



(51) International Patent Classification:

A61F 5/01 (2006.01) A61F 2/28 (2006.01)  
A61F 2/32 (2006.01)

(21) International Application Number:

PCT/US20 12/0684 16

(22) International Filing Date:

7 December 2012 (07.12.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/568,345 8 December 2011 (08.12.2011) US

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(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, KM, 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,  
ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

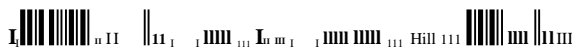
[Continued on nextpage]

(54) Title: ANATOMIC SOCKET ALIGNMENT GUIDE AND METHODS OF MAKING AND USING SAME

FIG. 6



(57) Abstract: This disclosure provides an anatomic socket  
alignment guide set, for total hip replacement arthroplasty.  
The guide set is created from patient-specific medical images,  
allowing the guide set components to recreate the native cen-  
ter of rotation of a patient's hip joint, thereby permitting ac-  
curate placement of the hip replacement prosthesis.



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- *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))*

## **ANATOMIC SOCKET ALIGNMENT GUIDE AND METHODS OF MAKING AND USING SAME**

### **Cross Reference to Related Applications**

This application claims the benefit of U.S. Provisional Patent application Ser. No. 61/568,345 entitled "Anatomic Socket Alignment Guide and Methods of Making and Using Same," which was filed December 8, 2011. The entirety of the aforementioned application is herein incorporated by reference.

### **Field of the Invention**

[0001] This disclosure is in the field of orthopedic medicine. More specifically, this disclosure is related to an anatomic socket alignment guide set, for total hip replacement arthroplasty.

### **Background**

[0002] Correct positioning of the socket in total hip replacement arthroplasty is difficult to achieve, using currently available jigs and alignment guides. Such variables as, for example patient positioning on the operating table, anatomic issues including patient-to-patient variability, and questions of parallax, all must be considered in the surgeon's judgment at the time of the arthroplasty procedure. Any resultant inaccuracies can threaten hip stability and durability. While surgical navigation may address some of these problems, this approach is not universally available, and adds both expense and time to the procedure, which also lengthens the concomitant time a patient is subject to the risks of anesthesia. Accordingly, there remains a need in the surgical arts, for improved alignment guides that can aid a surgeon in a total hip replacement arthroplasty procedure, improving the precision of the procedure and enhancing surgical outcome.

**Brief Description of the Drawings**

[0003] FIG. 1 illustrates the positioning guide of the guide set.

[0004] FIG. 2 shows the positioning guide aligned within the acetabulum of a human patient. Guide pins extend through the positioning guide at reference locations on the pelvis.

[0005] FIG. 3 shows the pelvis with the positioning guide removed and the guide pins in place.

[0006] FIG. 4 illustrates the insertion guide of the guide set.

[0007] FIG. 5 shows the insertion guide affixed to the guide pins in a cut-away view, illustrating the acetabulum of the patient.

[0008] FIG. 6 shows the insertion guide having an acetabular socket prosthesis, aligned centrally to the acetabulum.

**Detailed Description**

[0009] Current patient imaging techniques such as MRI and CT scans, provide high-definition three-dimensional maps of patient joints and tissues. Anatomical structures can be resolved to sub-millimeter levels based on MRI imaging technologies in widespread availability, and high spectral and spatial resolution (HiSS) systems promise even greater resolution. While current imaging technologies deliver better information to the surgeon, allowing informed decisions prior to the surgery, these technologies still do not substitute for the surgeon's skill when performing the total hip replacement arthroplasty. However, high resolution mapping technologies provide the basis for creating anatomically matched guides.

[0010] Current commercial efforts have resulted in patient-specific cutting blocks for knee replacements (see, for example Signature (Biomet); Visionaire (Smith & Nephew); and Patient Specific Instrument (Zimmer) systems). In knee replacement procedures, anatomically configured pre-formed cutting jigs allow for a planar cut with the possibility of indicating rotation in the same plane. However, for hip replacement procedures, the efforts are complicated in that the acetabulum requires the two rotational axes of abduction and anteversion.

