



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

11/120,115

05/02/2005

Antonio M. Goncalves

6056-316CT2 (207359)

2469

23973

7590

02/02/2009

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/120,115	Applicant(s) GONCALVES, ANTONIO M.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/02/2005 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,15,19,42,43 and 46-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,15,19,42,43,46-50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/02/2005</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS of 9/29/2008</u> . |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,905,585 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the “liquid buffer” and “the cover being spaced apart from the body for receipt of a substrate which contains samples to be tested with the substrate being between the reservoirs” are obvious. Claim 6 of ‘585 states that the

Art Unit: 1795

cover is attached to the body “with a seal so as to form a substantially liquid tight seal between the cover and the body of the cassette to prevent leakage of buffer during use.” Thus there is buffer in the cassette. One would ordinary skill in the art would expect the buffer to be liquid buffer located at least in the reservoirs , which each have at least one electrode. Also since claim 6 (through claim 1) of ‘585 requires “an electrophoretic substrate disposed on the substrate support” between the liquid reservoirs this implies “the cover being spaced apart from the body for receipt of a substrate which contains samples to be tested with the substrate being between the reservoirs.” Also see related method claim 45 in ‘585 in regard to this limitation.

3. Claim 3 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,905,585 B2. Claim 1, from which claim 3 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2, which depends from claim 1 of ‘585, provides the additional features of claim 3 of the instant application.

4. Claim 5 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,905,585 B2. Claim 1, from which claim 5 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8, which describes a very similar cassette as set forth in claim 1 of '585, provides the additional features of claim 5 of the instant application. One with ordinary skill in the art at the time of the invention would consider all of the claims in '585 in order to determine obvious variants of the claimed invention.

5. Claim 6 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,905,585 B2. Claim 5, from which claim 6 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 provides the additional features of claim 6 of the instant application.

Art Unit: 1795

6. Claim 15 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,905,585 B2. Claim 1, from which claim 15 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 provides the additional features of claim 1 of the instant application.

7. Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,905,585 B2. Claim 1, from which claim 19 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 provides the additional features of claim 19 of the instant application.

8. Claim 42 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 68 of U.S. Patent No. 6,905,585 B2. The claimed identification device in claim 42 is strongly suggested by the bar code reader in claim 68 of '585.

9. Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,905,585 B2 in view of Merrick et al. US 5,534,121 ("Merrick"). Claim 1, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because barring a contrary showing, the dimensions of the substrate is just a matter of scale. As shown by Merrick, for example, it was known at the time of the invention to make substrates that were 20x25 cm. See the abstract and col. 02:66-67.

10. Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 44 of U.S. Patent No. 6,905,585 B2. Claim 1, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because related method claim 44 requires urging the cover down toward the body. Since the substrate is between the body and the cover and is also between the reservoirs. When the cover reaches the surface of the substrate it will seal the reservoirs.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented 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. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1795

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unno et al. US 6,495,104 B1 ("Unno").

Unno discloses a substrate assembly comprising a substrate for receiving samples on which an analysis is to be performed and an identification device associated with the substrate for providing information pertaining to a separation process. See the abstract; Figures 1-6; col. 02:20 – 03:64; and col. 05:25-50. Although Unno does not specifically mention that electrophoresis is to be performed and that the identification device provides information pertaining to an electrophoresis process it would have been obvious to one with ordinary skill in the art to use the substrate for performing electrophoresis and so also have the identification device provide information pertaining to an electrophoresis process because Unno states, the identification device provides "... an indication of the functionality of the microfluidic device, e.g., the particular application for which the device is used, i.e. nucleic acid *separations*, protein *separations*, ...[emphasis added]" and shortly thereafter, "These electrodes 328 that are operably coupled to power sources (not shown) within the instrument 320, provide actuation of material movement within the channels of the device 300 via electrokinetic forces." See col. 05:36-43 and col. 05:65 - col. 06:01. Together these passages would suggest using the device for electrophoresis analysis.

For the additional limitations of claim 46 see Figures 1-6.

15. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Arai Akihiro JP 08-233778 ("Akihiro") in view of Frazier US 6,726,820 B1 ("Frazier")

Akihiro discloses an electrophoresis substrate assembly (10) comprising a substrate for receiving samples on which electrophoresis analysis is to be performed (11), and an identification device (17) associated with the substrate (Drawings 1 and 2) for providing information pertaining to an electrophoresis process. See also the abstract; paragraphs [0013] and [0014] of the Detailed Description. Moreover, the identification device is a part of a frame (12) that surrounds the substrate (Drawings 1-3), identification device providing information related to the substrate which is used for establishing parameters to be used in the electrophoresis analysis (paragraphs [0013] and [0014] of the Detailed Description).

The identification device on Akihiro, though, is a bar code, not a microchip. Frazier discloses an electrophoresis substrate assembly (10) comprising a substrate for receiving samples on which electrophoresis analysis is to be performed (12), and an identification device (18) associated with the substrate (Figure 1) for providing

Art Unit: 1795

information pertaining to an electrophoresis process. See the abstract; Figures 1 and 2; col. 02:46-47; col. 02:25-32; and col. 09:20-41. Moreover, the identification device is a microchip attached to the substrate. See Figure 1. It would have been obvious to one with ordinary skill in the art at the time of the invention to use a microchip as taught by Frazier for the identification device instead of a bar code because the microchip can hold more information that can be easily changed. Also, the frame in Akihiro is already configured with electrical contacts, so the microchip can be situated near these contacts so that the microchip contacts can also be connected to means for reading and programming the microchip.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1795

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 42 and 46 are rejected under 35 U.S.C. 102(e) as being completely anticipated by Amshey et al. US 6,521,111 B1. See the abstract; Figures 3-5; col. 01:43-50; and col. 08:66 – col. 09:19.

18. Claim 43 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the JPO abstract and Figure 1 of Koichi et al. JP 04-190155 A.

19. Claims 42, 46, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Frazier US 6,726,820 B1. See the abstract; Figures 1 and 2; col. 02:46-47; col. 02:25-32; and col. 09:20-41.

20. Claims 42, 46, and 47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by paragraphs [0006], [0009], [0010] of the Detailed Description and Figures 1A and B in the English language translation of Hiroshi Tanaka JP 2001-188061 A .

21. Claims 42, 46, and 49 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the English language translation of Arai Akihiro JP 08-233778. See the abstract; paragraphs [0013] and [0014] of the Detailed Description; and Drawings 1-3. Note identification device 17 on frame 12.

22. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO 01/55707 A2, based on the Supplementary International Search Report for Application Number EP 03749588. See page 5, lines 8-17; page 10, line 25 – page 11, line 3 and Figure1.

Supplementary International Search Report for Application Number EP 03749588
("Search Report")

23. WO 01/55707 A is cited as an "X" reference against claims 1-3 and 5-7, and as a "Y" reference against claims 8 and 10 in the Search Report. It has been applied under 35 U.S.C. 102(a) against claims 1-3 and 5-7 above. Claims 8 and 10 have been cancelled in the instant application.

24. WO 93/13415 A is cited as a "Y" reference against claims 8 and 10 in the Search Report. Claims 8 and 10 have been cancelled in the instant application. Also, WO 93/13415 A concerns a detachable column cartridge for gas chromatograph. It is not clear how it would be combinable with the horizontal gel electrophoresis device of WO 01/55707 A.

25. WO 96/34276 A1 is cited as an "X" reference against claim 1 in the Search Report. Claim 1 requires "a support substrate located between the liquid reservoirs and adapted to support an electrophoresis substrate. In WO 96/34276 A1 the substrate (18) lies directly the bottom of the body (12) of the cassette. Also the thickness of the substrate is the same as the distance between the bottom of the cassette and the cover, so there is no room of a substrate support. See Figures 9 and 10.

Art Unit: 1795

26. US 4,415,418 is cited as an "X" reference against claim 1. Claim 1 requires "at least one port in fluid communication with at least one of the reservoirs and extending to an external surface of the cassette," which is not disclosed in US 4,415,418.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
January 29, 2009