tydings are configured to retain an assay means including one or more test strips enclosed in channels defined by an impermeable backing and a front cover; Ex. 1009, Fig. 4, and the laminate of Lee-Own includes a test strip enclosed in a channel defined by an impermeable backing and a front cover; *e.g.*, Ex. 1008, Figs. 2-3. Furthermore, the holders of Tydings would position the laminate of Lee-Own so that the

laminate could be read through the transparent wall of the container as taught by Tydings and Lee-Own. Ex. 1009, 4:27-30, 5:9-12; Ex. 1008, 8:57-59.

2. Dependent Claim 4: "… holder and … container are curved …"

Tydings further discloses that the holder (rear cover 16 and tabs 18 in Fig. 2 and slotted rear cover 30 in Figs. 7 and 9) and fluid sample container 2 (Figs. 1 and 2) are curved in shape and the respective holders follow the curvature of the inner diameter of the container. Ex. 1009, Figs. 2, 7 & 9, 4:42-45, 4:61-67.

3. Dependent Claim 5: "… cup …"

Both Lee-Own and Tydings disclose a fluid sample container that is a cup.

Fig. 5 of Lee-Own shows a collection vessel 30 has a base, mouth, walls for connecting the base to the mouth, and a cap 32, which can be screwed on to seal the container. Ex. 1008, Fig. 5, 8:63-64.

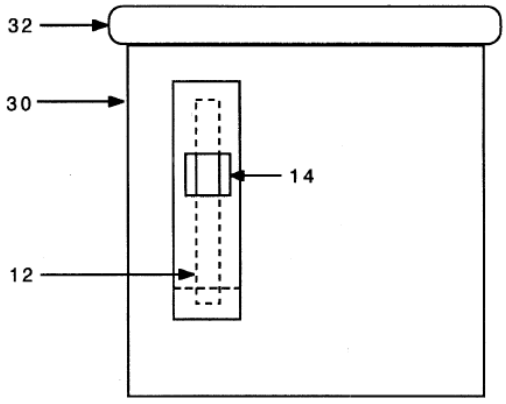
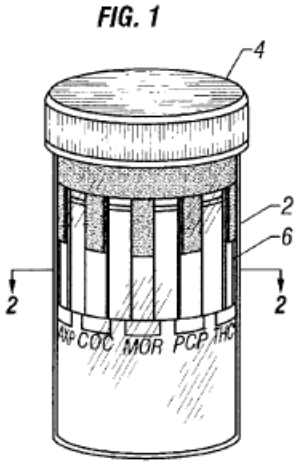


FIG. 5

Collection vessel 30 is a cup. Decl. ¶ 131.

In Tydings, "[t]he assay device generally includes a container 2 with a screw lid 4 for closing the open end of the container 2." Ex. 1009, Fig. 1, 2:32-34, 4:18-21, 5:30-33.



Container 2 of Tydings is a cup. Decl. ¶ 132.

4. Dependent Claim 6: "… watertight cap ..."

Both Lee-Own and Tydings disclose a watertight cap fittable over the mouth of the cup. Decl. ¶ 133. In Lee-Own, a screw-on cap 32 seals the container. Ex. 1008, Fig. 5, 8:63-64. In Tydings, "[t]he assay device generally includes a container 2 with a screw lid 4 for closing the open end of the container 2." Ex. 1009, 2:32-34, 4:18-21, 5:30-33. The lid seals the opening of the container. *Id.*, 1:46-48, 4:18-22, 5:30-33.

G. Ground VII: Claims 9, 11, 12, 14 and 15 are Rendered Obvious by Lee-Own in view of DE

1. Dependent Claim 9: "… additional strips ..."

Petitioner contends that Lee-Own anticipates claim 9, *supra* at 46; however, to the extent Lee-Own does not disclose additional assay test strips that detect different analytes, devices with multiple test strips that detect the presence or absence of different analytes in a biological fluid were well known. Decl. ¶¶ 134-35.

DE discloses a multiple test strip card. Ex. 1010, 2:15-20. DE further discloses that multiple test strips, each detecting a different analyte, are used when detection of a plurality of substances is desired. *Id.*, 2:22-24. DE provides the motivation to use the laminate of Lee-Own with multiple test strips, each of which detects the presence or absence of different analytes in a biological fluid. Decl. ¶ 135. Specifically, DE teaches that when testing for drugs of abuse, it must be assumed that the person being tested consumes a variety of narcotics and that testing for multiple narcotics with multiple strips, each of which tests for a different analyte, in a single device "makes it possible to combine multiple working steps into one working step." Ex. 1010, 2:22-25; *see also id.,*1:21-24. The benefit of combining multiple test strips, each testing for a different analyte, would be equally applicable to the multiple strip embodiment of Lee-Own because

Lee-Own is concerned with the same problem as DE, testing urine samples for drugs of abuse. Ex. 1008, 8:9-15.

2. Dependent Claim 11: "… separate flow control channel[s]"

Lee-Own discloses multiple assay test strips but does not expressly teach they should be placed in separate channels. However, the use of multiple assay strips disposed in separate flow control channels was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 136-37.

DE teaches a test strip holder for holding multiple assay test strips in separate flow control channels. DE teaches a "flat plastic plate with five recesses in strip form" into which test strips are inserted. Ex. 1010, Fig. 1, 4:21-26. A "cover film is glued on the holder 1 with the inserted test strips," forming multiple flow control channels comprising five liquid impervious sides and one liquid pervious side (the opening). *Id.*, 5:9-11.