[0011] The present disclosure provides patient-specific guides, derived from high-resolution anatomical images of the patient obtained through common imaging techniques known in the medical arts. Imaging devices appropriate for the present invention include x-ray devices, MRI or ultrasound equipment, or similar means of generating patient-specific imaging data. Patient-specific data used to generate such a virtual model can be obtained from one or more patient data sources. The data is rendered e.g., by computer using standard computer aided design (CAD) or animation modeling software, to produce detailed three-dimensional anatomical models of the patient, for specific surgical sites (e.g., the hip joint), which are further processed e.g., by computer aided manufacturing (CAM) systems. The CAM system accesses the data specifying the virtual model, as configured and finalized by the operator, then transforms the model into thin, virtual, horizontal cross-sections, which it uses to create successive layers to fabricate a physical model, for example using additive manufacturing techniques, such as rapid prototyping, stereolithography, or other similar technologies. Such techniques are described in greater detail by M. Robiony et al, "Cranio-Maxillofacial Bone Surgery," J. Oral Maxfac. Surg. (2007) 1198-1208; Ono I et al., "Method for Preparing an Exact-Size Model Using Helical Volume Scan Computed" Plast. Reconstr. Surg. (1994) 93: 1363; S. Swan, "Integration of MRI and Stereolithography to Build Medical Models. A Case Study," Rapid Prototyping Journal, (1996) 2:41; H. P. Wolf et al, "High Precision 3-D Model Design Using CT and Stereolithography," CAS (1994) 1:46. See also, Schendel, S., Methods, Systems, And Computer Program Products for Shaping Medical Implants Directly from Virtual Reality Models, U.S.S.N. 12/263,309; as well as U.S. Pat. No. 7,245,977 to Simkins, and U.S. Pat. No. 7,076,980 to Butscher et al.

[0012] An exemplary system according to some embodiments, includes at least one modeling server that is communicatively coupled to one or more clients by a communications infrastructure. Clients can be represented by a variety of devices, such as but not limited to, personal computers, personal digital assistants, or smart phones. Clients can include one or more output mechanisms that output information to the user (e.g., physician, surgeon, clinician, technician, and other medical professionals). Such output mechanisms include but are not limited to a monitor, an LCD screen, or a printer. One or more input mechanisms can be included to permit a user to input information to

the clients. Such input mechanisms include a keyboard, a mouse, a stylus, etc. Clients can include client software such as web browser software. The web browser software can include a browser program, such as the MICROSOFT® INTERNET EXPLORER® browser application. For example, clients can access the software tools, patient data, or other information residing on the modeling server or other system components via the web browser software when the communications infrastructure includes the global-based Internet. The web browser software can include a plug-in, applet or similar executable process. A plug-in can be obtained from the modeling server or from a third party. Alternatively, plug-ins can be pre-installed on clients. Clients include network interface hardware and software that allows the client to transmit and receive data over communications infrastructure. Communications infrastructure can be a wired and/or wireless local area network (LAN), virtual LAN (VLAN), wide area network (WAN), and/or metropolitan area network (MAN), such as an organization's intranet, a local internet, the global-based Internet (including the World Wide Web (WWW)), an extranet, a virtual private network (VPN), licensed wireless telecommunications spectrum for digital cell (including CDMA, TDMA, GSM, EDGE, GPRS, CDMA2000, WCDMA FDD and/or TDD or TD-SCDMA technologies). Communications infrastructure can support wired, wireless, or combinations of both transmission media, including satellite, terrestrial (e.g., fiber optic, copper, UTP, STP, coaxial, hybrid fiber-coaxial (HFC), or the like), radio, free-space optics, and microwave transmission.

[0013] The modeling server includes a set of computer-executable instructions that cause a computer to visualize and manipulate a virtual reality model. The instructions may be executed at the modeling server and interactive images of the virtual model can be transmitted to the clients, or alternatively, an application program can be distributed to a client, so that the interactive visualization operations can be executed on the local client. The software instructions include a set of functions or routines that cause the user interface for a client to display a high-resolution, three-dimensional representation of a patient's anatomical structures, and provide the medical professional with tools for visualizing and analyzing the virtual model. Virtual cutting and shaping tools allow the medical professional to segment the model by showing slices or sections through the model at arbitrary, user-defined planes. For example, the visualization tools include routines and functions for simulating changes in the anatomical position or shape of an

anatomical structure. The elements of the anatomical structure can be analyzed quickly in either static format (e.g., no movement of the anatomical structures relative to each other) or in a dynamic format (e.g., during movement of anatomical structures relative to each other, such as during abduction and anteversion of the leg, etc.).

