

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALERE INC.,
Petitioner,

v.

REMBRANDT DIAGNOSTICS, LP,
Patent Owner.

Case IPR2016-01502
Patent 6,548,019 B1

Before CHRISTOPHER L. CRUMBLEY, JON B. TORNQUIST, and
KIMBERLY McGRAW, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Alere Inc.¹ (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–6 and 9–15 of U.S. Patent No. 6,548,019 B1 (Ex. 1001, “the ’019 patent”). Rembrandt Diagnostics, LP (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 12. Upon consideration of the Petition and the Preliminary Response, we determined that Petitioner had demonstrated a reasonable likelihood that it would prevail with respect to claims 1–5, 9, and 11–15 of the ’019 patent. Paper 13, 36–37 (“Inst. Dec.” or “Institution Decision”). Thus, we instituted *inter partes* review with respect to those claims. We did not institute review, however, with respect to challenged claims 6 and 10. *Id.* at 36.

On May 11, 2017, Patent Owner disclaimed claims 1, 9, and 11–15 of the ’019 patent, leaving only claims 2–5 remaining in this proceeding. Ex. 2016, 1. Subsequent to its disclaimer, Patent Owner filed a Patent Owner Response (Paper 15, “PO Resp.”), to which Petitioner filed a Reply (Paper 20, “Pet. Reply”). An oral hearing was held on November 7, 2017, and a transcript of the oral hearing is included in the record. Paper 33 (“Tr.”).

In support of their respective arguments, Petitioner relies upon the declaration testimony of Dr. Robert C. Bohannon (Exs. 1003 and 1023) and Patent Owner relies upon the testimony of Dr. Salvatore J. Salamone (Ex. 2018).

¹ During the course of this proceeding, Alere Inc. was acquired by Abbott Laboratories. Paper 29, 1.

We have jurisdiction under 35 U.S.C. § 6 and this Final Written Decision is entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

B. Related Proceeding

The parties state that 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.” Pet. 1; see Paper 5, 1.

C. The '019 Patent

The '019 patent is directed to immunoassay devices. Ex. 1001, 1:15. Figure 2 of the '019 patent, reproduced below, shows a portion of a prior art immunoassay device:

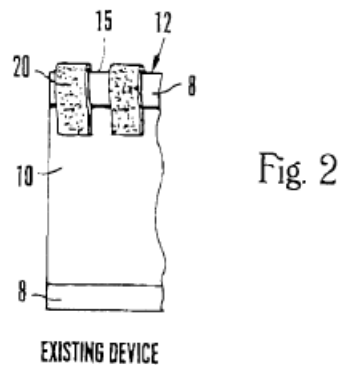


Figure 2 is a cut-away view of one assay means known in the art.

As shown in Figure 2, in the disclosed prior art device two-sided solid support backing 8 is covered with wicking material 10 on one side. *Id.* at 4:6–8, 4:16–17. One or more assay test strips 12 are provided on backing 8 and are folded over top edge 15 to bring loading zone 20 of test strips 12 into contact with wicking material 10. *Id.* at 4:6–9, 4:17–20. The '019 patent explains that when backing 8 is brought into contact with a test sample in a collection cup, “the fluid wicks up wicking material 10 to contact sample loading zone 20 of assay test strip 12.” *Id.* at 4:23–29.

The '019 patent reports that the wicking method of the prior art is undesirable because it is relatively slow to produce results, liquid may not wick evenly if a small volume of a sample is introduced into the collection cup, and the need to overlap wicking material 10 and assay test strip 12 results in increased manufacturing costs. *Id.* at 4:34–53. The '019 patent discloses, however, that these disadvantages may be overcome by removing the wicking material and directly introducing a sample to the sample loading zone of an assay test strip, if a means is provided to prevent oversaturation of the test strip when a substantial volume of assay sample fluid is present. *Id.* at 4:65–5:6.

Figures 3 and 4 of the '019 patent, reproduced below, show a means for directly contacting the sample loading zone of an assay test strip with a sample fluid:

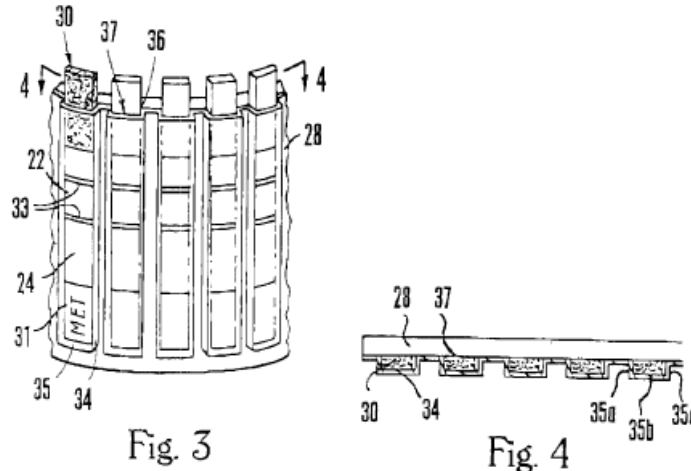


Figure 3 is a front view of a flow control dipstick assay means.