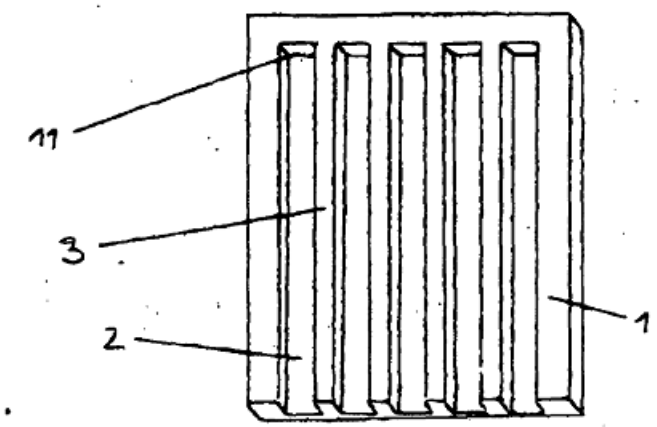


Fig. 1

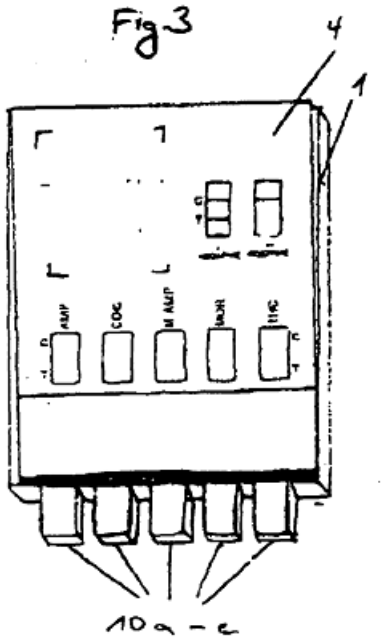
DE provides the motivation to implement the multiple assay test strip of Lee-Own (which does not specifically teach whether the multiple strips are in a single channel or in separate channels) by disposing the strips in separate flow control channels, as taught by DE. Decl. ¶ 138. DE teaches that the recesses holding the strips are spaced apart by ridges (referred to as "webs 3") by a distance sufficient to ensure that the strips "do not make contact with each other." *Id.*, 4:27-5:7. It would have been obvious to implement Lee-Own by creating a laminate in which the strips are separated sufficiently far apart to preclude contact with each other, and where the upper and lower sheets of the laminate make contact between the strips to seal them in separate flow control channels. Decl. ¶ 138. Both Lee-Own and DE utilize an adhesive film to seal the test strips in flow control channels. Ex. 1008, 7:27-36; Ex. 1010, 3:16-17. Separation of strips in Lee-Own, as taught by DE, using the adhesive film of Lee-Own would have been a routine design choice, and there would have been an expectation that it would have been successful and accomplished the goal of separating the strips. Decl. ¶ 138. Accordingly, the combination of Lee-Own in view of DE renders claim 11 obvious.

3. Dependent Claim 12: "… different narcotics ..."

Petitioner contends that Lee-Own anticipates claim 12; however, to the extent Lee-Own does not disclose that different analytes are different narcotics,

using a multi-strip test card to detect analytes of different narcotics on different test strips was well known in the art before the priority date of the '019 patent.

For example, the holder of DE, Fig. 3 depicts test strips 10a-e for amphetamines (labeled "AMP"), cocaine (labeled "COC"), methamphetamine (labeled "M AMP"), morphine (labeled "MOR") and tetrahydrocannabinol (labeled "THC"). Decl. ¶ 140.



DE provides the motivation to use the multiple strip embodiment of Lee-Own to test for analytes of different narcotics. DE teaches that typical test strips test for only a specific substance, and therefore testing of drug addicts, which requires testing for a variety of narcotics, required test administration with several different strips. Ex. 1010, 1:21-24. A POSITA would have readily understood the advantage of using the multiple strip embodiment of Lee-Own for drug testing, and

specifically for using multiple strips in Lee-Own, wherein the strips detect different narcotics analytes. Accordingly, the combination of Lee-Own in view of DE renders claim 12 obvious. Decl. ¶¶ 139-41.

4. Dependent Claims 14 and 15: "… urine"

Both Lee-Own and DE disclose testing urine. Ex. 1008, 5:1-6, 7:58-62, 8:54-57; Ex. 1010, 1:18-19.

H. Ground VIII: Claim 13 is Rendered Obvious by Lee-Own in view of DE and EP0860701

Neither Lee-Own nor DE disclose the integrity monitoring system required by claim 13. However, the use of a sample integrity monitoring system, as claimed in 13, with the multiple strip narcotics testing system of claim 12 was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 143-44.

For example, EP0860701 teaches a modification to the multi-strip card of DE whereby one of the strips in the card "indicates that the body fluid to be analyzed, *i.e.*, in particular, urine, has not been altered and has not been tampered with." Ex. 1007, 3:9-12, 3:25-27.

As discussed above, it would have been obvious to combine the teachings of DE with Lee-Own to create a multi-strip laminate for drug testing, *supra* Section X.G, and EP0860701 provides a suggestion and motivation to combine its teachings with Lee-Own and DE. EP0860701 expressly teaches the combination of an integrity monitoring system with the multi-strip holder of DE, *id.*, 2:85-89,

3:23-25. EP0860701 teaches that drug addicts try to conceal their drug consumption by tampering with the urine analysis. *Id.*, 1:28-31, 36-38, 41-43. EP0860701 expressly identifies a need for test strip combinations, *i.e.*, multi-strip devices that detect foreign substances in urine and identify tampering. *Id.*, 1:44-48. It would have been easy to add an integrity monitoring strip to a multi-strip version of Lee-Own, and a POSITA would have had a reasonable expectation such a combination would have succeeded. Decl. ¶ 145. Accordingly, the combination of Lee-Own in view of DE and EP0860701 renders claim 13 obvious. *Id.*

I. Ground IX: Claims 1-6, 9, 11, 12, 14 and 15 are Rendered Obvious by DE Alone or in View of Cipkowski

1. Independent Claim 1

a) *Preamble: "A device for collecting and assaying a sample of biological fluid, the device comprising:"*

DE discloses a test strip card (referred to in DE as a "holder") holding one or more test strips for detecting foreign substances, such as illicit drugs, where exposed portions of test strips are dipped or immersed in a sample of bodily fluids, such as blood or urine. Ex. 1010, 1:10-11, 2:15-20. DE's disclosure of dipping or immersing test strips in a sample of bodily fluid inherently discloses that the bodily fluids have been collected. Decl. ¶ 146.

Furthermore, it would have been obvious to use the multiple-strip test card of DE with a cup for collecting biological fluid disclosed in Cipkowski. Decl.

¶ 147. As discussed in Cipkowski, the use of containers for collecting samples to be assayed by on-site drug testing devices, such as the device taught by DE, was common prior to the alleged invention of the '019 Patent. Ex. 1005, 1:17-25, 1:39-60. Cipkowski also teaches that further off-site analysis of samples testing positive for drugs may be required, and that a container with a sealing cap can be used to ship samples for further analysis. *Id.*, 1:15-17, 1:64-67, 2:26-31. Accordingly, Cipkowski provides a suggestion and motivation to use the multiple-strip test card of DE with a cup for collecting the biological fluid. Decl. ¶ 147.

b) *"(a) a flow control channel …"*

DE teaches a test strip card for holding multiple assay test strips in separate flow control channels. DE teaches a "flat plastic plate with five recesses in strip form" into which test strips are inserted. Ex. 1010, Fig. 1, 4:21-26. A "cover film is glued on the holder 1 with inserted test strips," forming multiple flow control channels, each of which is defined by five liquid impervious sides, the four sides of the recesses and the under surface of the film, and one liquid pervious side (the opening). *Id.*, 5:9-11.

