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11/070,502 2 March 2005 (02.03.2005) US
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- (74) Common Representative: **ROCHE DIAGNOSTICS GMBH**; -Patent Department-, 68298 Mannheim (DE).
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Declaration under Rule 4.17:

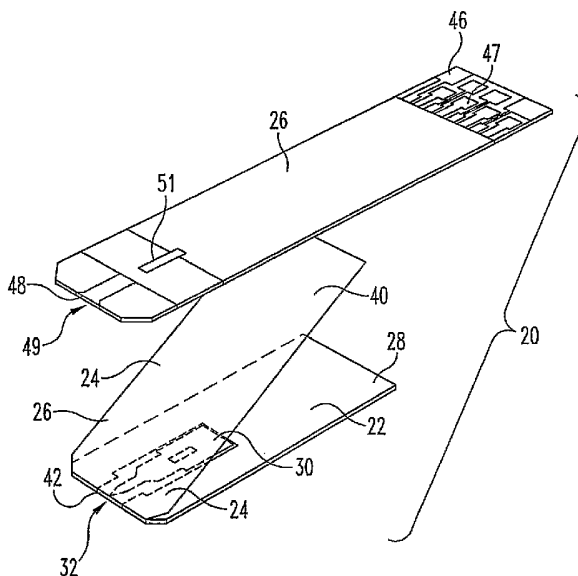
— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: DYNAMIC INTEGRATED LANCING TEST STRIP WITH STERILITY COVER



(57) Abstract: An integrated lancing test strip includes a test strip and a lancet packet coupled to the test strip. The lancet packet includes a sterility sheet enclosing a lancet to maintain the sterility of the lancet and prevent cross-contamination between the test strip and the lancet. The sterility sheet allows the lancet to be sterilized separately from the test strip. The sterility sheet gives the integrated strip a low profile, which is attractive for packaging multiple integrated strips in cassettes, drums, magazines or the like. In one form, the integrated strip is loaded in a meter that includes an adjustment mechanism that adjusts the position of the test strip relative to the skin being sampled. This allows the user to adjust the position of the test strip so as to not apply excessive pressure against skin, which could hamper bleeding from the incision in the skin.

WO 2006/092281 A3



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2 November 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/001857

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-17

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

An integrated test strip and lancet apparatus and the method to fabricate it.

2. claims: 18-24

A meter configured to hold and position a test strip relative to tissue.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/001857

<p>A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/15</p> <p>According to International Patent Classification (IPC) or to both national classification and IPC</p>																	
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) A61B</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p> <p>Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal</p>																	
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>EP 1 402 812 A (BECTON, DICKINSON AND COMPANY) 31 March 2004 (2004-03-31) abstract paragraphs [0020] - [0034], [0042] figures 1-3</td> <td>1-17</td> </tr> <tr> <td>A</td> <td>US 6 071 294 A (SIMONS ET AL) 6 June 2000 (2000-06-06) abstract figures 1a-2c column 4, line 60 - column 7, line 51</td> <td>1-17</td> </tr> <tr> <td>A</td> <td>WO 2004/066822 A (ROCHE DIAGNOSTICS GMBH; F. HOFFMANN-LA ROCHE AG; ROE, STEVEN, N; RANEY) 12 August 2004 (2004-08-12) column 11, line 14 - column 16, line 2</td> <td>1</td> </tr> <tr> <td></td> <td style="text-align: center;">-/--</td> <td></td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	A	EP 1 402 812 A (BECTON, DICKINSON AND COMPANY) 31 March 2004 (2004-03-31) abstract paragraphs [0020] - [0034], [0042] figures 1-3	1-17	A	US 6 071 294 A (SIMONS ET AL) 6 June 2000 (2000-06-06) abstract figures 1a-2c column 4, line 60 - column 7, line 51	1-17	A	WO 2004/066822 A (ROCHE DIAGNOSTICS GMBH; F. HOFFMANN-LA ROCHE AG; ROE, STEVEN, N; RANEY) 12 August 2004 (2004-08-12) column 11, line 14 - column 16, line 2	1		-/--	
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<p><input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.</p>																	
<p>* Special categories of cited documents :</p> <table border="0"> <tr> <td style="vertical-align: top;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>													
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<p>Date of the actual completion of the international search</p> <p style="text-align: center;">4 May 2006</p>		<p>Date of mailing of the international search report</p> <p style="text-align: center;">30. 08. 2006</p>															
<p>Name and mailing address of the ISA/ European Patent Office, P.B. 5318 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016</p>		<p>Authorized officer</p> <p style="text-align: center;">Rivera Pons, C</p>															

INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2005/104949 A (ROCHE DIAGNOSTICS GMBH; F. HOFFMANN-LA ROCHE AG; WONG, DANIEL; WIEGEL,) 10 November 2005 (2005-11-10) page 21, line 15 - page 23, line 16 -----	1,2,8,9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2006/001857

Patent document cited in search report	Publication date	Patent family member(s)	-Publication date	
EP 1402812	A	31-03-2004	CA 2443318 A1	30-03-2004
			ES 2256636 T3	16-07-2006
			JP 2004267760 A	30-09-2004
			US 2004064068 A1	01-04-2004

US 6071294	A	06-06-2000	DE 19855458 A1	01-07-1999
			GB 2331935 A	09-06-1999

WO 2004066822	A	12-08-2004	EP 1589873 A2	02-11-2005

WO 2005104949	A	10-11-2005	NONE	