Figure 4 is a cross-section of Figure 3 taken along line 4–4.

As shown in Figures 3 and 4, in the disclosed embodiment “flow control channel 34 has five liquid impervious walls [35, 35a, 35b, 35c,] and backing 28, and one liquid pervious side consisting of an opening 36 through which sample loading zone 30 of assay test strip 22 protrudes.” *Id.* at 6:10–

15 (emphases omitted). When the flow control channel is oriented in a collection cup with opening 36 facing the bottom of the cup, fluid within the cup “contacts sample loading zone 30 and begins migrating upwards through assay test strip 22.” *Id.* at 5:53–56, 6:55–57. In this orientation, air trapped within flow control channel 34 prevents the test fluid from flooding the test strip. *Id.* at 5:59–64 (“[T]he ambient pressure within the flow control channel is maintained in substantial equilibrium with the ambient pressure outside of the flow control channel, even after placement of the flow control channel into [the] collection container which contains assay sample fluid.”), 6:28–34.

D. Illustrative Claims

Claims 1 and 2 are illustrative of the challenged claims and are reproduced below:

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.

Ex. 1001, 8:42–9:2; *see also* Certificate of Correction signed Aug 12, 2003.

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

Ex. 1001, 9:3–5.

E. Instituted Grounds of Unpatentability

As noted above, subsequent to our Institution Decision, Patent Owner disclaimed claims 1, 9, and 11–15 of the '019 patent. Ex. 2016, 1. Thus, only two grounds of unpatentability remain for resolution in this trial: (1) whether claim 2 is anticipated by MacKay², and (2) whether the subject matter of claims 3–5 would have been obvious over MacKay and Cipkowski.³

II. ANALYSIS

A. Principles of Law

A prior art reference anticipates a claim “if it discloses all the claimed limitations ‘arranged or combined in the same way as in the claim.’” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361 (Fed. Cir. 2012)).

² U.S. Patent No. 5,656,502, issued Aug. 12, 1997 (Ex. 1004).

³ U.S. Patent No. 5,976,895, issued Nov. 2, 1999 (Ex. 1005).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) if in the record, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Claim Construction

In an *inter partes* review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

For purposes of this Decision, two claim terms require construction: “device” and “when added to the container.”

1. *device*

In the Institution Decision, we preliminarily determined that the term “device”—in claim 1’s preamble phrase “[a] device for collecting and assaying a sample of biological fluid”—is not limiting. Inst. Dec. 8–10. Patent Owner disputes this conclusion, asserting that the claims, written description, and prosecution history of the ’019 patent make clear that the term “device” was intended as a substantive claim limitation. PO Resp. 16–18. Patent Owner further asserts that when the ordinary meaning of the term, as well as the disclosures of the specification and prosecution history of the ’019 patent and Petitioner’s statements in a prior district court proceeding are considered, it is evident that the claimed “device” is “designed to be a single, unitary structure for conducting a test, rather than a collection of separate items that may be used during the test.” *Id.* at 18–21.

Petitioner contends the term “device” is a non-limiting part of the preamble, but to the extent construction of the term is necessary, it means “one or more devices.” Pet. Reply 3–11.

a. The Preamble of Claim 1 is not Limiting

“In general, a preamble limits the invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mkt’g Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). For example, a preamble may be limiting when the disputed preamble phrase provides antecedent basis for a claim term in the body of a claim, the specification underscores that the additional structure recited in the preamble is important, or when the

patentee clearly relied upon the preamble during prosecution to distinguish the claimed invention from the prior art. *Id.* at 808–09.

“Conversely, a preamble is not limiting ‘where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention,’” *id.* at 808, or where the patentee uses the preamble to give “a descriptive name to the set of limitations in the body of the claim,” *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000) (“The phrase ‘control apparatus’ in the preamble merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention.”).

The term “device” is not recited in the body of any claim of the ’019 patent,⁴ the body of claim 1 recites a structurally complete invention, and the preamble phrase “device for collecting and assaying a sample of biological fluid” specifies the intended use of the invention. Thus, we find the claims of the ’019 patent do not support construing “device” as a limitation. *See Catalina Mkt’g*, 289 F.3d at 808–09.