[0014] The medical professional logs in to a defined web site, accesses a file containing the patient's imaging data, and then he or she uses the interactive visualization tools of the modeling server to plan the procedure and simulate the results. In one embodiment, a web-based system is provided to import the patient-specific data in the standard Digital Imaging and Communications in Medicine (DICOM) format. In another embodiment, an Active X control program is used to support data acquisition from medical images, and permit segmentation, visualization, integrated surface and volume rendering and simulation. Upon configuring and finalizing the virtual model, a fabrication system accesses the specification data for the virtual model from client or modeling server depending on which component contains the application for visualizing and finalizing the design of the guides.

[0015] It will be appreciated that the guides according to the present invention, will conform only in part to various features of the patient's anatomy. Other surfaces on the guide provide for features that imbue functionality to the guide but are not in contact with the patient and do not need to conform to the patient's anatomy. Accordingly, the guides of the present disclosure contain both patient-conforming and non-conforming regions. Patient conforming regions are specific to the anatomy of the patient. Non-conforming regions may take any suitable morphology that does not interfere with their functionality, i.e., positioning, aligning and inserting of a prosthetic hip socket device.

[0016] In a representative embodiment, the invention provides an orthopedic device set for total hip replacement arthroplasty procedures. The device set includes both a positioning guide and an insertion guide. The positioning guide, shown in FIG. 1, has a first surface substantially conforming to a patient's native acetabulum. In practice, the femur head is dislocated from the acetabulum during a total hip replacement procedure. The positioning guide is then placed within the acetabulum such that the first (conforming) surface engages the acetabular surface, and the unique morphology and features of the patient's anatomy secure the guide. Distal to the first surface is a second surface, which is external to the acetabulum. The second surface substantially conforms

to a region on the patient's native pelvis, and it engages the pelvic bone. The positioning guide "fits" and is therefore removably secured within the patient's acetabulum and at a region external to the acetabular notch. The positioning guide has at least one aperture through the second surface, defining positioning guide reference locations. There are two through-holes defining reference locations, shown in FIG. 1. These reference locations provide orientation positions on the patient's pelvis, which in conjunction with the insertion guide, shown in FIG. 4, facilitate subsequent socket alignment and insertion, as shown in FIG. 6. For example, the reference locations define the site of placement for surgical guide pins, which are inserted into the pelvis prior to removal of the positioning guide as shown in FIG. 2. One will appreciate that the "apertures" on the second surface of the positioning guide need not be limited to through-holes in this surface. It is sufficient that the second surface present enough material to permit secure placement of the guide pins or other reference markers. For example, a "U" shaped notch- contained on three sides but open on a fourth side, would permit surgical guide pin placement while facilitating positioning guide removal in a manner that does not disturb the guide pins. The guide pins can also serve as a reference for other types of guides, e.g., a leg length caliper may be affixed to one of the pins for intraoperative leg length determination. One of skill in the art will also appreciate, that the term "guide pins" exemplifies one potential means of identifying and securing surgical tools at a site; other means are deemed within the scope of this invention and will be apparent in view of the teachings provided.

[0017] Following placement of guide pins, the positioning guide is removed resulting in a secure reference point from which the surgeon may base further decisions, such as leg length and axis of rotation for the hip joint as described herein. This is shown in FIG. 3. The insertion guide is applied next. This first surface of the insertion guide overlaps in-part with the same region on the patient's pelvis as the positioning guide, though it does not need to conform to the patient's pelvis. Specifically, the overlap is defined by the area including the positioning guide reference locations. The positioning guide serves to place guide pins, and the guide pins are further used to position the insertion guide. Accordingly, the first surface of the positioning guide includes one or more securing features positioned such that the securing features are equidistant relative to the positioning guide second surface reference locations. As shown in FIG. 4, the



insertion guide first surface has securing features as exemplified by two through-holes positioned in the same relative locations as the positioning guide shown in FIG. 1. The through-holes permit secure but removable affixation of the insertion guide to the pins. Other types of structures such as a "U" shaped notch structure, which may further include features at the distal/open portions of the notch that can engage the guide pins, will be evident to those of skill in the art. However, it is useful if such securing features permit tight adherence between the insertion guide and pins, and the securing features "lock" the insertion guide into position. In one embodiment, the insertion guide has a first surface which does not conform to the patient's pelvis; the positioning guide positions the pins; and then the pins position the insertion guide, which therefore does not need to conform to any pelvic anatomy. In other embodiments, the insertion guide includes a first surface that conforms to the patient's pelvic anatomy. In such embodiments, since one side of the first surface of the insertional device conforms to the patient's pelvis, the patient's own anatomical features assist in aligning and securing the insertion guide.

