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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/924,351	09/24/2010	Bryan W. Kluttz	97-200-J13	7789

35467 7590 09/23/2016

BIOMERIEUX INC.
100 RODOLPHE STREET
DURHAM, NC 27712

EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1799	

NOTIFICATION DATE	DELIVERY MODE
09/23/2016	ELECTRONIC

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USPatents@na.biomerieux.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRYAN W. KLUTTZ, GEOFF A. MCKINLEY, FABIO GENNARI, MICHEL GUY, CHRISTOPHER COTTER, LUIGI CATANZARITI, LOUIS GRAZIANO, BRUNO COLIN, CECILE PARIS, and JACQUES DACHAUD[1]

Appeal 2013-009068
Application 12/924,351
Technology Center 1700

Before CHUNG K. PAK, MARK NAGUMO, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

PAK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134(a) from the Examiner's decision[2] finally rejecting claims 9–27. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

STATEMENT OF THE CASE

The subject matter on appeal is directed to a test device "for performing nucleic acid amplification reactions." Spec. 2, ll. 16–17 and 5, ll. 5–7. "The test device has a first reaction chamber containing a first nucleic acid amplification

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[1] The real party in interest is said to be bioMériux, Inc. Appeal Brief filed March 13, 2013 ("App. Br.") at 1.

[2] Final Action entered September 19, 2012 ("Final Act.") at 1–9 and the Examiner's Answer entered May 17, 2013 ("Ans.") at 2–6.

reagents . . . and a second reaction chamber either containing, or in fluid communication with , a second nucleic acid amplification reagent . . . ." *Id.* at 6, ll. 1–7. This test device is used in conjunction with an amplification station and is said to "substantially eliminate[] the risk of contamination, and provide a convenient, simple and easy to use approach for nucleic acid amplification reactions." *Id* at 5, ll. 5–7.

Figure 2, a test device (test strip) having a cover member according to one preferred embodiment of the invention, is reproduced below:

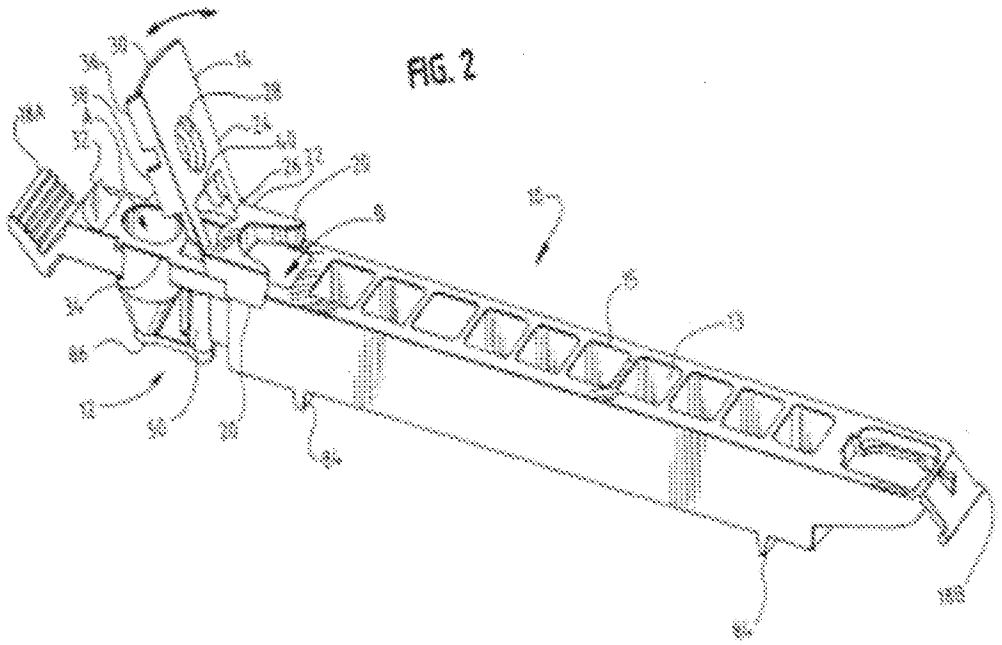

Figure 2 shows a test strip or device 10 having a dual chamber reaction vessel 12 that includes two separate reaction chambers A and B, with chamber A containing a heat stable sample/amplification reagent and chamber B containing a heat labile enzymatic reagent. Spec. 18, l. 10–19, l. 3. "The[se] two chambers are linked to each other by a fluid channel or connecting conduit 50 extending from the first chamber [A] to the second chamber [B]" with various fluid flow control means,

such as a valve. *Id.* at 19, ll. 7–11. The test strip or device 10 also "includes a plurality of hybridization and wash wells 13" and an associated cover member 14 comprising a pair of resilient legs 20, a rear portion 22, a second or forward portion 24, an integral hinge portion 26, an edge 30, and a central aperture 28 having a porous mesh filter placed therein. *Id.* at 19, ll. 18–19 and 22, l. 19–23, l. 18. "A sealing membrane [(not shown) having a free edge 32]. . . is applied to the upper surface 15 of the test strip or device [10] to cover the wells 13 and dual chamber reaction vessel 12, after the wells [13] and vessel 12 have been pre-loaded with the appropriate enzyme, reagent wash or buffer solution, etc." *Id.* at 20, l. 21–21, l. 1 and 23, ll. 18–21.

Details of the appealed subject matter are recited in illustrative claims 9 and 21, which are reproduced below from the Claims Appendix of the Appeal Brief (with disputed limitations in italicized form and bracketed reference characters of Figure 2):

> 9. A disposable nucleic acid amplification test device [10] for insertion into an amplification station conducting an amplification reaction using the test device [10], the test device [10] comprising:
>
> a body defining a first chamber [A] for receiving a sample and a second chamber [B] for conducting a nucleic acid amplification reaction therein;
>
> a conduit [50] connecting the first chamber [A] to the second chamber [B];
>
> a nucleic acid amplification reaction enzyme in fluid communication with the second chamber [B];
>
> a valve [not shown in Figure 2] controlling the flow of the sample through the conduit [50]; and
>
> wherein the portion of the body of the test device [10] defining the second chamber [B] has an external configuration sized and shaped so as to place the second chamber into thermal contact with controlled heating elements provided in the analytical instrument when the test device [10] is inserted into the instrument, the controlled

heating elements regulating the temperature of the second chamber [B]; and

wherein the test device [10] is constructed and arranged with a cover [14] connected to the test device [10] moveable from a first position covering the first chamber [A] to a second position so as to enable a user to supply the sample into the first chamber [A] directly.

21. A disposable nucleic acid amplification test device comprising:

a first chamber [A] containing a first reaction reagent;

a second chamber [B] containing a second reaction reagent;

an intermediate chamber [not shown in Figure 2] between the first chamber [A] and the second chamber [B];

an externally, mechanically actuated flow control element [not shown in Figure 2] selectively providing fluid communication between the first chamber [A] and the intermediate chamber [not shown in Figure 2]; and

a cover [14] connected to the test device moveable from a first position covering the first chamber [A] to a second position exposing the first chamber [A] so as to enable a user to supply the sample into the first chamber [A] directly.

App. Br. 16–17 and 19, Claims Appendix.

The Examiner maintains the following grounds of rejection:

1. Claims 9, 10, 14, 15, and 19–27 under 35 U.S.C. §103(a) as unpatentable over Zanzucchi (US 5,858,804 issued Jan. 12, 1999) in view of

Anderson (US 2006/0246490 A1 published Nov. 2, 2006) and Gerdes (US 5,955,351 published Sept. 21, 1999);

2. Claims 11–13 and 16 under 35 U.S.C. §103(a) as unpatentable over Zanzucchi in view of Anderson, Gerdes, and Thomas (US 4,330,627 issued May 18, 1982); and

3. Claims 17 and 18 under 35 U.S.C. §103(a) as unpatentable over Zanzucchi in view of Anderson, Gerdes and Schnipelsky (US 5,229,297 issued Jul. 20, 1993). Final Act. 2–9 and Ans. 2–6.