As noted by Patent Owner, the written description of the ’019 patent repeatedly refers to the inventive structure as a “device.” Ex. 1001, at [54] (“Device and Methods for Single Step Collection and Assaying of Biological Fluids”), 1:15–17 (“The invention relates to immunoassay devices and methods for collection and assaying of biological fluids, particularly urine.”); PO Resp. 16. We are directed to no disclosure in the written description, however, indicating that the term “device” has a non-generic meaning or was used to denote critical structure of the invention.

⁴ The term “device” is used only in the preamble of the dependent claims. Ex. 1001, 9:3–10:23.

See Catalina Mkt'g, 289 F.3d 808–09. It is, instead, the specific structural elements recited in the bodies of the claims, such as structure to provide for direct sample loading of assay fluid onto the assay test strip and a manner to control fluid flow of sample through the test strip to prevent oversaturation, that are identified as improving upon the prior art.

For example, the '019 patent states:

These enumerated limitations of the assay device of FIGS. 1 and 2 are overcome by the present invention. In particular, the invention provides an assay device in which assay fluid sample is introduced directly to the sample loading zone of an assay test strip, wherein the device further includes means to control and direct assay sample fluid flow into the test strip, thereby avoiding oversaturation of the test strip, even in the presence of a substantial volume of assay sample fluid.

Ex. 1001, 4:65–5:6. The '019 patent also states:

All of the foregoing embodiments of the invention share the advantage of providing for direct application of sample fluid to the assay test strip (as opposed to having the fluid migrate through an intermediate structure, such as wicking material 10 of FIGS. 1 and 2).

Id. at 7:54–58. Thus, we are not persuaded that the written description demonstrates that the term “device” was used to denote an important structural element of the invention.

It is true that the Patent Owner also used the term “device” repeatedly during prosecution, stating, for example, that “the device of the present invention is not an obvious variant of the '969 device.” Ex. 1002, 107 (“The '969 device does not teach or suggest sample flow control means as provided by the present invention. Therefore, the device of the present invention is not an obvious variant of the '969 device.”), 108 (“The '969 device clearly does not comprise or include a flow control channel.”); PO

Resp. 16–17. We are presented with no clear example in the prosecution history, however, wherein the patentee attempted to distinguish the claimed invention from the prior art based on it being a “device,” or asserted that this term denoted critical structure. Thus, the prosecution history does not demonstrate that the patentee intended the preamble of claim 1 to limit the scope of the invention. *See Catalina Mkt’g*, 289 F.3d at 808.

In view of the foregoing, we find the claims, written description, and prosecution history of the ’019 patent do not suggest that the preamble term “device,” as recited in each of the challenged claims, should be treated as a substantive limitation.

b. Even if the Term “Device” was Limiting, the Term Does Not Require a Single, Unitary Structure

Even if we were to give the term “device” patentable weight, we are not persuaded that the term requires a “single, unitary structure,” as asserted by Patent Owner.

To support its construction, Patent Owner primarily relies on a general purpose dictionary that defines “device” as “a piece of equipment or a mechanism designed to serve a special purpose or perform a special function.” PO Resp. 18 (quoting Ex. 2012, 3 (Webster’s Third New International Dictionary)). From this definition, Patent Owner concludes that the “device” set forth in the claims of the ’019 patent is a piece of equipment that is “designed to be a single, unitary structure for conducting a test, rather than a collection of separate items that may be used during the test.” *Id.*; Ex. 2018 ¶¶ 33–34. Patent Owner contends the written description and prosecution history of the ’019 patent use the term in a manner that is consistent with this ordinary meaning, exclusively describing

the invention as a unitary device that combines a cup and a flow-control channel. PO Resp. 18–20 (citing Ex. 2018 ¶¶ 31–40).

Patent Owner does not explain why the ordinary meaning of the term “device” set forth above requires a single, unitary structure rather than a collection of separate structures that could be used during the test. *See id.* at 18 (concluding without analysis that the dictionary definition requires a “single, unitary structure”). Indeed, despite the ubiquitous use of the term “device” in patents generally, we are directed to no case in which the term “device,” by itself, was found to require a single, unitary structure. *See Manual of Patent Examining Procedure*, Section 2106, I (identifying “devices” as one of the four categories of statutory subject matter); *Saffran v. Johnson & Johnson*, 712 F.3d 549, 565 (Fed. Cir. 2013) (O’Malley concurring in part) (confirming that, in general, the term “device” is generic). Thus, we are not persuaded that the ordinary meaning of the term “device” requires a “single, unitary structure.” *See* Ex. 1023 ¶ 66 (Dr. Bohannon testifying that the word device, like the words “apparatus” or “system,” is merely a generic term that does not have a specialized meaning in the art and does not require a single, unitary structure).

