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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* BRADLEY M. WILKINSON and  
C. MARK NEWBY<sup>1</sup>

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Appeal 2016-006122  
Application 12/257,057  
Technology Center 1700

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Before: JAMES C. HOUSEL, AVELYN M. ROSS, and  
MERRELL C. CASHION, JR., *Administrative Patent Judges*.

ROSS, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>2</sup>

Appellants appeal under 35 U.S.C. § 134(a) from a rejection of claims 1–4 and 6–21. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> Appellants identify the real party in interest as Becton, Dickinson and Company, the assignee of the instant application. Appeal Br. 3.

<sup>2</sup> In our Decision we refer to the Specification (“Spec.”) initially filed October 23, 2008 and as later amended, the Final Office Action (“Final Act.”) dated April 29, 2015, the Appeal Brief (Appeal Br.) filed December 1, 2015, the Examiner’s Answer (“Ans.”) dated April 12, 2016, and the Reply Brief (“Reply Br.”) filed May 25, 2016.

## STATEMENT OF THE CASE

The subject matter on appeal relates to closed kit for tissue containment and stabilization for molecular and histopathology diagnostics.

Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A system for storing a biological sample, comprising:
  - a container having a closed end, an open end, and a sidewall extending therebetween, defining a container interior;
  - a removable closure for enclosing the open end of the container;
  - a sample holder for housing a biological sample, insertable within the container interior;
  - a port disposed within at least one of the container and the removable closure; and
  - an injection device engageable with the port to allow a fluid to pass from within the injection device into the container interior, wherein the sample holder is matable with the closure, and wherein when the sample holder is mated with the closure and the closure is engaged with the container, the sample holder is located directly adjacent to and beneath the port along a longitudinal axis of the port.

Appeal Br. 22 (Claims App'x).

## REJECTIONS

The Examiner maintains the following rejections:

- A. Claims 1–4, 6–10, 12–14, and 16–21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Duymelinck.<sup>3</sup> Final Act. 4.

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<sup>3</sup> Duymelinck et al., WO 2007/014741 A2, published February 8, 2007 (“Duymelinck”).

- B. Claims 11 and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Duymelinck in view of Ryan<sup>4</sup> or Smith.<sup>5</sup> *Id.* at 9.
- C. Claims 1–4, 6–10, 12–14, and 16–21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Duymelinck. Ans. 9.

Appellants request reversal of Rejections A–C. Appellants argue rejections A and C together, and argue the independent claims 1, 16, and 21 together as a group. *See generally* Appeal Br. Appellants also do not present separate arguments for the remaining claims. *Id.* Therefore, consistent with the provisions of 37 C.F.R. § 41.37(c)(1)(iv) (2013), we limit our discussion to claim 1, and all other claims stand or fall together with claim 1.

#### OPINION

##### *Rejection A – Obviousness (claims 1–4, 6–10, 12–14, and 16–21)*

The Examiner rejects claim 1 as obvious over Duymelinck. Final Act. 4. The Examiner finds that Duymelinck teaches a system for storing a biological sample having each of the claimed elements, including a container, a removable closure, a sample holder, a port, and an injection device. Final Act. 4–5. The Examiner acknowledges that Duymelinck does not disclose a sample container that is “located directly adjacent and beneath the port along a longitudinal axis of the port.” Final Act. 5. The Examiner finds Duymelinck discloses “the elongated member (103) of [the Duymelinck] device can change lengths so that it [is] able to be at different

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<sup>4</sup> Dana Wm. Ryan, US 5,833,213, issued November 10, 1998 (“Ryan”).

<sup>5</sup> James C. Smith, US 6,375,028 B1, issued April 23, 2002 (“Smith”).

depth[s] within the inner space of the vial.” *Id.* The Examiner additionally finds Duymelinck discloses that in “an embodiment of the holder there is particular length and depth of the holder seen in Figure 21a and b so that it does not directly abut the bottom of the closure preventing any flow form [sic] an access port to the holder.” *Id.* The Examiner concludes that the broadest reasonable interpretation of “directly adjacent to and beneath the port” means “directly beneath the port.” *Id.* Therefore, the Examiner reasons that it would have been obvious to modify the length of the elongated member so that the sample holder is “directly adjacent to and beneath the port” for three alternative reasons: (1) “to directly exchange sample fluid from the injection to the holder minimizing any sort of risk of contamination or spillage;” (2) to rearrange the parts to adjust the sample holder location as a matter of design choice; or (3) as “a matter of design choice and wherein there is a finite number of placements, orientations and lengths of the elongated member relative to the holder to optimize the reaction time between components and flow from one part of the system to the other.” *Id.* at 6.