[0018] The insertion guide has a second surface distal to the first surface, the second surface having an aperture therethrough, the aperture being offset from the securing features by a patient-specific distance such that the midpoint of the aperture aligns centrally with the acetabulum of the patient. This is shown in FIG. 5 where the insertion device is affixed to the patient's pelvis. The second surface is not shown in order to permit visualization of the device relative to the acetabulum. This distance from the pins at the reference locations to the center of the patient's acetabulum varies from individual-to-individual, and is calculated with precision based on the patient's hip joint images; and based on such distance, the three-dimensional model and patient-specific surgical guide set is obtained as described above. The insertional guide aligns the socket insertional prosthetic device. If the logic determining creation of the guide set is based on the center of rotation, and the line that is its three-dimensional axis determines e.g., abduction, anteversion and medialization, then small differences in socket dimension or depth of reaming (of the acetabulum) will not cause significant problems, allowing for the surgeon to take into account bone density and reaming choices. The positioning guide determines cup abduction and anteversion. As the center of the cup

remains the same no matter the outer diameter, the guide set needn't be determinative of cup size.

[0019] The insertion guide may optionally include a third surface located distal to the aperture of the second surface at a distance defined by the radius of an acetabular socket prosthesis, the third surface further having an annular depression of sufficient size and depth to engage removably a portion of the acetabular socket prosthesis. Since the guide set is custom-created for each patient, it is a simple matter to determine the appropriate socket for use in that patient, and design the insertion guide to accommodate the exact size of the socket desired.

[0020] Continuing with the above example, where the positioning guide has been used to set reference guide pins, and the insertion guide has been placed into position based on these reference guide pins, the socket prosthesis is then introduced into the reamed acetabulum as shown in FIG. 6. The socket prosthesis is loaded into the insertional guide, with the outer circumference of the socket removably engaging the third surface of the insertional device. The configuration of the guide around the socket determines the limits of abduction and anteversion in the repaired joint. A push rod is inserted through the aperture of the second surface. This push rod aligns centrally in the socket, and when articulated, permits precise deposition of the socket into the reamed acetabulum. In certain embodiments, the push rod has a depth-stop feature, for example a geometric feature that engages or is otherwise stopped by the second surface of the insertion guide.

[0021] While the invention has been described in detail with respect to specific embodiments thereof, it will be apparent to those skilled in the art that various alterations, modifications and other changes may be made to the invention without departing from the spirit and scope of the present invention. It is therefore intended that the claims cover all such modifications, alterations and other changes encompassed by the appended claims. All references and patent documents cited herein are hereby incorporated by reference in their entirety.

## Claims:

## 1) An orthopedic device set comprising:

a positioning guide having:

a first surface substantially conforming to a patient's native acetabulum;  
and

a second surface distal to the first surface, the second surface substantially conforming to a region of the patient's native pelvis and comprising one or more apertures therethrough defining positioning guide reference locations; and

an insertion guide having:

a first surface comprising one or more securing features positioned such that the securing features are equidistant relative to the positioning guide second surface reference locations;

a second surface distal to the first surface, the second surface having an aperture therethrough, the aperture being offset from the securing features by a patient-specific distance such that the aperture aligns centrally with the acetabulum of the patient; and

a third surface located distal to the aperture of the second surface at a distance defined by the radius of an acetabular socket prosthesis, the third surface further comprising an annular depression of sufficient size and depth to engage removably a portion of the acetabular socket prosthesis.

2) The orthopedic device set of claim 1, wherein the insertion guide aperture is offset at a distance that is the center of rotation of the patient's native hip joint.

- 3) The orthopedic device set of claim 1, further comprising one or more guide pins having a thickness no greater than the positioning guide aperture(s).
- 4) The orthopedic device set of claim 3, further comprising a leg length caliper having a proximal end with a guide pin attachment means.
- 5) The orthopedic device set of claim 1, further comprising an acetabular socket prosthesis insertional device.
- 6) The orthopedic device set of claim 5, wherein the insertional device further comprises a feature larger than the diameter of the insertion guide aperture, the feature positioned distal to the acetabular socket prosthesis insertional device at a point defining the limit of insertion for the acetabular socket prosthesis.
- 7) A surgical kit comprising: the device set of claim 1 or claim 6, which is sterile, and further comprising appropriate packaging and instructions for use of the device set.
- 8) A method of manufacturing an orthopedic device set comprising:
  - obtaining a three-dimensional image of a hip joint of a patient, and rendering from the three-dimensional image a device set further comprising:
    - a positioning guide having:
      - a first surface substantially conforming to a patient's native acetabulum, and
      - a second surface distal to the first surface, the second surface substantially conforming to a region of the patient's native pelvis and comprising one or more apertures therethrough defining positioning guide reference locations; and
    - an insertion guide having:
      - a first surface comprising one or more securing features positioned such that the securing features are equidistant relative to the positioning guide second surface reference locations;

a second surface distal to the first surface, the second surface having an aperture therethrough, the aperture being offset from the securing features by a suitable distance such that the aperture aligns centrally to the acetabulum of a patient as determined from the three-dimensional image of the patient with reference to the positioning guide reference locations; and

a third surface located distal to the aperture of the second surface at a distance defined by the radius of an acetabular socket prosthesis, the third surface further comprising an annular depression of sufficient size and depth to engage removably a portion of the acetabular socket prosthesis selected for the patient.

- 9) The method of claim 8, comprising obtaining the image through CT or MRI imaging techniques.
- 10) The method of claim 8, comprising rendering the positioning and insertion guides by a computer using image-based modeling and sculpting software with an automated sculpting device controlled by the computer.
- 11) A surgical method, comprising:
  - identifying a patient in need of hip surgery requiring a hip prosthesis;
  - imaging the hip joint of the patient;
  - obtaining the patient-specific device set of claim 1; and
  - performing hip replacement surgery on the patient, the surgery comprising:
    - orienting and placing the positioning guide within the patient's native acetabulum;
    - securing one or more guide pins to the pelvic bone of the patient at locations defined by the one or more positioning guide reference points;

withdrawing the first guide device from the acetabulum while leaving the guide pins in position, then reaming the acetabulum of the patient;

securing the insertion guide to the one or more guide pins;

removably securing to the insertion guide, an acetabular socket prosthesis, such that the prosthesis, when secured by the insertion guide, is aligned centrally to the reamed acetabulum of the patient as determined from the three-dimensional image of the native acetabulum of the patient with reference to the positioning guide reference locations; and

inserting the socket prosthesis into the reamed acetabulum at a depth and orientation such that native abduction and anteversion of the hip joint is substantially preserved.

12) The method of claim 11, comprising affixing a leg length caliper to the guide pins following removal of the positioning guide.

13) The method of claim 11, comprising obtaining the image through CT or MRI imaging techniques.

14) The method of claim 11, comprising obtaining the patient-specific device set by rendering the positioning and insertion guides by a computer using image-based modeling and sculpting software with an automated sculpting device controlled by the computer.

1 of 6

FIG. 1



2 of 6

FIG. 2





3 of 6

FIG. 3



4 of 6

FIG. 4



5 of 6

FIG. 5





6 of 6

FIG. 6



## INTERNATIONAL SEARCH REPORT

 International application No.  
**PCT/US2012/068416**
**A. CLASSIFICATION OF SUBJECT MATTER**
*A61F 5/01(2006.01)i, A61F 2/32(2006.01)I, A61F 2/28(2006.01)i*

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)

A61F 5/01; A61F 2/28; A61B 17/60; A61F 2/38; A61B 17/58; A61F 5/00; A61F 2/32

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) &amp; Keywords: orthopedic, acetabulum, aperture, pelvis, insert, position, guide, image

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009-0163922 A1 (MERIDEW, J. D. et al.) 25 June 2009 See paragraphs [0019]-[0031]; figures 1-3; and claims 1, 4-5, 11, 16, 20.	1-10
Y	QS 8070752 B2 (METZGER, R. et al.) 6 December 2011 See columns 4-6; figures 1, 6, 9-14B; and claims 1, 2, 4-6.	1-10
A	QS 7967868 B2 (WHITE, J. R. et al.) 28 June 2011 See column 4; figures 4-7; and claims 1-4.	1-10
A	QS 4792337 A (MOLLER, M. E.) 20 December 1988 See columns 3-4; figure 1; and claims 1, 7, 10, 23.	1-10
A	QS 5376125 A (WINKLER, H.) 27 December 1994 See columns 6-8; figure 1; and claims 1-2.	1-10



Further documents are listed in the continuation of Box C.



See patent family annex.

\* 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 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

28 March 2013 (28.03.2013)

Date of mailing of the international search report

**29 March 2013 (29.03.2013)**

Name and mailing address of the ISA/KR

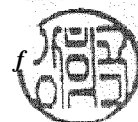

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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2012/068416****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.: 11-14  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 11-14 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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:

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 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

Information on patent family members

International application No.

**PCT/US2012/068416**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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