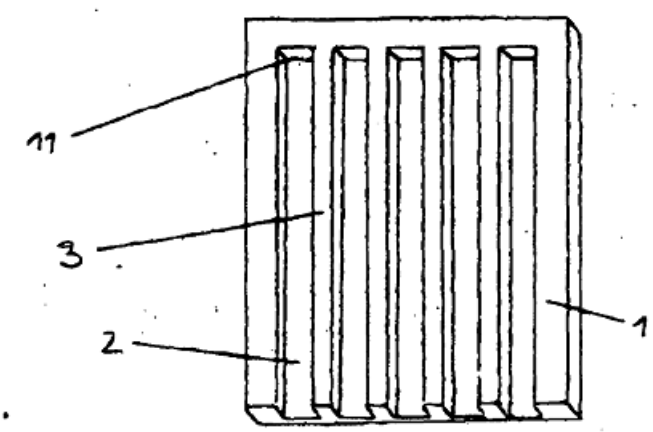


Fig. 1

The adhesive cover film forming one of the liquid impervious sides may have transparent windows for observing detection fields on the strips, and protects the strips against physical manipulation and destruction. *Id.*, 3:19-21. Accordingly, a POSITA would have understood that the adhesive cover film is made of plastic or similar material that is water and air tight. Decl. ¶ 149.

c) *"(b) an assay test strip within the flow control channel …"*

Test strips are inserted into the flow control channels defined by the flat plastic plate and the cover film. Ex. 1010, 5:9-11. DE discloses test strips comprising a plastic substrate to which an absorbing substrate material that absorbs fluid is applied. *Id.*, 1:11-13. Each test strip is disposed in a flow control channel so that the end that is to absorb sample fluid is at the open, liquid pervious end of the channel where it contacts sample fluid upon immersion in the sample fluid, and the end with the test indicator fields is oriented away from the opening and

protected by the cover film that secures the strips in the flow control channels. *Id.*, 2:18-20, 5:9-13, Figs. 2 & 3 (showing ends of strips 10a-c at opening of flow control channels and transparent windows over the indicator fields in the middle of the flow control channels); Decl. ¶ 150.

d) *"(c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth"*

As discussed above, DE discloses dipping or immersing the test strips in the sample fluid, and it is inherent or at least obvious that the sample fluid, such as urine, would be in a container to facilitate dipping or immersing. *Supra* at 57. It would also be inherent that any such container would have an opening to allow the strips to be dipped or immersed in the urine. Decl. ¶ 151. To the extent DE does not disclose a sample fluid container with a base and walls connecting the base to a mouth, it would have been obvious to use such a container, for example in the form of a urine cup, to permit the strips to be dipped into the sample in a hygienic manner. Ex. 1010, 2:22-25; Decl. ¶¶ 151-54.

For example, it would have been obvious to combine DE with the cup and holder of Cipkowski. Decl. ¶ 152. Cipkowski discloses a cup 13 with a closed bottom, open top end 14 and a cylindrical wall 12 connecting the bottom with the opening. Ex. 1005, Figs. 1 & 2, 3:27-33.

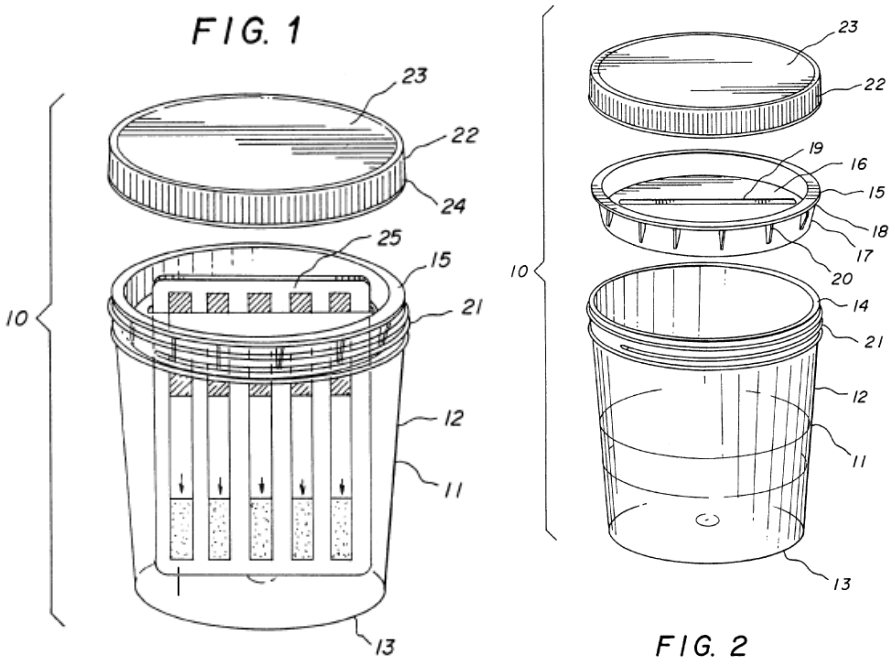


FIG. 2

A test card with multiple test strips can be inserted into the slit 19 of inner closure insert 15. *Id.*, 4:29-33. Cipkowski's cup and inner closure insert 15 accomplishes the goal of allowing strips to be dipped into a biological sample fluid in a hygienic manner. Decl. ¶ 153.

Both DE and Cipkowki identify the need to provide a multiple-strip drug test card for dipping or immersing test strips in a biological sample fluid, urine, in a hygienic manner. Ex. 1010, 2:22-25; Ex. 1005, 1:15-25. Therefore, both DE and Cipkowki contain the suggestion and motivation to combine the multiple-strip test card of DE with the additional hygiene features of Cipkowski's cup and holder. Both DE and Cipkowski employ the same form factor, *i.e.*, a multiple-strip test card. *Compare* Ex. 1010, Fig. 3 *with* Ex. 1005, Fig. 9. Therefore, combining DE and Cipkowski would have involved a simple substitution of one known element

(DE's multiple-strip card) for another (Cipkowki's multiple-strip card) to produce predictable results. Decl. ¶ 154; *KSR*, 550 U.S. at 417; MPEP § 2141(I). No design changes would be necessary to either the test card of DE or the cup and holder of Cipkowski to obtain the benefits of Cipkowski's cup and holder. Decl. ¶ 154.

e) *"wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container …"*

DE discloses that the test strips, which are inside the flow control channels of the test strip card and protruding through the liquid pervious side, are dipped or immersed in the sample fluid. Ex. 1010, 2:18-25. As discussed above, disclosure of a sample fluid container is inherent or obvious in view of DE's disclosure of dipping or immersing test strips in sample fluid. It is inherent that the liquid pervious openings of the test card are oriented toward the base of the sample fluid container so the ends of the test strips can be immersed in a sample that has been added to the container and sample fluid is delivered to the sample loading zone. *Id.*, 2:18-25, 4:25-26. Delivery of sample fluid to the sample loading zone is without migration through an intermediate structure because DE does not disclose any intermediate wicking structure. Decl. ¶ 155.

To the extent DE does not inherently disclose that the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented

toward the base of the sample fluid container, it would have been obvious to do so because there would be no other way to cause DE's test strips to be dipped or immersed in the sample fluid, and to do so would comport with common sense. *KSR*, 550 U.S. at 421-22; Decl. ¶ 156. Furthermore, as discussed above, *supra* at 60-62, it would also have been obvious to use DE's test strip card the same way as the multiple test strip card in Cipkowski is used, namely, to insert DE's test strip card into Cipkowski's cup through the slot in the holder so the test strip card is submerged in the sample fluid above the bottom of the card with sample fluid delivered to the sample loading zone at the liquid pervious opening of the test card. Ex. 1005, 2:15-26, 3:55-57, 4:1-3, 4:29-38; Decl. ¶ 156.