Appellants contend that the Examiner’s claim construction is too broad and impermissibly broadens the plain meaning of independent claims 1, 16, and 21. Appeal Br. 12. According to Appellants, the Examiner’s definition does not give full effect to “*directly adjacent* and beneath.” *Id.* at 13; *see also* Reply Br. 2 (“this interpretation fails to give any weight to the word ‘adjacent’”). Appellants assert that “adjacent” should be interpreted as “close or near, or sharing a border, wall, or point.” App. Br. 13. Appellants offer the following comparison figures, Figure 4 and Modified Figure 4 to illustrate their position.

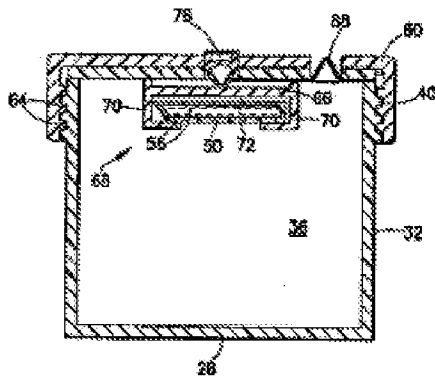
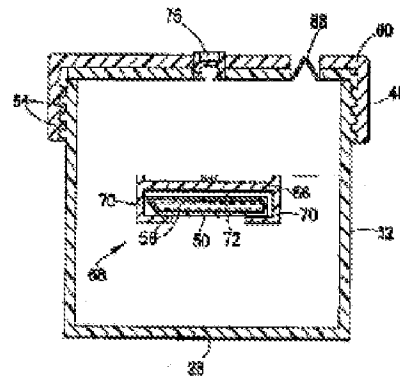


FIG. 4



Modified FIG. 4

*Id.* Appellants explain that Figure 4 shows a holder *directly adjacent to and beneath* the port 76 while Modified Figure 4 simply shows a sample holder 50 *directly beneath* the port—not adjacent. *Id.* at 13–14. According to Appellants, the Examiner acknowledges that placement directly adjacent and beneath the port is not taught. *Id.* at 14.

The Examiner finds that even using Appellants’ “shared border” definition, the modification results in the claimed invention and provides a “motivation to adjust the elongated member so that it does satisfy the embodiment of sharing a boarder [sic].” Ans. 16.

Appellants contend that the claimed placement is not a matter of design choice and such a modification requires a reason to make the changes proposed. Appeal Br. 14. Appellants direct attention to the teachings of Duymelinck that suggest the sample holder is positioned in the inner space of the vial. *Id.* at 15. In particular, Appellants note Duymelinck teaches that the sample holder is advantageously placed “in the lower half, lower third, lower fourth of the body of the vial, or otherwise adjacent or closely proximal to the base of the vial.” *Id.* at 15–16. In light of these teachings, Appellants urge that Duymelinck teaches away from the Examiner’s

modification to move the sample holder adjacent the port as claimed. *Id.* at 16.

This argument is not persuasive, however, because “[a] reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). Appellants have not identified any passage in Duymelinck that actually criticizes, discredits, or discourages placement of the sample holder directly adjacent to and beneath the port.

Moreover, we agree with the Examiner (Ans. 17) that Duymelinck suggests modification in the length of the elongated member because the elongated member is taught to be placed a different depths within the vial according to the solution level and a desire to immerse the sample. Ans. 17. Specifically, Duymelinck explains that

[s]uch elongated member 103 may serve to suitably position the sample holding means within the inner space 241 of the vial 84, such that this would become immersed in solutions introduced thereto, advantageously by being placed, e.g., in the lower half, lower third, lower fourth of the body of the vial, or otherwise adjacent or closely proximal to the base of the vial.

Duymelinck 39. Thus, there is a suggestion that the length of the elongated member is a design choice.

Appellants also contend that the proposed modification would render Duymelinck unsatisfactory for its intended purpose. Appeal Br. 15. In particular, Appellants insist that

[p]ositioning the sample holder of Duymelinck as suggested by the Examiner would render Duymelinck inoperative for its intended purpose; not because the rearrangement would prevent the fluid access means (88, 89) from expelling solutions over the sample and into the interior of the vial as the Examiner has attempted to rebut, but because without the ability to insert the fluid transfer means (88, 89) at least into the lower half of the vial and advantageously “adjacent or closely proximal to the base of the vial” as taught by Duymelinck, the device would be unable to clear each fluid solution in between steps.

*Id.* at 18. As a result, “upon penetrating breakable seals (92, 93) the fluid access means (88, 89) would immediately contact a surface of the sample holder (104), thereby preventing the tip of the fluid access means (88, 89) from breaking the surface of the solution” and thereby requiring manual manipulation, as opposed to an automated process, for producing paraffin sections of biological tissue. *Id.* at 19; *see also* Reply Br. 6.