That said, we must also look to the disclosures of the ’019 patent to determine whether the patentee redefined the term “device” to require a “single, unitary structure.” *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315, 1322 (Fed. Cir. 2005). As noted by Patent Owner, the title of the ’019 patent is “Device and Methods for Single Step Collection and Assaying of Biological Fluids,” and every embodiment set forth in the ’019 patent is described as a “combination assay test strip/assay fluid collection cup.” Ex. 1001, at [54], 5:13–16; PO Resp. 7, 16, 18; Ex. 2018 ¶ 38. These

disclosures tend to support Patent Owner's argument that a device used in a single step method may constitute a "single, unitary" device. The preamble of claim 1, however, conspicuously drops the reference to a "single step" device, and the '019 patent describes at least one embodiment in which the flow control channel is placed "into [a] collection container which contains assay sample fluid," suggesting that neither a "unitary" structure nor a structure capable of "single step" testing is required by the term "device." Ex. 1001, 5:57–64, 6:22–27, 8:42–43. In addition, the '019 patent explains that the consistent description of a "combination assay test strip/assay fluid collection cup" in the written description was "[f]or ease of understanding" and that "[i]t should be apparent to those skilled in the art that the above-described embodiments are merely illustrative of but a few of the embodiments which could be created by one of ordinary skill in the art without departing from the spirit and scope of the present invention." *Id.* at 5:13–20, 8:36–40.

Moreover, Patent Owner conceded at oral hearing that the various components of the claimed "device" need not be physically connected into one single, unitary structure. *See* Tr. 24:20–25:20. Significantly, Patent Owner stated the claimed device encompasses an embodiment in which the flow control channel is not physically connected to any other portion of the "device," but rather, is floating in the assay sample fluid. *Id.*; *see also* Ex. 1001, 2:24–31, 5:57–64 (placing the flow control channel into a collection container that contains assay sample fluid); 9:6–11, 9:18–19 (reciting a holder and watertight cap that are "fittable" inside or over the container, and not necessarily physically attached to the "device"). This

again cuts against Patent Owner's construction requiring a single, unitary structure.

Based on the foregoing, and upon review of the record as a whole, we find the ordinary meaning of "device," when viewed in light of the specification of the '019 patent, does not require a "single, unitary structure." We further find that the intrinsic evidence does not evidence a clear intent by the patentee to redefine the term "device" to require such a structure.

Looking to extrinsic evidence, Patent Owner asserts that Petitioner and its expert in a prior district court litigation agreed that "a 'test device' would be understood in the art as a single, self-contained unit, and would not be understood to include a separate component such [as] a test tube." PO Resp. 19 (citing Ex. 2013, 12; Ex. 2014 ¶ 3). We are not persuaded that this evidence is sufficient to demonstrate that the term "device," as used in the '019 patent, requires a single, unitary structure. First, the declaration and brief in question are directed to a different patent, a different claim term, and a different prior art structure, and Patent Owner does not explain what construction was ultimately adopted by the fact finder in that case. Second, even if this extrinsic evidence were considered a binding admission by Petitioner, it may not be used to contradict the disclosures of the '019 patent, which suggest that a "device" need not be a single, unitary structure. See *Vitronics Corp v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (noting that extrinsic evidence "may not be used to vary or contradict the claim language" or "the import of other parts of the specification").

In view of the foregoing, we conclude that the preamble term "device," as used in the '019 patent claims, is not a substantive claim

limitation. We also determine that, even if the term “device” was limiting, it does not require a single, unitary structure, as asserted by Patent Owner.

2. *when added to the container*

The first “wherein” clause of element (c) of claim 1 (“claim 1(c)”) states:

wherein the flow control channel is disposed inside the sample fluid container with the liquid pervious side oriented [towards] 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

Ex. 1001, 8:57–64 (emphasis added). The parties agree that the first portion of this claim phrase requires that the flow control channel be disposed within the sample fluid container with its liquid pervious side oriented towards the base of the sample fluid container. The parties dispute, however, what the remainder of this claim phrase requires. In particular, the parties dispute whether fluid must be able to enter the container when the flow control channel is properly oriented therein. PO Resp. 23; Pet. Reply 12–14, 17 (“The dispute here centers on how ‘when added’ interacts with ‘the flow control channel is disposed.’”).

Patent Owner contends the express language of the claim requires that the flow control channel be oriented in such a way that fluid can enter the container and reach the test strips. PO Resp. 23, 32–33. Petitioner responds that claim 1 does not require that a sample actually be added to the container and “[i]t is not the timing of when the fluid contacts the flow control channel that matters to the invention, but the fact that after contact, the flow control

channel operates as claimed and reduces or eliminates potential flooding of the test strip by sample.” Pet. Reply 14–15.