As discussed above, DE's adhesive cover film and the plastic plate with recesses form substantially air-tight and liquid-tight channels. When the test strip card is dipped or immersed in the sample fluid, the sample enters through the liquid pervious side of the flow control channels (*i.e.*, the exposed ends of the recesses in the flat plate) and migrates up the strip. Decl. ¶ 157; Ex. 1010, 2:18-20, 4:25-27. Because each flow control channel is closed on all sides other than the bottom, air pressure inside the flow control chamber prevents the liquid from rising into the flow control chamber in an uncontrolled manner. Decl. ¶ 157. The equilibrium between the air pressure inside the flow control channel and the

pressure outside the flow control channel prevents excess liquid from entering the flow control channel. *Id.*

2. Dependent Claim 2: "… loosely fitted …"

DE teaches a "flat plastic plate with five recesses in strip form" into which test strips are inserted. Ex. 1010, Fig. 1, 4:21-26. The recesses are loose enough so that strips can be pushed into the recesses up to a "stop" at the end of the recess. Ex. 1010, 3:9-10. Furthermore, in a detailed description of the invention, DE discloses that the width of the recesses can be more than the width of a commercially available test strip. *Id.*, 4:21-23. A POSITA would have understood this means that the sides of the recesses are loosely fitted around the test strips. Decl. ¶ 158.

3. Dependent Claim 9: "… additional strips ..."

DE discloses a multiple test strip card. Ex. 1010, 2:15-20. DE further discloses that multiple test strips, each of which detects a different analyte, are used when detection of a plurality of substances is desired. *Id.*, 2:22-24. Cipkowski also discloses a test card with a plurality of strips, each of which detects a different analyte, fastened side-by-side to provide simultaneous detection of multiple analytes." Ex. 1005, 2:46-53.

4. Dependent Claim 11: "… separate flow control channel[s]"

As discussed above, DE teaches a "flat plastic plate with five recesses in strip form" into which test strips are inserted. Ex. 1010, Fig. 1, 4:21-26. When the cover film is glued onto the flat plastic plate, the recesses form separate flow control channels, each with a separate test strips. *Id.*, 5:9-11.

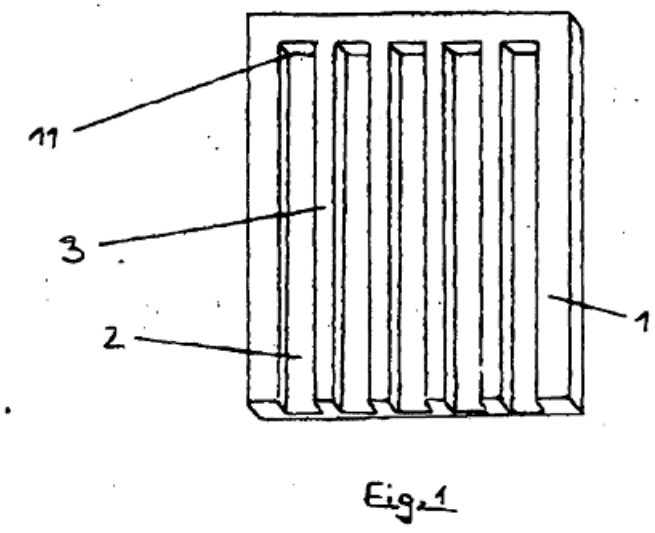
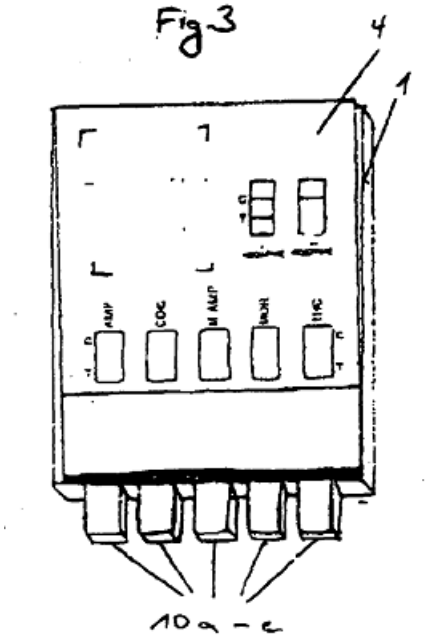


Fig. 1

5. <u>Dependent Claim 12: "… different narcotics ..."</u>

The test strip card in DE is intended to solve problems associated with the testing of urine from drug addicts, and in particular with testing addicts for a variety of narcotics using different test strips. Ex. 1010, 1:21-24, 2:15-16. The multiple test strip card illustrated in Fig. 3 of DE includes test strips 10a-e for amphetamines (labeled "AMP"), cocaine (labeled "COC"), methamphetamine (labeled "M AMP"), morphine (labeled "MOR") and tetrahydrocannabinol (labeled "THC"). Decl. ¶ 161.



Cipkowski also discloses multiple assay test strips that detect different analytes, where the different analytes are different narcotics. Ex. 1005, 2:6-10, 2:50-52.

6. <u>Dependent Claims 14 and 15: "… urine"</u>

Both DE and Cipkowski disclose devices for testing urine. Ex. 1010, 1:10-11, 2:15-20; Ex. 1005, 1:4-5, 1:63-67.

J. Ground X: Claim 13 is Rendered Obvious by DE in view of Cipkowski and EP0860701

Neither DE nor Cipkowski discloses the integrity monitoring system required by claim 13. However, the use of a sample integrity monitoring system, as claimed in 13, with the multiple strip narcotics testing system of claim 12 was well known in the art before the priority date of the '019 patent. Decl. ¶¶ 164-65.

For example, EP0860701 teaches a modification to the multi-strip card of DE whereby one of the strips in the card "indicates that the body fluid to be analyzed, *i.e.*, in particular, urine, has not been altered and has not been tampered with." Ex. 1007, 3:9-12, 3:25-27.

EP0860701 provides a suggestion and motivation to combine its teachings with DE and Cipkowski. EP0860701 expressly teaches the combination of an integrity monitoring system with the multi-strip card of DE. *Id.*, 2:85-89, 3:23-25. Accordingly, the combination of DE in view of Cipkowski and EP0860701 renders claim 13 obvious. Decl. ¶ 166.

K. Ground XI: Claims 3-6 are Rendered Obvious by DE in view of Cipkowski

1. Dependent Claim 3: "… liquid impervious backing; and … a holder …"

DE does not disclose the holder of claim 3; however, Cipkowski does disclose the claimed holder and it would have been obvious to combine the holder of Cipkowski with DE. Decl. ¶¶ 167-73.