Appellants’ arguments are not persuasive of reversible error by the Examiner. We agree with the Examiner that the intended purpose of Duymelinck is not frustrated by the proposed modification because “[i]n the case where the cassette 201, Figure 21 a and b . . . the cassette still includes a particular depth where the sample is enclosed within the cassette and there would still be fluid access means.” Ans. 17. According to Duymelinck,

in most cassettes at least the bottom plate of the receptacle member and/or the top plate of the cover member, and preferably both, *are conducive to liquids so as to enable the exposure of the tissue sample enclosed in the cassette to liquid agents* when the cassette is submerged in the latter. Typically, this may be



achieved by provision of suitably sized and shaped *perforations* in the said plates.

Duymelinck 4 (emphasis added).

Moreover, we note that Duymelinck is not limited to the cassette design of Figures 21a and b, but instead teaches plural embodiments of sample holders. *See e.g.*, Duymelinck 4 (“tissue sample holders or tissue sample cassettes can adopt variable forms”), 24 (“sample supporting means can be any suitable structure such as a gridded platform provided with a clip to hold the sample on the platform”), and 28 (sample holder “refer[s] to any receptacle employed in the art . . . for the storage and processing of samples.”); *see also id.* Figure 8 (element 87) and Figure 11 (item 104). In the embodiments depicted in Figures 8 and 11, the fluid access means (88, 89) is positioned next to the sample holder (87) and does not preclude access to the surface of the solution. *Id.* Figures 8, 11.

Lastly, and for the first time in reply, Appellants urge that there is no reason to modify the teachings of Duymelinck because the Examiner’s purported reason, i.e., to minimize any sort of risk of contamination or spillage, is already addressed by Duymelinck. Reply Br. 4. Appellants contend that the “Examiner has not provided any reasoning why a distance of the sample holding means (104) relative to the port (92, 93) has any effect on contamination or spillage when the lid (101) is connected to the vial.” *Id.*

Appellants have not explained, nor is it apparent, that these arguments were necessitated by the Examiner’s Answer or could not have been presented in the principal brief. Therefore, these arguments are untimely and we will not reach arguments presented for the first time in a reply brief in the absence of good cause. 37 C.F.R. §41.41(b)(2).

*Rejection C – Anticipation (claims 1–4, 6–10, 12–14, and 16–21)*

The Examiner also rejects claims 1–4, 6–10, 12–14, and 16–21 as anticipated by Duymelinck. Ans. 9. The Examiner finds that Duymelinck teaches a system for storing a biological sample having each of the claimed elements, including a container, a removable closure, a sample holder, a port, and an injection device. *Id.* at 9–10. With respect to the rejection under 35 U.S.C. § 102(b), the Examiner concludes that the broadest reasonable interpretation of “directly beneath the port” means “close or near” and adjacent similarly means “close or near.” *Id.* at 10. As a result, the Examiner finds the claim limitation requiring that “the sample holder [to be] located directly adjacent to and beneath the port along a longitudinal axis of the port” is met by Duymelinck’s disclosure that “the elongated member (103) of its device can change lengths so that it able to be at different depth[s] within the inner space of the vial . . . and is placed in a location close or near and beneath the port and within a defined space of the container interior.” *Id.*

Appellants contend that the Examiner’s interpretation of “directly adjacent to and beneath”—as applied to the rejection under 35 U.S.C. § 102(b)—fails to give weight to the word “beneath.” Reply Br. 3. Appellants additionally argue that the sample holder of Duymelinck, depicted in Figure 10, is not close or near. *Id.*

We agree with Appellants. “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation.” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012) (citing *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1336–37 (Fed. Cir. 2010)). In this instance, Duymelinck teaches embodiments where the sample holder

is positioned within the vial and at a distance away from the port. *See e.g.*, Duymelinck 39 and Figures 8, 10A, 10B, 11, 12, 24a, 24b, 25, and 26a–g. We agree that the Examiner’s construction of “directly adjacent to and beneath the port” as meaning “close or near” does not give full effect to the words of the claim. Reply Br. 3. Moreover, a sample holder, like that of Duymelinck, placed “in the lower half, lower third, lower fourth of the body of the vial, or otherwise adjacent or closely proximal to the base of the vial” is not “close or near” a port located at the top of the vial. Duymelinck 39. Therefore, on this record, we cannot sustain the Examiner’s rejection of claims 1–4, 6–10, 12–14, and 16–21 under 35 U.S.C. § 102(b).

#### CONCLUSION

The Examiner did not reversibly err in rejecting claims 1–4, 6–10, 12–14, and 16–21 under 35 U.S.C. § 103(a) as being unpatentable over Duymelinck.

The Examiner did not reversibly err in rejecting claims 11 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Duymelinck in view of Ryan or Smith.

The Examiner *did reversibly err* in rejecting claims 1–4, 6–10, 12–14, and 16–21 under 35 U.S.C. § 102(b) as being unpatentable over Duymelinck.

#### DECISION

For the above reasons, the Examiner’s rejection of claims 1–4 and 6–21 is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED