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[Continued on next page]

(54) Title: BREAST IMPLANT WITH ANALYTE SENSORS RESPONSIVE TO EXTERNAL POWER SOURCE

(57) Abstract: Breast implants including sensor modules and related methods are described herein. Breast implants include those with: a shell configured to be substantially filled with a viscous material; and a plurality of sensor modules attached to the shell and positioned at a distance from each other, each of the plurality of sensor modules oriented to detect one or more analytes in a fluid adjacent to the shell, wherein each of the plurality of sensor modules includes a unique identifier and is configured to utilize energy transmitted from an external source.

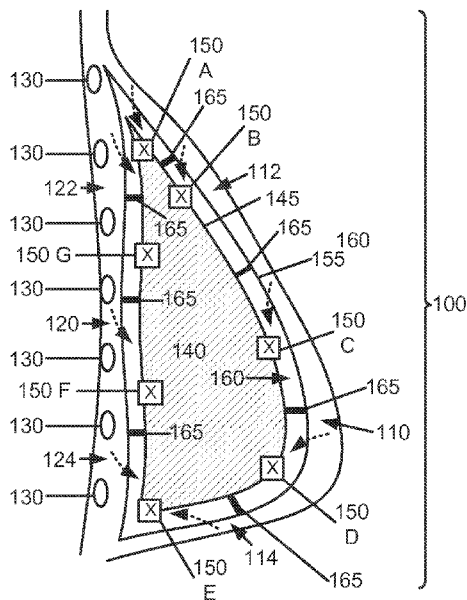


FIG. 1

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## INTERNATIONAL SEARCH REPORT

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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61F 2/12 (2013.01) USPC - 623/8 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61B 5/145; A61F 2/02, 2/12 (2013.01) USPC - 600/309; 623/7, 8 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC - A61B 5/14503; A61F 2/02, 2/12 (2013.01) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase, Google Patents, Google Scholar		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/0077736 A1 (ROFOUGARAN) 31 March 2011 (31.03.2011) entire document	1-3,5-7,9-12,14,16-20,22-24,26-29,31-33,35-37,39-43,45-47,50-52,54,55
Y		4,8,13,15,21,25,30,34,38,44,48,49,53,56-74,145-170
Y	US 2009/0012372 A1 (BURNETT et al) 08 January 2009 (08.01.2009) entire document	4,13,15,30,38,48,59,148
Y	US 2011/0098576 A1 (HOLLSTIEN) 28 April 2011 (28.04.2011) entire document	8,34,63,154,157
Y	US 2007/0077265 A1 (KLUEH et al) 05 April 2007 (05.04.2007) entire document	21,44
Y	US 2011/0257623 A1 (MARSHALL et al) 20 October 2011 (20.10.2011) entire document	25,53,74,145-170
Y	US 2008/0300660 A1 (JOHN) 04 December 2008 (04.12.2008) entire document	49,56-74,145-170
A	US 2007/0128420 A1 (MAGHRIBI) 07 June 2007 (07.06.2007) entire document	1-74, 145-170
A	US 2008/0188836 A1 (WEBER et al) 07 August 2008 (07.08.2008) entire document	1-74, 145-170
A	US 2009/0254179 A1 (BURNETT) 08 October 2009 (08.10.2009) entire document	1-74, 145-170
A	US 2009/0318802 A1 (BOYDEN et al) 24 December 2009 (24.12.2009) entire document	1-74, 145-170
A	WO 2010/022130 A1 (SCHUESSLER) 25 February 2010 (25.02.2010) entire document	1-74, 145-170
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "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 "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 "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 "&" document member of the same patent family		
Date of the actual completion of the international search 20 December 2013		Date of mailing of the international search report <b>08 JAN 2014</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/045212

**Box No. 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 No. 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 last page.

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 additional fees, this Authority did not invite payment of additional fees.
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.:  
1-74, 145-170

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/045212

Continuation of Box III.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

Species I) at least one optically powered transducer configured to harvest optical energy from a source external to the breast implant; and at least one connector operably connecting the at least one optically powered transducer, figure 8, element 800

Species II) at least one transmission unit attached to the plurality of sensor modules, the at least one transmission unit configured to initiate a signal in response to one or more of the plurality of sensor modules, figure 9, element 450

Species III) at least one fluid-permeable cover, the cover completely enveloping the shell, figure 1, element 155

Species IV) a plurality of projections extending from an external surface of the shell, the projections forming a plurality of compartments adjacent to the external surface of the shell, figure 6, element 165

Species V) forming an initial record from the first information and the second information from first and second sensor modules; calculating deviation limits regarding the initial record; setting deviation parameters based on the deviation limits and a predetermined set of standards; saving the initial record and the deviation parameters in memory in a computing device, figure 10.