DISCUSSION

Having considered the evidence on this appeal record in light of the respective positions advanced by the Examiner and Appellants, we do not sustain the Examiner's decision rejecting claims 9–27 under 35 U.S.C. §103(a) substantially for the reasons set forth at pages 4 through 12 of the Appeal Brief and pages 3 and 4 of the Reply Brief filed July 10, 2013 ("Reply Br."). We add the following primarily for emphasis.

Figure 1B of Zanzucchi relied upon by the Examiner is reproduced below:

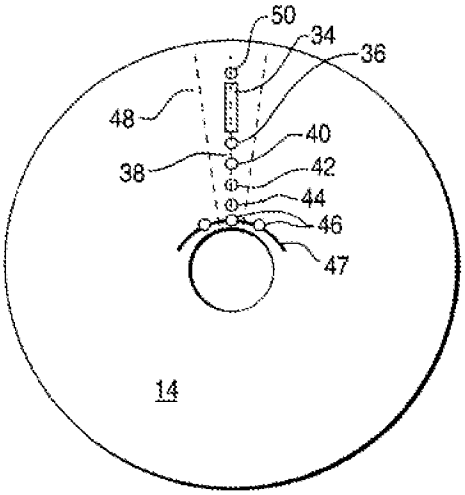

FIG. 1B

Figure 1B illustrates a microlaboratory disc 14 having a large number of modules 48 in "parallel" connected to well 46 to perform a large number of tests, with each module defining loading channel 34 and/or 50 (identified by the Examiner as a chamber at page 3 of the Final Action) and a plurality of wells 36, 40, 42, and 44 connected by channel 38. *See, e.g.,* Zanzucchi, col. 4, ll. 21–30 and 55–62 and col. 5, ll. 3–6. One or more capillary tubes 32 containing a sample (not shown in Figure 1B) is loaded into loading channel 34 or into loading channel 50 for vertical insertion into the loading channel 34. *See, e.g.*, Zanzucchi, col. 4, ll. 15–27. "As the sample loading tube 32 is inserted into the loading channel 34, a sealant, which can be adhered to the edge of the capillary sample tube 32 or to the loading channel 34, seals the capillary tube 32 to the channel 34." Zanzucchi, col. 5, l. 65–col. 6, l. 2.

The sample is then subsequently treated in a series of wells 36, 40, 42, and 44, with first well 36 being used for separating or filtering the sample from the loading channel 34 and second well 40 being used for amplifying the separated or filtered sample from first well 36 via using the conventional PCR method. *See, e.g.*, Zanzucchi, col. 4, ll. 35–44. Because a significant vapor pressure may develop in first well 36, valves 62 and 63 (not shown in Figure 1B) are used to prevent "a back pressure in both directions [of first well 36]–back toward the sample loading channel 34 and forward to the succeeding second well 40." Zanzucchi, col. 9, ll. 34–54.

Once all of the wells have been prepared and loaded, "a glass cover plate 63 [not shown in Figure 1B] is affixed to the microlaboratory disc 14 . . . to complete a capillary structure for the connecting channel 38 [(identified by the Examiner as a conduit at page 3 of the Final Action)] and to ensure that fluids in the well do not evaporate." Zanzucchi, col. 8, ll. 35–39. "The cover plate 63 can be made of the

same or different material as the microlaboratory disc, but the thermal coefficient of expansion of the cover plate 63 and the material used to make the microlaboratory disc 14 must be similar." Zanzucchi, col. 8, ll. 38–43. "The sealing temperature required to seal the cover plate 63 to the disc 14 must also be below the flow temperature of the disk material to prevent distortion of the etched channels and wells." Zanzucchi, col. 8, ll. 42–46.