DE teaches a multiple test strip card with flow control channels formed from a "flat plastic plate with five recesses in strip form" into which test strips are inserted. Ex. 1010, 4:21-26. The bottom of the flat plastic plate defines one of the liquid impervious sides of the flow control channels and is formed as a portion of a liquid impervious backing.

Cipkowski also teaches a multiple test strip card with a liquid impervious side formed as a portion of a liquid impervious backing. The test card of Cipkowski includes a plurality of test strips each disposed in a channel defined by an impervious backing (bottom ply 46), cover (top ply 47), and side walls (central ply 45). Ex. 1005, Fig. 11, 5:9-19, 5:45-46, 5:52-57 (test card may be made of a plastic material, plastic coated cardboard, or thin sheets of plastic which are laminated together).

Cipkowski discloses the holder required by claim 3. Cipkowski discloses a cup-like container 11 having a side wall 12, a closed bottom 13, an open top 14, and an outer cover 22. *Id.*, Fig. 2, 3:27-33. A holder, inner closure insert 15, is fittable within the cup and includes a diametrical slot 19 shaped to accommodate a test card 25. *Id.*, 3:33-40, 4:29-31.

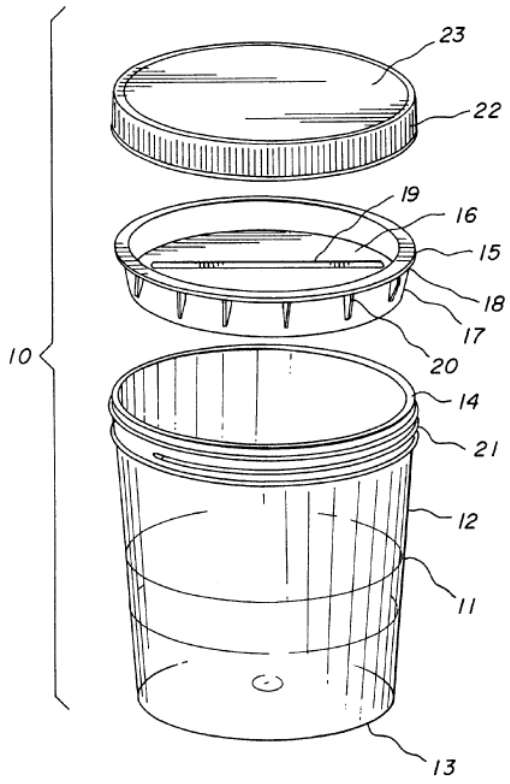
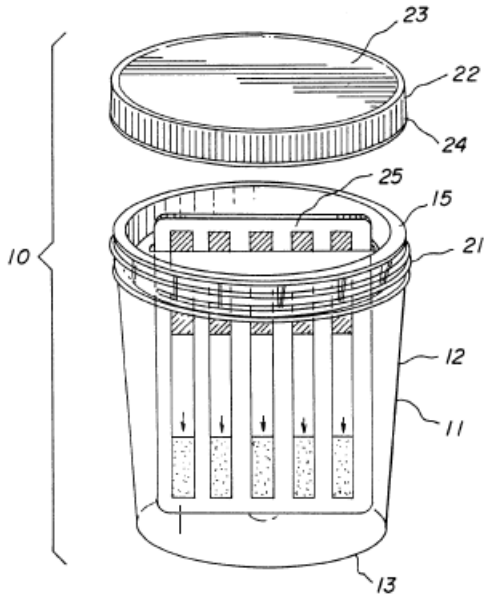


FIG. 2

The test card 25 is inserted into the slot 19 in the holder (insert 15) with the impervious backing (bottom ply 46) in slot 19. *Id.*, Fig. 1, 3:55-57, 4:33-38.

FIG. 1



It would have been obvious to combine the cup and holder of Cipkowski with the multiple strip test card of DE. Decl. ¶ 172. Both references disclose multiple strip test cards for testing urine for illicit drugs, and the test cards in both references are substantially similar, *compare* Ex. 1010, Fig. 3 *with* Ex. 1005, Fig. 9 below, the main difference being that the flow control channels of Cipkowski are not fully enclosed, as they are in DE. Decl. ¶ 172.

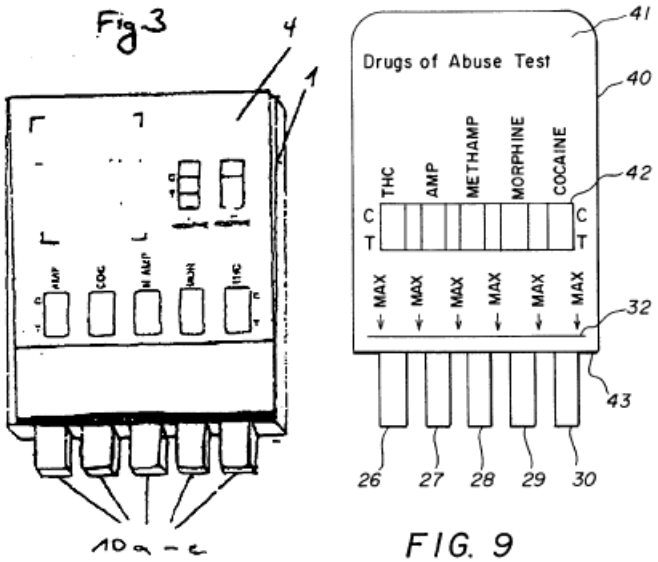


FIG. 9

The test card of DE could easily be used with the cup and holder of Cipkowski without any modification simply by inserting the test card of DE into the slot in the holder of Cipkowski. Decl. ¶ 173. Furthermore, DE and Cipkowski are concerned with solving the same problems present in the prior art: creating a hygienic and convenient way of testing urine for multiple illicit drugs. Ex. 1010, 1:21-2:16; Ex. 1005, 1:21-67. Cipkowski provides the motivation to combine the test card of DE with the cup and holder of Cipkowski because Cipkowski itself advocates the use of its holder for the nearly identical multiple strip test card as used in DE. Ex. 1005, 2:1-5, 2:11-26.

2. Dependent Claim 4: "… holder and … container are curved …"

Cipkowski discloses that the holder (insert 15) and fluid sample container (cup-like container 11) in Cipkowski are curved in shape and that the curved

holder fits into the inside of the cup. Ex. 1005, Figs. 1 & 2. For reasons stated above with respect to claim 3, it would have been obvious to combine DE with the curved holder and cup of Cipkowski.

3. Dependent Claim 5: "… cup …"

Cipkowski discloses a cup-like container 11 having a side wall 12, a closed bottom 13, an open top 14, and an outer cover 22. *Id.*

4. Dependent Claim 6: "… watertight cap ..."

Cipkowski discloses a drug testing cup with a threaded cover 22 to seal the container against leakage from the fluid specimen. Ex. 1005, 3:48-54, 4:60-65 (describing cover 22 as sealing container against leakage).

L. Ground XII: Claims 1-6, 9-11, 12, 14 and 15 are Rendered Obvious by Tydings in View of MacKay or Lee-Own

1. Independent Claim 1

a) *Preamble: "A device for collecting and assaying a sample of biological fluid, the device comprising:"*

Tydings discloses an assay device for field urine testing including a container for collecting a urine sample and an assay assembly for chemically analyzing the urine sample. Ex. 1009, Abstract, 4:16-25, 5:1-7, 5:29-36, 6:14-18.

b) *"(a) a flow control channel …"*

The test device of Tydings includes an assay means having a liquid impermeable backing 8 with assay strips provided on a front surface of the backing. Ex. 1009, Fig. 4, 2:37-40, 2:46-47, 4:23-30, 4:46-50, 5:7-12, 5:35-6:3.

The front surface of the backing is covered by a front cover which seals the assay strips at the bottom and both sides of the assay strips to isolate each assay strip from each other and prevent contamination from either the urine or another assay strip. *Id.*, 2:59-63, 4:37-41, 4:57-60, 5:19-22, 6:10-13, 6:21-32. The front and back covers may be made from plastic and the front cover sealed to the backing by a suitable adhesive or other means such as ultrasonic heat welding. *Id.*, 2:37-40, 2:63-65, 3:14-16, 4:37-41, 4:57-60, 5:19-22.

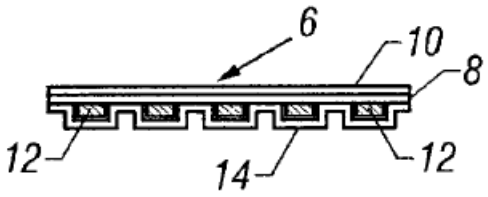


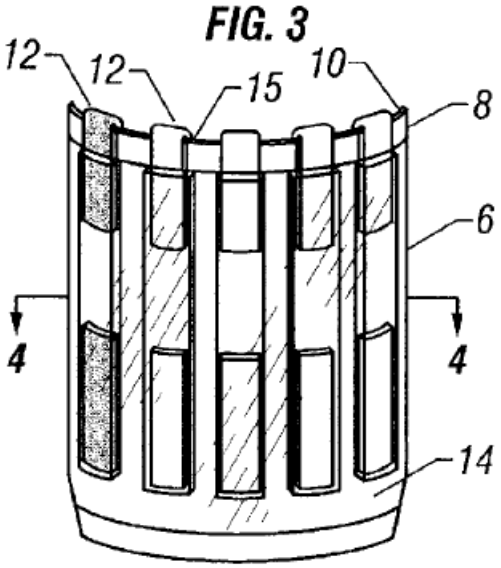
FIG. 4

So sealed, the backing and front cover of Tydings define five liquid impervious sides of a flow control channel as claimed: (a) a back, defined by the backing and (b) a front, bottom, and two sides, defined by the front cover. The backing and front cover also define a liquid pervious side of the channel through which an assay test strip protrudes. *Id.*, Fig. 3, 4:37-41, 4:57-60, 5:19-22, 6:10-13, 6:21-32.

c) *"(b) an assay test strip within the flow control channel …"*

Each test strip 12 is disposed within a respective channel so that a sample loading zone protrudes from the liquid pervious side of the channel and folds over

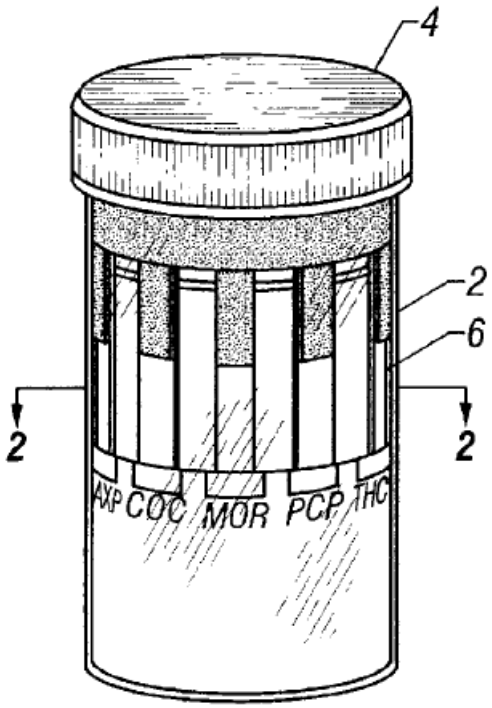
the top edge 15 of the backing 8. *See* Ex. 1009, Fig. 3, 4:37-41, 4:57-60, 5:19-22, 6:10-13, 6:21-32.



d) *"(c) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth"*

Tydings discloses a drug testing cup with a base, an open mouth, and walls connecting the base to the mouth as claimed. Ex. 1009, Fig. 1, 4:19-20, 5:3-5, 5:30-31, 6:15-18.

FIG. 1



e) ***"wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented toward the base of the sample fluid container …"***

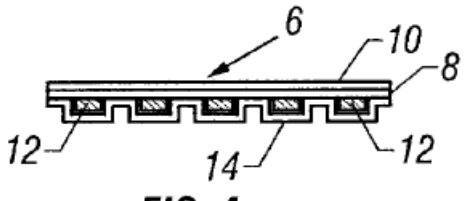
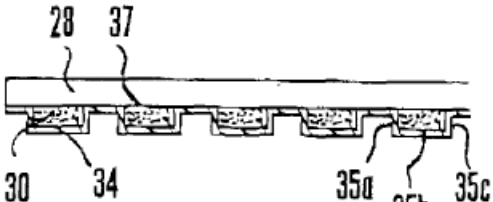
Tydings discloses that the flow control channel defined by the backing and front cover, and strip enclosed therein, is disposed inside the drug testing cup. Ex. 1009, Fig. 1, 4:27-30, 5:5-7, 5:30-36, 6:15-19.

Tydings does not disclose that the liquid pervious side of the flow control channel, *i.e.*, the side from which the end of the assay strip protrudes, is oriented toward the base of the sample fluid container as claimed.

However, at the time of the priority date of the '019 patent, a POSITA would have considered it obvious to orient the flow control channel of Tydings

with the liquid pervious side oriented toward the base of the container. Decl. ¶¶ 184-90.

First, the '019 Patent itself recognizes that the wicking material could be eliminated by "simply reversing the orientation of sample loading zone 20 in cup 2 so it is adjacent with base 1, rather than mouth 3, retaining all other features of the device. In such an orientation, sample loading zone 20 would come into direct contact with assay sample fluid introduced into cup 2." Ex. 1001, 4:54-61. The only reason provided for not making this obvious change to Tydings is that "subjects usually provide such quantities of assay sample fluid into urine collection cups that assay test strip 12 rapidly becomes flooded." *Id.*, 4:61-64. However, this argument about non-obviousness misstates the facts. Reversing the orientation of the assay device in Tydings would not have resulted in flooding. That is because the holder-laminate in Tydings has the exact same structure as the laminated flow control channels of the '019 Patent. Figure 4 in both Tydings and the '019 Patent show a cross-section of the holder-laminate of each patent.

