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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) Title: IMAGE BASED CLINICAL TRIAL ASSESSMENT

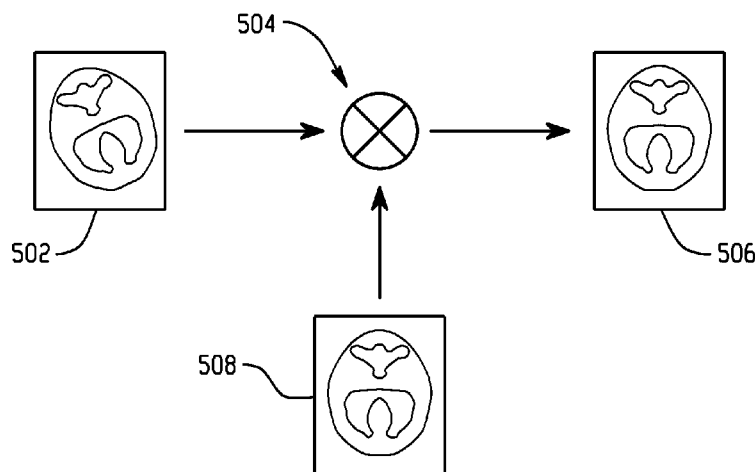


Fig. 5

(57) Abstract: A method for assessing a treatment in a trial includes obtaining images generated from image data acquired at different times during a trial time period for a same region of interest of a subject. The treatment is administered to the subject for the trial. The method further includes co-registering the images and mapping the co-registered images to a reference image representing the region of interest. The method further includes generating a trial image of the region of interest showing at least one of structural or functional physiological changes that occurred during the trial time period based on the mapped co-registered images, and displaying the trial image.



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- *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))*

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/055614

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06T7/00

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)
G06T

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)
EPO-Internal, BIOSIS, COMPENDEX, EMBASE, INSPEC, IBM-TDB, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KELVIN K LEUNG ET AL: "Automatic Quantification of Changes in Bone in Serial MR Images of Joints" IEEE TRANSACTIONS ON MEDICAL IMAGING, IEEE SERVICE CENTER, PISCATAWAY, NJ, US LNKD-DOI:10.1109/TMI.2006.884216, vol. 25, no. 12, 1 December 2006 (2006-12-01), pages 1617-1626, XP011151092 ISSN: 0278-0062 abstract	1-3, 6-18, 21-24
Y	sections I.A, II and III figures 5-8	4, 5, 19, 20

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :

<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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Date of the actual completion of the international search 31 March 2010	Date of mailing of the international search report 05/08/2010
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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, Fax: (+31-70) 340-3016	Authorized officer Engels, Angela
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2009/055614

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ALEX P ZIJDENBOS ET AL: "Automatic Pipeline Analysis of 3-D MRI Data for Clinical Trials: Application to Multiple Sclerosis" IEEE TRANSACTIONS ON MEDICAL IMAGING, IEEE SERVICE CENTER, PISCATAWAY, NJ, US, vol. 21, no. 10, 1 October 2002 (2002-10-01), XP011076380 ISSN: 0278-0062	19,20
A	abstract section II.B and V figure 1	1,16
A	----- US 2005/141757 A1 (AYACHE NICHOLAS [FR] ET AL) 30 June 2005 (2005-06-30) abstract paragraph [0054]	1-24
A	----- REY D ET AL: "A spatio-temporal model-based statistical approach to detect evolving multiple sclerosis lesions" MATHEMATICAL METHODS IN BIOMEDICAL IMAGE ANALYSIS,, 9 December 2001 (2001-12-09), pages 105-112, XP010584865 ISBN: 978-0-7695-1336-2 abstract sections 2, 3 and 4 figures 2,6,8	1-24
Y	----- LORENZO-VALDES M; SANCHEZ-ORTIZ G I; MOHIADDIN R; RUECKERT D: "Atlas-based segmentation and tracking of 3D cardiac MR images using non-rigid registration" LECTURE NOTES IN COMPUTER SCIENCE (PROC. MEDICAL IMAGE COMPUTING AND COMPUTER-ASSISTED INTERVENTION - MICCAI 2002), vol. 2488, 2002, pages 642-650, XP002576171 abstract section 3 figure 3	4,5
A	----- US 2005/031210 A1 (SHEN DINGGANG [US] ET AL) 10 February 2005 (2005-02-10) abstract figure 1	1,16
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INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2009/055614

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	<p>TOMOHIRO KANETA ET AL: "Dementia clinical trials with longitudinal FDG PET: Improved statistical power using intra-subject registration"</p> <p>JOURNAL OF NUCLEAR MEDICINE, SOCIETY OF NUCLEAR MEDICINE, RESTON, VA, US, vol. 50, no. Suppl, May 2009 (2009-05), page 26, XP009131533 ISSN: 0161-5505 the whole document</p> <p style="text-align: center;">-----</p>	1,16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2009/055614

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 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 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.:

see additional sheet(s)

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-24

stereotaxic registration of the images involved in a clinical trial;

2. claims: 25-30

estimating a suitable trial population size and trial cost given a desired statistical power and a desired image analysis algorithm, and indicating a suitable image analysis algorithm given a desired trial budget and a desired statistical power;

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2009/055614

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005141757	A1 30-06-2005	EP 1440413 A1	28-07-2004
		FR 2830962 A1	18-04-2003
		WO 03044719 A1	30-05-2003

US 2005031210	A1 10-02-2005	NONE	