The Examiner acknowledges that Zanzucchi does not disclose, inter alia, "a cover connected to the test device moveable from a first position covering the first chamber to a second position so as to enable a user to supply the sample into the first chamber directly" as recited in claims 9 and 21.[3] Final Act. 4. To account for

[3] The Examiner also acknowledges that Zanzucchi does not indicate that its "second chamber [(second well 40)] has an external configuration sized and shaped so as to place the second chamber into thermal contact with controlled heating elements provided in the analytical instrument when the test device [(microlaboratory disc 14)] is inserted into the instrument" as recited in claim 9 because it describes using heating elements within the test device to conduct amplification in second well 40. Final Act. 3. However, the Examiner finds, and Appellants do not dispute, that "Anderson discloses a microfluidic amplification test device in which at least one first chamber (Figure 3:206) [configured to separate a sample] is in communication with a second chamber (Figure 3:210) configured to conduct PCR. Paragraphs [0166]-[0167] [of Anderson] teach that the test device itself may include a heating element, or, alternatively, . . . contact heating elements provided within an associated analytical instrument ('the amplification chamber will incorporate a controllable heater disposed within or adjacent to the amplification chamber')." *Compare* Final Act. 3–4 *with* App. Br. 8–9; *see also* Anderson ¶¶164–166. Stated differently, there is no dispute that a heating element can be provided in the associated analytical instrument (Zanzucchi's station 16 not shown in Figure 1B) for heating second well 40 (configured for PCR amplification) of the microlaboratory disc taught by Zanzucchi per the teachings of Anderson. *Id.* Implicit in this suggestion in the applied prior art is that second well 40 of the microlaboratory disc taught by Zanzucchi must also be designed or shaped to be fitted into and heated by Zanzucchi's station (analytical instrument) having such heating element. Thus,

this missing feature in the microlaboratory disc taught by Zanzucchi, the Examiner relies upon the disclosure of Gerdes. Final Act. 4–5. Figure 1 of Gerdes relied upon by the Examiner is reproduced below:

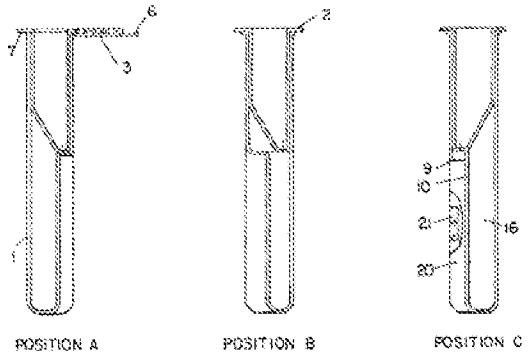

FIG. 1

In Gerdes' Figure 1, "an extraction, amplification and detection device consists of a first hollow elongated cylinder 1 having one closed end and an integrally-molded cover 3 hinged to the opposing, open end and a second hollow elongated cylinder 2 [having an aperture 13 not shown] that is positioned contiguously inside the first cylinder 1 and capable of relative rotation." Gerdes, col. 6, ll. 36–42; *see also* Final Act. 4–5. "The first cylinder 1 further consists of 2 chambers: a reservoir 16 and a detection chamber 20, said detection chamber further consisting of a pad 9 and a strip 10." Gerdes, col. 6, ll. 45–47. "When sample is introduced into the device, nucleic acid extraction and amplification takes place in the second cylinder 2 . . . ." *Id.* at col. 6, ll. 58–60; *see also* Final Act. 4–5. The second cylinder 2 is rotated "relative to the first cylinder 1" to lock into positions A, B, and C, with positions B and C allowing the amplified sample from the second cylinder 2 to

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Appellants' argument directed to the external configuration and the shape of a second well for conducting PCR amplification does not convince us of harmful error in the Examiner's §103(a) rejections.

flow into the reservoir 16 and the detection chamber 20, respectively. Gerdes, col. 6, l. 64–col. 7, l. 12; *see also* Final Act. 4–5.

