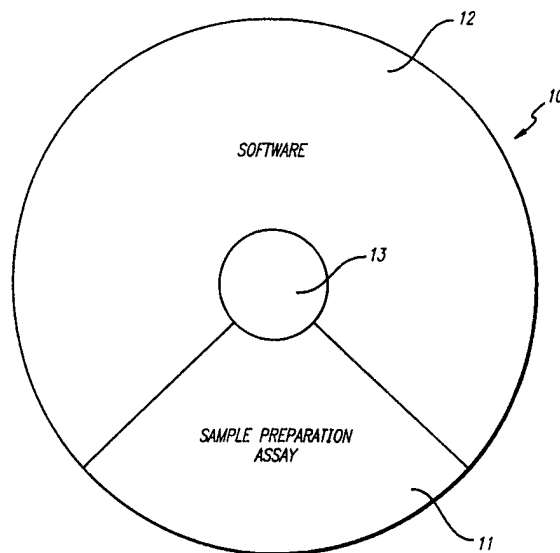




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification<sup>6</sup> : <b>G01N 35/02, 33/487, 33/50, 21/64, 33/483 // C12Q 1/68</b></p>	<p><b>A3</b></p>	<p>(11) International Publication Number: <b>WO 98/38510</b></p> <p>(43) International Publication Date: 3 September 1998 (03.09.98)</p>
<p>(21) International Application Number: PCT/US98/04377</p> <p>(22) International Filing Date: 27 February 1998 (27.02.98)</p> <p>(30) Priority Data: 60/039,419 28 February 1997 (28.02.97) US</p> <p>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/039,419 (CIP) Filed on 28 February 1997 (28.02.97)</p> <p>(71) Applicant (for all designated States except US): BURSTEIN LABORATORIES, INC. [US/US]; 33601 Avenida Calita, San Juan Capistrano, CA 92675 (US).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): VIRTANEN, Jorma [US/US]; 5005 Paseo Segovia, Irvine, CA 92612 (US).</p> <p>(74) Agent: HALLUIN, Albert, P.; Howrey &amp; Simon, 1299 Pennsylvania Avenue, N.W., Box 34, Washington, DC 20004-2402 (US).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 28 January 1999 (28.01.99)</p>	

(54) Title: LABORATORY IN A DISK



## (57) Abstract

An apparatus is described that includes an optical disk, adapted to be read by an optical reader, comprising a first sector having substantially self-contained assay means for localizing an analyte suspected of being in a sample to at least one, predetermined location in the first sector and a second sector containing control means for conducting the assay and analyte location information, with respect to one or more analytes suspected of being in a sample, accessible to the reader, wherein the presence or absence of the analyte at said location is determinable by the reader using the control means and the location information. Depending on the nature of the assay, the disk will include fluid storage means, fluid transfer means, such as one or more capillary ducts, valves, batteries, dialyzers, columns, filters, sources of electric fields, wires or other electrical conductive means such as metallic surface deposits and the like.

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 98/04377

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 6 G01N35/02 G01N33/487 G01N33/50 G01N21/64 G01N33/483  
 //C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 IPC 6 G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 09548 A (THE UNIVERSITY COURT OF THE UNIVERSITY OF GLASGOW) 28 March 1996	1, 3-5, 12, 15, 16
Y	see page 10, line 16 - page 24, line 10; figures 1-7	6, 7, 10, 11, 13
Y	EP 0 417 305 A (IDEMITSU PETROCHEMICAL CO. LTD.) 20 March 1991 see column 5, line 35 - column 15, line 13; figures 1-12	6, 7, 11, 13
Y	CAROL T. SCHEMBRI, ET AL.: "Portable Simultaneous Multiple Analyte Whole-Blood Analyzer for Point-of-Care Testing" CLINICAL CHEMISTRY., vol. 38, no. 9, September 1992, pages 1665-1670, XP000319980 WINSTON US see the whole document	10
	-/--	

Further documents are listed in the continuation of box C.       Patent family members are listed in annex.

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Date of the actual completion of the international search  <b>22 September 1998</b>	Date of mailing of the international search report  <b>07. 12. 98</b>
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  <b>Osborne, H</b>
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## INTERNATIONAL SEARCH REPORT

 International Application No  
 PCT/US 98/04377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category <sup>2</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 35940 A (CIBA-GEIGY AG) 14 November 1996 see the whole document ---	1-16
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P,Y	WO 98 01533 A (BURSTEIN LAB INC) 15 January 1998 see the whole document ---	14
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A	WO 93 20092 A (ZENECA LTD ;MCLEAN MICHAEL JOSEPH (GB); HOLLAND DAVID (GB); GARMAN) 14 October 1993 see the whole document ---	14
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A	EP 0 707 076 A (AMOCO CORP) 17 April 1996 see figure 1B -----	14

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/04377

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see attached 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.:

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

The claims do not satisfy the requirements of unity of invention (Rule 13 PCT). The reasons are as follows:

The only concept in common of all the independent claims, being a biochemical assay, is well known in the art. See e.g. WO9322053 or EP417305.

1). The claims can be grouped according to their special technical features:

I. Claims 1- 13, 15,16, directed towards locating biochemical assays on an optical disk with CD- like characteristics. This solves problems of speed, automation and miniaturising of biochemical assays.

II. Claim 14, directed towards the biochemical constitution of an assay element, namely complementary oligonucleotides, connected by a cleavable spacer molecule, one of the oligonucleotides being connected to a substrate. This solves the problem of efficient regeneration of the assay element.

2). There is no feature in common to the groups, which could be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence. Biochemical assays as such, as mentioned before, are already well known in the art. Thus, no technical relationship within the meaning of PCT Rule 13, between the two groups of inventions, can be seen.

3). Consequently, it appears that claims 1- 16 do not satisfy the requirements of unity of invention within the meaning of PCT Rule 13.

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