



- (51) International Patent Classification:
A61F 2/12 (2006.01)
- (21) International Application Number:
PCT/US2013/045206
- (22) International Filing Date:
11 June 2013 (11.06.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
- | | | |
|------------|---------------------------|----|
| 13/495,212 | 13 June 2012 (13.06.2012) | US |
| 13/495,252 | 13 June 2012 (13.06.2012) | US |
| 13/495,275 | 13 June 2012 (13.06.2012) | US |
| 13/495,288 | 13 June 2012 (13.06.2012) | US |
| 13/495,299 | 13 June 2012 (13.06.2012) | US |
| 13/495,310 | 13 June 2012 (13.06.2012) | US |
- (71) Applicant: **ELWHA LLC** [US/US]; 11235 SE 6th Street, Suite 200, Bellevue, Washington 98004-6481 (US).
- (72) Inventors: **BOYDEN, Edward S.**; 57 Clearwater Rd, Chestnut Hill, Massachusetts 02467 (US). **DELLA**

ROCCA, Gregory J.; 2417 Lacewood Dr, Columbia, Missouri 65201 (US). **DUESTERHOFT, Paul**; 668 Bear Ridge Dr NW, Issaquah, Washington 98027 (US). **HAWKINS, Daniel**; 1818 Sannita Ct., Pleasanton, California 94566 (US). **HYDE, Roderick A.**; 9915 - 161st Avenue N.E., Redmond, Washington 98052 (US). **LANGER, Robert**; 98 Montvale Road, Newton, Massachusetts 02459 (US). **LEUTHARDT, Eric C.**; 6358 Pershing Avenue, St. Louis, Missouri 63130 (US). **MYCKATYN, Terence**; 10421 Whitebridge Lane, St. Louis, Missouri 63141 (US). **PARIKH, Parag Jitendra**; 10500 Anton PL, St. Louis, Missouri 63128 (US). **RIVET, Dennis J.**; 1548 Pine Grove Lane, Chesapeake, Virginia 23321 (US). **SHIMONY, Joshua S.**; 721 N Spode Rd, St. Louis, Missouri 63141 (US). **SMITH, Michael A.**; 3824 E Expedition Way, Phoenix, Arizona 85050 (US). **SWEENEY, Elizabeth A.**; 702 N. 143rd Street, Seattle, Washington 98133 (US). **TEGRENE, Clarence T.**; 5910 E Mercer Way, Mercer Way, Washington 98040 (US).

- (74) Agents: **MALASKA, Stephen L.** et al.; 11235 SE 6th Street, Suite 200, Bellevue, Washington 98004-6841 (US).

[Continued on next page]

- (54) Title: BREAST IMPLANT WITH ANALYTE SENSORS AND INTERNAL POWER SOURCE

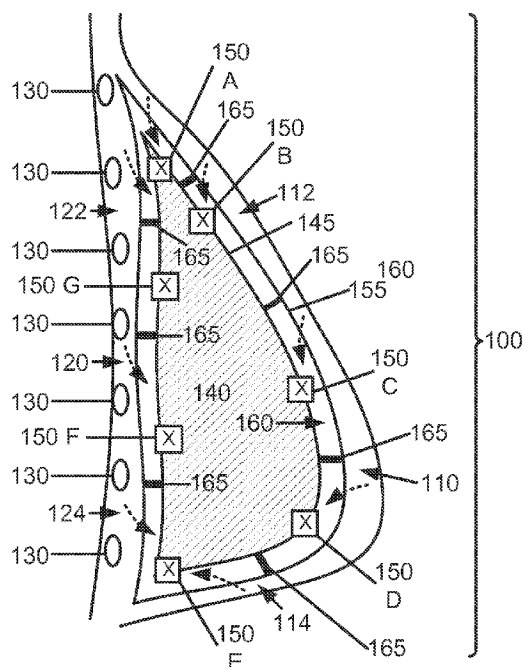


FIG. 1

(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; a plurality of sensor modules attached to the shell, the sensor modules oriented to detect one or more analytes in a fluid adjacent to the shell, the sensor modules positioned at a distance from each other, wherein each of the plurality of sensor modules includes a unique identifier; and at least one power source operably attached to the plurality of sensor modules.



(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,

UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(88) **Date of publication of the international search report:**

13 March 2014

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/045206

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/12 (2013.01)

USPC - 623/8

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(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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2011/0077736 A1 (ROFOUGARAN) 31 March 2011 (31.03.2011) entire document	1-3,5-7,9-11,13-17,19-21, 25-29,31-33,35-37,39-43, 45-48,52-55,57-59,61-63, 65-69,71-74,76,77,80,82- 84,305
Y	US 2009/0012372 A1 (BURNETT et al) 08 January 2009 (08.01.2009) entire document	4,8,12,18,22-24,30,34,38, 44,49-51,56,60,64,70,75, 78,79,81,184-186
Y	US 2011/0098576 A1 (HOLLSTIEN) 28 April 2011 (28.04.2011) entire document	4,12,22,24,30,38,49,51, 56,64,75,79,81
Y	US 2007/0077265 A1 (KLUEH et al) 05 April 2007 (05.04.2007) entire document	8,34,60
Y	US 2011/0257623 A1 (MARSHALL et al) 20 October 2011 (20.10.2011) entire document	18,44,70
Y	US 2011/0257623 A1 (MARSHALL et al) 20 October 2011 (20.10.2011) entire document	23,50,78,184-186
A	US 2008/0300660 A1 (JOHN) 04 December 2008 (04.12.2008) entire document	1-84, 184-186, 305
A	US 2007/0128420 A1 (MAGHRIBI) 07 June 2007 (07.06.2007) entire document	1-84, 184-186, 305
A	US 2008/0188836 A1 (WEBER et al) 07 August 2008 (07.08.2008) entire document	1-84, 184-186, 305
A	US 2009/0254179 A1 (BURNETT) 08 October 2009 (08.10.2009) entire document	1-84, 184-186, 305

☒ Further documents are listed in the continuation of Box C.

* 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

07 JAN 2014

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/US2013/045206

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/0318802 A1 (BOYDEN et al) 24 December 2009 (24.12.2009) entire document	1-84, 184-186, 305
A	WO 2010/022130 A1 (SCHUESSLER) 25 February 2010 (25.02.2010) entire document	1-84, 184-186, 305

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2013/045206

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 extra 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 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.:
1-84, 184-186, 305

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/US2013/045206

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 transmission unit operably attached to at least one processor and/or the plurality of sensor modules, and/or the power source attached to the transmission unit, figure 10, element 1000

Species II) at least one fluid-permeable cover, the cover completely enveloping the shell, the sensor modules oriented to detect one or more analytes in a fluid between the shell and the cover, figure 11, element 155

Species III) 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 8, element 165

Species IV) receiving first information from a first sensor module attached to a shell of a breast implant within an individual, wherein the first information includes a first unique sensor module identifier and sensor data from the first sensor module; receiving second information from a second sensor module attached to the shell of the breast implant; forming an initial record from the first information and the second information; 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; receiving third information from the first sensor module attached to the shell of the breast implant within the individual, wherein the third information includes the first unique sensor module identifier and the sensor data from the first sensor module; receiving fourth information from the second sensor module attached to the shell of the breast implant within the individual, wherein the fourth information includes the second unique sensor module identifier and the sensor data from the second sensor module; updating the initial record with the third information and the fourth information; saving an updated record in the memory in the computing device; comparing the updated record to the initial record and to the deviation parameters; and indicating if the updated record is within the deviation parameters of the initial record, page 48, lines 23-35; page 49, lines 1-8.

Species V) receiving a response signal including information from the one or more sensor modules; processing, in a computing device, the response signal to identify information from the one or more sensor modules; and identifying, for each of the one or more sensor modules, a detection result and a unique identifier, page 50, lines 5-13.

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

Species I) figure 10, element 1000; claims 53-84, 184-186, 305

Species II) figure 11, element 155; claims 85-183

Species III) figure 8, element 165; claims 187-302

Species IV) page 48, lines 23-35; page 49, lines 1-8; claims 303-304

Species V) page 50, lines 5-13; claims 306-313

The following claims are generic: claims 1-52

Continuation of Box III (continued)

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) figure 10, element 1000; have the special technical feature of at least one transmission unit operably attached to at least one processor and/or the plurality of sensor modules, and/or the power source attached to the transmission unit. This special technical feature is not present in species II, III, IV or V.

Species II) figure 11, element 155; have the special technical feature of at least one fluid-permeable cover, the cover completely enveloping the shell, the sensor modules oriented to detect one or more analytes in a fluid between the shell and the cover. This special technical feature is not present in species I, III, IV or V.

Species III) figure 8, element 165; 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, IV or V.

Species IV) page 48, lines 23-35; page 49, lines 1-8; have the special technical feature of receiving first information from a first sensor module attached to a shell of a breast implant within an individual, wherein the first information includes a first unique sensor module identifier and sensor data from the first sensor module; receiving second information from a second sensor module attached to the shell of the breast implant; forming an initial record from the first information and the second information; 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; receiving third information from the first sensor module attached to the shell of the breast implant within the individual, wherein the third information includes the first unique sensor module identifier and the sensor data from the first sensor module; receiving fourth information from the second sensor module attached to the shell of the breast implant within the individual, wherein the fourth information includes the second unique sensor module identifier and the sensor data from the second sensor module; updating the initial record with the third information and the fourth information; saving an updated record in the memory in the computing device; comparing the updated record to the initial record and to the deviation parameters; and indicating if the updated record is within the deviation parameters of the initial record. This special technical feature is not present in species I, II, III or V.

Species V) page 50, lines 5-13; have the special technical feature of receiving a response signal including information from the one or more sensor modules; processing, in a computing device, the response signal to identify information from the one or more sensor modules; and identifying, for each of the one or more sensor modules, a detection result and a unique identifier. This special technical feature is not present in species I, II, III or IV.

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; a plurality of sensor modules attached to the shell, wherein each of the plurality of sensor modules includes a unique identifier, each of the plurality of sensor modules oriented to detect one or more analytes in a fluid adjacent to the shell; at least one processor operably attached to the sensor module; and at least one power source operably attached to the at least one processor and/or the 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), 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), at least one processor 50 operably attached to the sensor module 10, at least one transmission unit 48 operably attached to the at least one processor (fig. 8, showing communication module 48 attached to processor 50 and within biomedical unit 10); and at least one power source operably attached to the at least one processor and/or the sensor modules (power harvesting unit 46 within biomedical unit 10, and providing power Vdd 56, which is shown as powering all the other modules within the unit, fig. 8).

Species I and II 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.