Based on Figure 1B of Zanzucchi and Figure 1 of Gerdes discussed *supra*, the Examiner concludes that "[a]t the time of the invention, it would have been obvious to provide the opening to the first chamber 50 of Zanzucchi with a cover component capable of being moved from a first position to a second position in order to enable the addition of fluid." Final Act. 5.

However, on this record, the Examiner has not demonstrated that Gerdes' hinged cap or cover suitable for a rotating cylinder (test tube) device would be useful for the microlaboratory disc taught by Zanzucchi. As correctly stated by Appellants, "Zanzucchi's cover 63 (Fig. 5B) must remain fixed and sealed to the top of the device in order to define a capillary channel 38 . . . and allow fluid to move along the channels from the sample introduction well 50 to the remaining wells . . . and to prevent the fluids pre-loaded into the wells from evaporating after manufacture." App. Br. 9–10. In particular, Zanzucchi discloses that:

> When all of the wells have been prepared and loaded, a glass cover plate 63 is affixed to the microlaboratory disc 14, as shown in FIG. 5B, to complete a capillary structure for the connecting channel 38 and to ensure that fluids in the wells do not evaporate[.] The cover plate 63 can be made of the same or different material as the microlaboratory disc, but the thermal coefficient of expansion of the cover plate 63 and the material used to make the microlaboratory disc 14 must be similar. The sealing temperature required to seal the cover plate 63 to the disc 14 must also be below the flow temperature of the disk material to prevent distortion of the etched channels and wells. The use of electric fields to seal the cover plate to the disk is suitable because sealing will take place at a lower temperature than the flow temperature, e.g., about 700° C. or less, which is well below the flow temperature of silicon, about 1400°C., or of Corning 7059 glass, (about 844° C.), available from Corning Glass Co., for example. [Zanzucchi, col. 8 lines 35–51.]

Zanzucchi also discloses that "[a]s the sample loading [capillary] tube 32 is inserted into the loading channel 34, a sealant, which can be adhered to the edge of the capillary sample tube 32 or to the loading channel 34, seals the capillary tube 32 to the channel 34." Zanzucchi, col. 5, l. 65–col. 6, l. 2; *see also* Reply Br. 3. Zanzucchi further teaches using an alternate, but similar, configuration involving the capillary tube 32 inserted into the loading channel 50. Zanzucchi, col. 4, ll. 15–27 and col. 6, ll. 2–8; *see also* Reply Br. 3. In other words, Zanzucchi teaches using both the cover 63 and the capillary tube 32 containing a sample to seal the surface of its microlaboratory disc to form capillary channels connecting sealed chambers to prevent evaporation of the sample during the use of the microlaboratory disc in an analytical device (station 16) as indicated *supra*. Such cover and capillary tube also allow Zanzucchi's microlaboratory disc to have up to 1500 parallel modules for conducting broad DNA screening in parallel, i.e., conducting a large array of parallel tests at the same time, without evaporating samples, during their use in the analytical device. Zanzucchi, col. 5, ll. 3–12.

On this record, the Examiner does not identify any prior art teaching or evidence that would have indicated that Gerdes' hinged cap or cover would be useful for the purposes taught by Zanzucchi, i.e., suitable for forming capillary channels connecting sealed chambers in a manner that would allow Zanzucchi's microlaboratory disc to have up to 1500 parallel modules useful for conducting a large array of parallel tests, without causing any evaporation of the sample, in a particular analytical device. Final Act. 3–10; Ans. 2–6. Hence, we concur with Appellants that a preponderance of the evidence does not support the Examiner's determination that the applied prior art would have rendered the subject matter

recited in claims 9–27 obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. § 103(a).

ORDER

In view of the foregoing, the decision of the Examiner to reject claims 9–27 under 35 U.S.C. § 103(a) is REVERSED.

REVERSED