Tydings	'019 Patent
 FIG. 4	 Fig. 4

The laminate in Tydings includes strips 12 sealed between liquid impervious backing 8, made from non-reactive plastic, and plastic front cover 14. Ex. 1009, 2:37-40, 2:59-65, 3:15-17, 5:8-12, 5:19-22. The laminate in the '019 Patent includes strips (the sample loading zone of a strip is labeled 30 in Fig. 4) sealed between liquid impervious backing 28, made from non-reactive material such as plastic, and liquid impervious walls 35a, 35b and 35c. Ex. 1001, 5:26-30, 6:9-14, 6:35-40. Assay results can be viewed through the cup and front side 35b, *id.*, 7:52-53, and a POSITA would have understood that the walls 35a, 35b and 35c are made from a clear, non-reactive material such as clear plastic. Decl. ¶ 186.

The principle of air pressure equilibrium said to be new in the '019 Patent would have also prevented flooding of the strips in Tydings if the holder-laminate in Tydings was oriented with the open end toward the bottom of the container. Decl. ¶ 187. Accordingly, the specification of the '019 Patent teaches that it would have been "simple" to merely reorient the assay means of Tydings to make the invention of the '019 Patent, and there would have been no problem with flooding of the test strips.

Furthermore, both MacKay and Lee-Own had already disclosed a test strip holder disposed inside a sample container with an open end of the test strip holder oriented toward the base of the container. Ex. 1004, Fig. 3B, 3:38-42; Ex. 1008, Fig. 5, 8:59-61, 9:2-4 (laminate with membrane strip 12 and detection window 14

attached to the inner wall of container 30 with the cut marks (dashed lines) oriented toward the base of the container). MacKay explicitly taught that orienting a sealed test strip holder with the open end down created a flow control channel as claimed because it prevented flooding of the test strip within the holder. *See* Ex. 1004, 2:29-33, 5:35-38, 7:55-57, 7:64-67, 8:1-3, 8:54-59, 9:11-17. Lee-Own taught that strips can be sealed in substantially air-tight and liquid-tight manner and thus migration of sample is controlled by physical limitations imposed by the confinement of the test-strip membrane in the laminate. Ex. 1008, 6:48-53, 7:21-23, 8:9-20, 8:28-32.

The test strip holders of MacKay and Lee-Own and the assay means of Tydings also have the same construction, *i.e.*, each device has a flow control channel having five liquid impervious sides and one liquid pervious side defined by a plastic backing and a plastic cover having a slot configured to receive a test strip. *Compare* Ex. 1004, Figs. 9-10, 8:34-53 (plastic test strip receiving part 21" and test strip covering part 22" sealed together by adhesive or ultransonic welding) *and* Ex. 1008, Figs. 1-3, 3:28-39, 7:28-39, 7:53-62 (describing holder-laminate sealed together by adhesive or sonic welding) *with* Ex. 1009, Figs. 3 & 4, 2:37-40, 2:63-65, 3:14-16 (plastic backing and front cover joined by adhesive or other means such as ultrasonic heat welding).

A POSITA would have found it obvious to dispense with the wicking member of Tydings and insert the flow control channel and test strips of Tydings (*i.e.*, the backing and front cover with enclosed strips) with the liquid pervious side oriented toward the bottom of the container to achieve the benefits of having the liquid sample contact the test strip only a predetermined designated area designed for direct contact with the liquid as taught by MacKay or Lee-Own. Decl. ¶ 190. Orienting the liquid pervious side of the flow control channel of Tydings toward the bottom of the container would have been the mere substitution of one known flow control channel orientation (liquid pervious side up) for another (liquid pervious side down). There would have been an expectation of success because MacKay teaches that, for a flow control channel having five liquid impervious sides and one liquid pervious side formed from a plastic backing sealed by adhesive or ultrasonic welding to a cover having a slot configured to receive a test strip, air pressure within the remaining portion of the test strip holder increases so that liquid is prevented from further entering the channel. Ex. 1004, 2:29-34; Decl. ¶ 190. Likewise, Lee-Own teaches flooding of the test strip is avoided because that migration of the sample onto the test strip is strictly controlled by the physical limitations imposed by confinement of the test strip in the laminate, *i.e.*, the confinement of the test strip in an air- and liquid-tight enclosure oriented with the

opening toward the bottom of the container prevents uncontrolled movement of liquid into the flow control chamber. Ex. 1008, 8:24-31; Decl. ¶ 190.

2. Dependent Claim 2: "… loosely fitted …"

The plastic backing 8 and front cover 14 are shown as leaving gaps surrounding the enclosed test strip 12. *See* Ex. 1009, Fig. 4, 4:37-41, 4:57-60, 5:19-22, 6:10-13.

3. Dependent Claim 3: "… liquid impervious backing; and … a holder …"

Tydings discloses several alternatives for holding the backing 8, strips 12, and front cover 14 (the "assay means") in the urine cup. In Fig. 2, the assay means are held in place by a rear cover 16 and tabs 18. Ex. 1009, 3:2-6, 4:42-45; 4:61-67. The rear cover and tabs retain the assay means in a slot against the inner wall of the cup. *Id*.

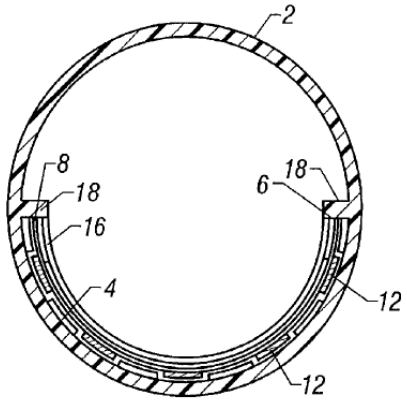


FIG. 2

In the embodiment of Fig. 9, the assay means are held in place by a molded cover having slots that retain the back and front cover of the assay means. *Id.*, 3:36-60, 4:42-45, 4:61-67.

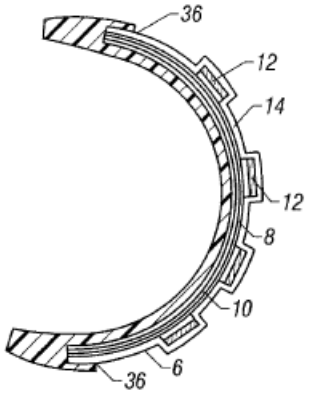


FIG. 9

The assay results are read through the transparent wall of the cup. *Id.*, 4:27-30, 5:9-12, 6:1-3, 6:21-22.

4. Dependent Claim 4: "… holder and … container are curved …"

As discussed above with respect to claim 3, Tydings discloses an assay device for field urine testing including a container for collecting a urine sample and an assay assembly for chemically analyzing the urine sample. Ex. 1009, Abstract. Tydings discloses alternatives for holding the backing 8, strips 12, and front cover 14 (the "assay means") in the urine cup. In each alternative, both the holder and the fluid sample container are curved in shape and the curvature of the holder follows the curvature of the inner diameter of the fluid sample container. In Fig. 2, reproduced above, the assay means are held in place by a holder that includes a

curved rear cover 16 and tabs 18. *Id.*, 3:2-6, 4:42-45, 4:61-67. In Fig. 9, reproduced above, the assay means are held in place by a molded, curved cover 30 having slots that retain the back and front cover of the assay means. *Id.*, 3:36-60, 4:42-45, 4:61-67. The assay results are read through the transparent wall of the cup. Ex. 1009, 4:27-30, 5:9-12, 6:1-3, 6:21-22.

5. Dependent Claim 5: "… cup …"

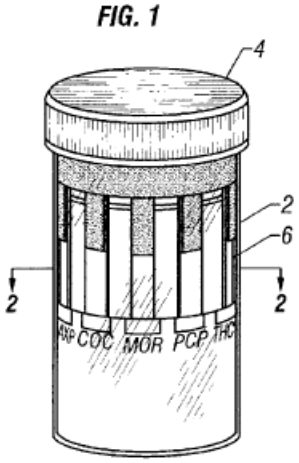
Tydings discloses a drug testing cup with a base, an open mouth, and walls connecting the base to the mouth as claimed. Ex. 1009, Fig. 1, 4:18-21, 5:30-33.

6. Dependent Claim 6: "… watertight cap ..."

The cup of Tydings has a screw lid 4, shown in Fig. 1 below, for closing the open end of the container 2. Ex. 1009, 2:32-34, 4:18-21, 5:30-33.

7. Dependent Claim 9: "… additional strips ..."

The cup of Tydings includes test strips to detect cocaine, morphine, PCP, and THC. *See* Ex. 1009, Fig. 1, 2:46-50 (disclosing detection of drugs such as amphetamines, cocaine, morphine, PCP, THC and/or their metabolites).



8. Dependent Claim 10: "… single flow control channel"

Tydings does not disclose multiple assay test strips disposed in a single flow control channel; however, the '019 patent itself concedes that a POSITA with an understanding of the "role of ambient pressure equilibrium in flow rate control" would "appreciate that flow restriction could also be provided by alternative flow control channel designs," specifically, a single flow control channel with multiple test strips disposed in a single flow control channel. Ex. 1001, 6:47-54. MacKay explicitly provides the teaching that ambient pressure equilibrium in a sealed flow control channel can be used to restrict flow into a flow control channel. Ex. 1004, 2:29-32. Accordingly, a POSITA would already have understood the required teaching concerning the role of ambient pressure equilibrium in flow rate control, and it would have been obvious to apply that teaching to Tydings to employ a single flow control channel with multiple strips. Decl. ¶ 199.

9. Dependent Claim 11: "… separate flow control channel[s]"

The test strips of Tydings are enclosed in separate flow control channels that isolate each test strip from the others. Ex. 1009, Fig. 4, 2:59-63.

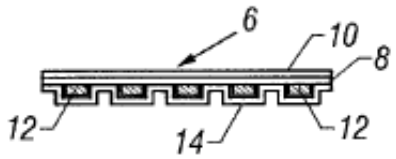


FIG. 4

10. Dependent Claim 12: "… different narcotics ..."

The cup of Tydings includes test strips to detect cocaine, morphine, PCP and THC. *See* Ex. 1009, Fig. 1, 2:46-50 (disclosing detection of drugs such as amphetamines, cocaine, morphine, PCP, THC and/or their metabolites).

11. Dependent Claims 14 and 15: "… urine"

Tydings discloses an assay device for field urine testing including a container for collecting a urine sample and an assay assembly for chemically analyzing the urine sample. Ex. 1009, Abstract, 4:16-25, 4:46-50, 5:1-7, 5:29-36, 6:14-20.

M. Ground XIII: Claim 13 is Rendered Obvious by Tydings in view of MacKay or Lee-Own and EP0860701

Neither Tydings nor MacKay nor Lee-Own discloses the integrity monitoring system required by claim 13. However, the use of a sample integrity monitoring system, as claimed in 13, with the multiple strip narcotics testing

system of claim 12 was well known in the art before the priority date of the '019 patent. Decl. ¶ 203.

For example, EP0860701 teaches a modification to the multi-strip card of DE whereby one of the strips in the card "indicates that the body fluid to be analyzed, *i.e.*, in particular, urine, has not been altered and has not been tampered with." Ex. 1007, 3:9-12, 3:25-27.

EP0860701 provides a suggestion and motivation to combine its teachings with Tydings and MacKay or Lee-Own. EP0860701 teaches that drug addicts try to conceal their drug consumption by tampering with the urine analysis. *Id.*, 1:28-31. It specifically identifies a need for test strip combinations, *i.e.*, multi-strip devices that detect foreign substances in urine and identify tampering. *Id.*, 1:44-48. The need identified by EP0860701 is directly applicable to the narcotics assay test devices of Tydings. It would have been easy to add an integrity monitoring strip to Tydings, and a POSITA would have had a reasonable expectation such a combination would have succeeded. Decl. ¶ 205. Accordingly, the combination of Tydings in view of MacKay or Lee-Own and EP0860701 renders claim 13 obvious. *Id*. ¶¶ 203-05.

XI. Conclusion

Petitioner requests IPR of claims 1-6 and 9-15 of the ’019 patent to cancel the claims.

Respectfully Submitted,

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ADDENDUM: LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 6,548,019
1002	Prosecution History for U.S. Patent No. 6,548,019
1003	Declaration of Robert Bohannon, Ph.D.
1004	U.S. Patent No. 5,656,502 ("MacKay")
1005	U.S. Patent No. 5,976,895 ("Cipkowski")
1006	U.S. Patent No. 5,985,675 ("Charm")
1007	EPO Publication EP0860701 ("EP0860701")
1008	U.S. Patent No. 5,500,375 ("Lee-Own")
1009	U.S. Patent No. 6,379,620 ("Tydings")
1010	German Utility Model No. DE 297 02 825 ("DE") and certified English translation
1011	U.S. Patent No. 4,857,453 ("Ullman")
1012	U.S. Patent No. 5,602,040 ("May")
1013	Rembrandt Diagnostics, LP's Disclosure of Asserted Claims and Infringement Contentions, Case No. 16-cv-0698-CAB (NLS), U.S. District Court for the Southern District of California (July 20, 2016)
1014	U.S. Patent No. 4,943,522 ("Eisinger")
1015	U.S. Patent No. 6,808,682 ("Bates")
1016	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")
1017	U.S. Patent No. 7,347,972 (the "'972 patent")

CERTIFICATE OF WORD COUNT

The undersigned certifies that the attached Petition for Inter Partes Review of U.S. Patent No. 6,548,019 contains 13,996 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, that a complete copy of this Petition for Inter Partes Review of U.S. Patent No. 6,548,019 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for U.S. Patent No. 6,548,019 shown in PAIR and Patent Owner's current litigation counsel:

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