Claim 1 of the ’019 patent is directed to an apparatus, not a method of using the apparatus. Thus, we do not understand the phrase “so that the assay sample fluid, when added to the container” to require a method step of adding liquid to the container or a temporal requirement as to when the liquid enters the container. See *Hewlett–Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) (“[A]pparatus claims cover what a device *is*, not what a device *does*.”); *IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (noting that care must be taken to avoid reading process limitations into an apparatus claim); see also Tr. 29:10–15 (Patent Owner conceding that the claims do not require any liquid to be in the container). We understand this claim phrase, instead, to be a functional limitation dictating certain structural relationships between the flow control channel and the loading zone of the assay test strip and the capabilities of the claimed flow control channel and its liquid pervious side when the flow control channel is properly oriented within the container. See *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (“A patent applicant is free to recite features of an apparatus either structurally or functionally.”); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363–64 (Fed. Cir. 1999) (“That is, the functional language tells us something about the structural requirements of the attachment between the bootie and the base”).

Construing the claim phrase as a functional limitation, we agree with Patent Owner that the first wherein clause of claim 1(c) requires a structure that is capable of allowing liquid to enter the container when the flow control channel is properly disposed therein, and capable of directing this

liquid to the sample loading zone of the assay test strip without the liquid having to migrate through an intermediate structure. Such a construction is consistent with the language of claim 1, which expressly contemplates that liquid may be added to the container when the flow control channel is properly disposed therein. Conversely, broadly construing this wherein clause to cover embodiments in which fluid could not enter the container after the flow control channel is properly disposed therein, as asserted by Petitioner, would be inconsistent with the claim language, which clearly contemplates that liquid can be “added to the container,” and would essentially read the “when added to the container” phrase out of the claim. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (“That is not to say, however, that the Board may construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles.”); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (“While not an absolute rule, all claim terms are presumed to have meaning in a claim.”).

Therefore, for the foregoing reasons, we construe the wherein clause to require a structure that is capable of allowing liquid to enter the container when the flow control channel is disposed therein and capable of directing this liquid to the sample loading zone of the assay test strip without the liquid having to migrate through an intermediate structure.

C. Anticipation of Claim 2 by MacKay

Petitioner contends the subject matter of claim 2 is anticipated by MacKay. Pet. 21–26.

1. MacKay

MacKay discloses a test strip holder and a method of using the same.

Ex. 1004, 1:6–7. Figures 4 and 6 of MacKay are reproduced below:

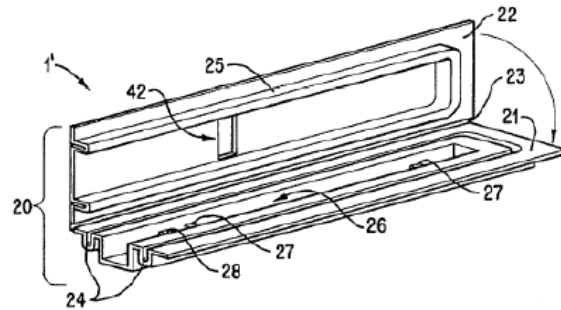


FIG. 4

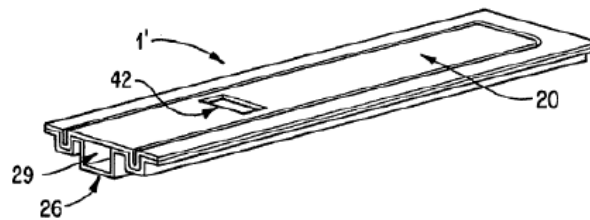


FIG. 6

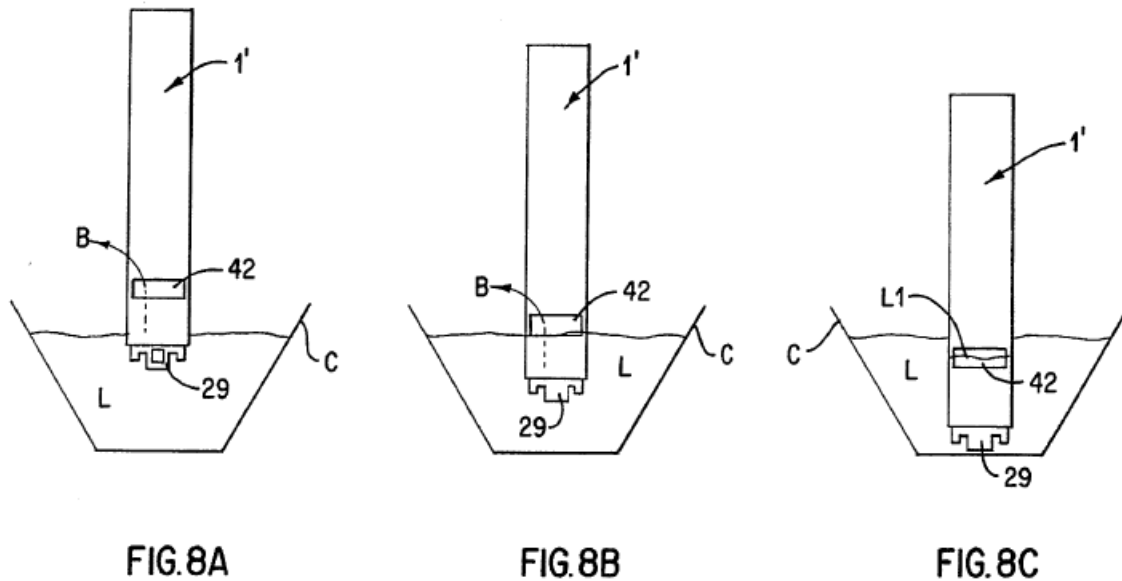
Figure 4 is a front view of the test strip holder of MacKay in “open condition.”

Figure 6 is a front view of the test strip holder of MacKay in “closed condition.”

Figures 4 and 6 depict test strip holder 1'. *Id.* at 5:55–56. In this embodiment, elongated hollow member 20 is formed from test strip receiving part 21 and test strip covering part 22, which are connected at hinge 23. *Id.* at 5:56–60. A test strip is positioned within test strip receiving part 21 and is “maintained spaced from the sidewalls” by test strip holders 27. *Id.* at 6:41–48. When test strip covering part 22 is closed on test strip receiving part 21, peripheral groove or channel 24 is mated with peripheral protrusion 25 to form an airtight seal. *Id.* at 6:4–11. Opening 29 is provided in hollow member 20 to allow for the entry of liquid into the

device, and vent or window 42 is provided to allow air to exit from the holder when it is immersed in fluid. *Id.* at 7:1–7, 7:55–59.

Figures 8A–C of MacKay are reproduced below:



Figures 8A–C illustrate the insertion of the test strip holder of Figure 4 into a liquid.

As shown in Figure 8A–C, as test strip holder 1' is inserted into liquid L within container C, liquid L enters open end 29 of elongated hollow member 20 (as shown in Figure 6). *Id.* at 7:54–57. Air within elongated hollow member 20 is displaced through vent 42 until liquid L reaches level L1. At this point, the vent path is no longer open to air, resulting in increased pressure within elongated member 20 that prevents liquid L from further entering the holder. *Id.* at 7:61–67.

2. Analysis

Petitioner contends MacKay discloses every limitation of claim 1, including: (1) a flow control channel; (2) an assay test strip within the flow control channel; (3) a sample fluid container having a base, an open mouth, and walls connecting the base to the mouth; and (4) disposing the flow

control channel inside the sample fluid container with the liquid pervious side oriented towards the base of the sample fluid container. Pet. 21–25; Pet. Reply 17–19. Petitioner also demonstrates that the sides of the flow control channel in MacKay are loosely fitted around the assay test strip, as recited in challenged dependent claim 2. Pet. 26.

Patent Owner argues that, “[b]ecause MacKay’s container C and test strip holder are separate devices and not designed to be a unitary structure,” they do not constitute “‘a device for collecting and assaying a sample of biological fluid,’ as required by Claim 2.” PO Resp. 27. We do not find this argument persuasive because, as discussed above, we do not construe the claim term “device” to be limiting.⁵

Patent Owner also argues that, because the sample fluid of MacKay is added to the container before the flow control channel and test strip are added, the holder of MacKay is “not disposed inside the container in such a way that the sample fluid, when added to the container, is delivered to the test strip.” *Id.* (citing Ex. 1004, 2:54–55, 2:66–67, 5:21–23, 7:54–55; Ex. 2018 ¶ 46). According to Patent Owner, the sample fluid must be added when the test strip is oriented within the container and, although it may be possible to add the liquid of MacKay after the test strip and holder are inserted into the container, that is not what is disclosed in MacKay. *Id.*; Tr. 26:10–17; *see NetMoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

⁵ Even if the term “device” was limiting, we are persuaded that the container, holder, and test strip combination of MacKay, which work in concert to collect and assay a sample fluid, constitute a “device for collecting and assaying a sample of biological fluid.”

We do not find this argument persuasive. As noted above, we do not construe claim 1 to contain a method step of adding fluid to the container. We construe the first wherein clause of claim 1(c), instead, to require a *structure* that is capable of allowing liquid to enter the container when the flow control channel is properly disposed therein and is capable of directing this liquid to the sample loading zone of the assay test strip without the liquid having to migrate through an intermediate structure, such as a wicking material. We are persuaded—and Patent Owner does not dispute—that the apparatus of MacKay, as disclosed in Figures 8A–C, has a structure that is capable of achieving both functions. *See, e.g.*, Tr. 26:10–30:20. First, given the open nature of the container, it is evident that liquid may be added to the container when the flow control channel is disposed within the container, and Patent Owner does not assert otherwise. *See, e.g., id.* Second, even if the fluid present in Figures 8A–C is considered, there is no intermediate structure in the container of MacKay that would prevent additional assay sample fluid from entering the container and being immediately directed to the sample loading zone of the assay test strips.⁶

Based on the foregoing, we find that MacKay discloses every limitation of claims 1 and 2 of the '019 patent. Accordingly, Petitioner has demonstrated by a preponderance of the evidence that claim 2 is anticipated by MacKay.

⁶ Neither party asserts, nor do we understand, that the assay sample fluid within the container in Figures 8A–C of MacKay would be an intermediate structure to itself.

D. Obviousness of Claims 3–5 over MacKay and Cipkowski

Petitioner contends the subject matter of claims 3–5 would have been obvious over MacKay and Cipkowski. Pet. 26–30.

1. Cipkowski

Cipkowski discloses a “device for the collection, testing, and shipment of body fluid samples.” Ex. 1005, at [54], 1:4–8. Figures 1 and 2 of Cipkowski are reproduced below:

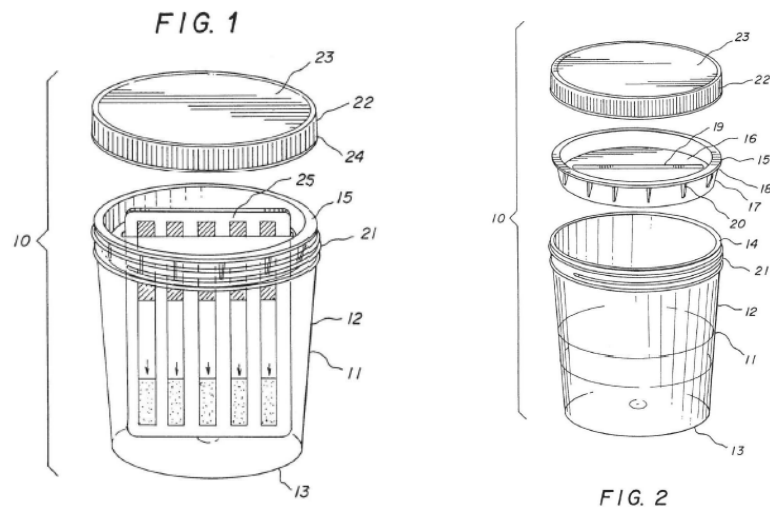


Figure 1 is an exploded perspective view of the drug abuse test kit.

Figure 2 is an exploded perspective view
of the container of the invention.

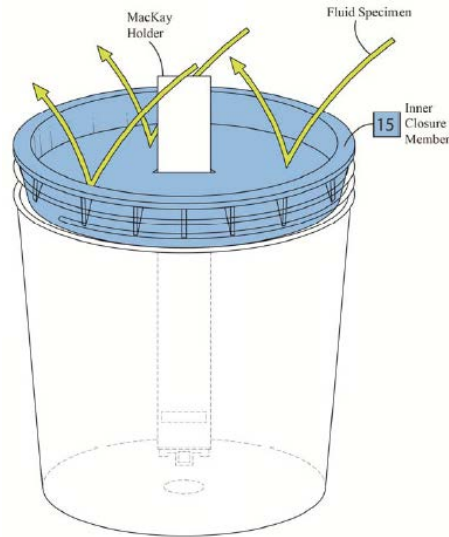
As shown in Figure 2, the container of Cipkowski includes transparent container or test cup 11, outer cover 22, and insert 15 having slot 19 shaped to accommodate a test card. *Id.* at 3:28–42. During a test, test cup 11 is provided with a test specimen, insert 15 is placed within the test cup, and multiple drug test card 25 is then inserted into slit 19 such that the bottom of the test card rests upon the bottom of the test cup. *Id.* at 4:23–39.

2. Analysis

Claim 3 requires, among other things, a holder fittable inside the fluid sample container having “at least one slot formed therein to receive” the liquid impervious backing of the flow control channel. Ex. 1001, 9:6–11. Claim 4 depends from claim 3 and further requires that the holder and the fluid sample container are curved in shape, with the curvature of the holder following the curvature of the inner diameter of the fluid sample container. *Id.* at 9:12–15. Claim 5 depends from claim 4 and requires that the fluid sample container is a cup. *Id.* at 9:16–17.

Petitioner asserts that the combination of MacKay and Cipkowski discloses the subject matter of claims 3–5 of the ’019 patent. Pet. 26–30. Petitioner also asserts that one of ordinary skill in the art would have sought to insert the test strip and flow control channel of MacKay in the holder of Cipkowski, in order to prevent “flooding of the test strip as taught in MacKay.” *Id.* at 29.

Patent Owner contends claims 3–5 would not have been obvious over MacKay and Cipkowski because this combination does not teach or suggest “wherein the flow control channel is disposed inside the sample fluid container . . . so that the assay sample fluid, when added to the container, is delivered to the . . . assay test strip.” PO Resp. 28–29 (citing Ex. 1001, 8:57–62; Ex. 2018 ¶¶ 47–49). In support of its argument, Patent Owner provides the following annotated figure (*id.* at 32):



Patent Owner's Figure depicts the device resulting from the combination of Cipkowski and MacKay.

As shown in the figure above, once the holder of MacKay is inserted through the inner closure insert of Cipkowski, these elements would effectively block any liquid from entering the container and reaching the flow control channel. *Id.*; Ex. 2018 ¶ 49. And, because we have construed the first wherein clause of claim 1(c) to require a structure that is capable of allowing liquid to enter the container when the flow control channel is disposed therein, we find that the combination of MacKay and Cipkowski proposed by Petitioner does not teach or suggest every limitation of claims 3–5 of the '019 patent.

During oral argument, Petitioner suggested that sample fluid could be pipetted into the container of Cipkowski and MacKay. Tr. 13:22–14:14. Petitioner did not make this argument in its briefs and, therefore, the argument is waived.⁷ *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301

⁷ Petitioner did note in its Reply that Dr. Salamone testified on cross-examination that the challenged claims would cover liquid that is pipetted into the container. Pet. Reply 12. Petitioner did not assert, or present

(Fed. Cir. 2016) (noting that the Board may not rely on a factual assertion made for the first time at oral argument); Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012) (noting that no new evidence or arguments may be presented at the oral argument); *see also* Tr. 35:21–36:8 (Petitioner counsel asserting that “I’m not relying specifically on pipetting.”)

Based on the foregoing, we find that Petitioner has not demonstrated by a preponderance of the evidence that the combination of MacKay and Cipkowski would have rendered the subject matter of claims 3–5 of the ’019 patent obvious.

III. MOTION TO EXCLUDE

Petitioner moves to exclude several of Patent Owner’s exhibits pursuant to 37 C.F.R. § 42.64. Paper 24 (Mot. to Excl. or Motion to Exclude). We address these exhibits below.

A. Exhibits 2001, 2002, 2003, 2004, 2006, 2007, 2008, 2009, 2010, 2011, 2015, and 2017

Petitioner contends that Exhibits 2001, 2002, 2003, 2004, 2006, 2007, 2008, 2009, 2010, 2011, 2015, and 2017 should be excluded because they are not cited in Patent Owner’s Response. Mot. to Excl. 1–2. Patent Owner does not oppose Petitioner’s request to exclude Exhibits 2001, 2002, 2003, 2004, 2006, 2007, 2008, 2009, 2010, 2011, and 2015, but contends Exhibit 2017 should not be excluded because it was relied upon by Dr. Salamone in his Declaration. Paper 26, 1–2 (citing Ex. 2018 ¶ 52).

evidence to establish, however, that one of ordinary skill in the art would have been able to pipette assay sample fluid into the container of Cipkowski and MacKay when the flow control channel was properly oriented within the container. Ex. 1022, 39:15–41:6; Pet. Reply 12.

Upon review of the parties arguments, we *grant* the Motion to Exclude with respect to Exhibits 2001, 2002, 2003, 2004, 2006, 2007, 2008, 2009, 2010, 2011, and 2015, but *deny* the motion with respect to Exhibit 2017, as Patent Owner has demonstrated that this exhibit was relied upon by Dr. Salamone in his declaration.

B. Exhibits 2005, 2012–2014, and 2018

Petitioner also moves to exclude Exhibits 2005 and 2012–2014, as well as any portions of Exhibit 2018 that refer to these exhibits. Mot. to Excl. 2–9. Exhibit 2005 is a publication directed to the ONTRAK TESTCUP, presented by Patent Owner to demonstrate the structure of a particular prior art device (PO Resp. 2; Pet. Reply 10); Exhibit 2012 is the dictionary definition of “device”; Exhibits 2013 and 2014 are documents submitted by Petitioner’s predecessor-in-interest to the district court regarding the meaning of the term “test device”; and Exhibit 2018 is the Declaration of Dr. Salamone. Because we have considered these exhibits and still found in favor of Petitioner on the matters for which the exhibits were presented, we *dismiss* the Motion to Exclude the recited exhibits as moot.

IV. ORDER

It is hereby:

ORDERED that claim 2 of the ’019 patent is unpatentable;

FURTHER ORDERED that claims 3–5 of the ’019 patent have not been shown to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude is *granted* with respect to Exhibits 2001, 2002, 2003, 2004, 2006, 2007, 2008, 2009,

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2010, 2011, and 2015; *denied* with respect to Exhibit 2017; and *dismissed as moot* with respect to Exhibits 2005, 2012–2014, and 2018; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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