The claims are deemed to correspond to the species listed above in the following manner:

Species I) figure 8, element 80; claims 56-74, 145-170

Species II) figure 9, element 450; claims 75-77, 171-173, 284-292

Species III) figure 1, element 155; claims 78-144

Species IV) figure 6, element 165; claims 174-281

Species V) figure 10; claims 282-283

The following claims are generic: claims 1-55.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Species I) figures 7-10; have the special technical feature of at least one optically powered transducer configured to harvest optical energy from a source external to the breast implant; and at least one connector operably connecting the at least one optically powered transducer. This special technical feature is not present in species II, III, IV or V.

Species II) figure 42; have the special technical feature of at least one transmission unit attached to the plurality of sensor modules, the at least one transmission unit configured to initiate a signal in response to one or more of the plurality of sensor modules. This special technical feature is not present in species I, III, IV or V.

Species III) figures 36-37; have the special technical feature of at least one fluid-permeable cover, the cover completely enveloping the shell. This special technical feature is not present in species I, II, IV or V.

Species IV) figure 32; have the special technical feature of a plurality of projections extending from an external surface of the shell, the projections forming a plurality of compartments adjacent to the external surface of the shell. This special technical feature is not present in species I, II, III or V.

Species V) figure 38; have the special technical feature of forming an initial record from the first information and the second information from first and second sensor modules; calculating deviation limits regarding the initial record; setting deviation parameters based on the deviation limits and a predetermined set of standards; saving the initial record and the deviation parameters in memory in a computing device. This special technical feature is not present in species I, II, III or IV.

Continuation of Box III (from previous sheet).

Species I, II, III, IV and V lack unity of invention because even though the inventions of these species require the technical feature of a breast implant comprising: a shell configured to be substantially filled with a viscous material; and a plurality of sensor modules attached to the shell and positioned at a distance from each other, each of the plurality of sensor modules oriented to detect one or more analytes in a fluid adjacent to the shell, wherein each of the plurality of sensor modules includes a unique identifier and is configured to utilize energy transmitted from an external source, the sensor including at least one antenna; an energy harvesting unit attached to the at least one antenna; and at least one connection between the energy harvesting unit and each of the plurality of sensor modules, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of US 2011/0077736 A1 (ROFOUGARAN) 31 March 2011(31.03.2011). Roufougaran teaches a breast implant (abstract) comprising: a shell configured to be substantially filled with a viscous material (para. 159); and a plurality of sensor modules (plurality of biomedical units, para. 0159) attached to the shell (para. 162) and positioned at a distance from each other (see 310, fig. 32), each of the plurality of sensor modules oriented to detect one or more analytes in a fluid adjacent to the shell (detects leaks in shell, para. 164; monitors white cell count, red cell count, para. 116; blood sample analysis, para 73), wherein each of the plurality of sensor modules includes a unique identifier (identity of the biomedical unit, para. 114) and is configured to utilize energy transmitted from an external source (harvesting energy from magnetic, electromagnetic or electrical fields, para. 64-65), the sensor including at least one antenna (biomedical sensors communicate with one another or with communication device 24 using an RF channel, and use a communication protocol, para. 74; fig. 6; see antenna, fig. 8); an energy harvesting unit attached to the at least one antenna (see antenna connected to communication module 48 within biomedical unit 10, fig. 8); and a connection between the energy harvesting unit and the plurality of sensor module (see power harvesting module 46 within bio-medical unit 10, fig. 8).

Species I, II, III and IV lack unity of invention because even though some of the inventions of these species require the technical feature of a breast implant comprising a fluid-permeable cover, the cover completely enveloping the shell, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of WO 2010/022130 A1 (SCHUESSLER) 25 February 2010 (25.02.2010), fig. 1, 2A, 2B; page 8, lines 4-24.

Since none of the special technical features of the Species I, II, III, IV and V inventions is found in more than one of the inventions, unity of invention is lacking.