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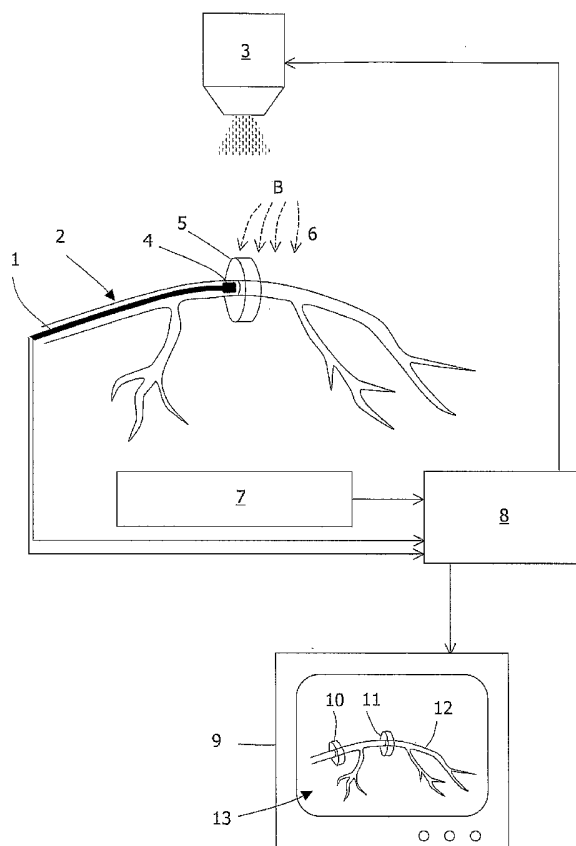
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[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR GENERATING AN IMAGE OF A VASCULAR SYSTEM



(57) Abstract: The invention relates to an apparatus and a method for the joint three-dimensional display of an angiogram (12) and local intravascular images (10, 11). The angiogram (12) is preferably recorded by means of an X-ray apparatus (3, 7), while the local intravascular images are generated by an ultrasound probe (4) on a catheter (1). The position of the probe (4) is determined by a position determination unit and is used to assign the recorded volume (5) to the angiogram (12).

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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*

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Published:

— *with international search report*

Apparatus and method for generating an image of a vascular system

The invention relates to an apparatus and method for generating an image of a vascular system using an angiogram.

An angiogram is usually produced in order to diagnose and treat diseases of a patient's vascular system. Said angiogram is a two-dimensional or three-dimensional image
5 which shows the vascular tree or part thereof either on its own or emphasized with respect to the background. Angiograms are typically produced by means of an X-ray apparatus and with injection of an X-ray contrast agent. Moreover, a method for producing a three-dimensional angiogram by means of magnetic resonance tomography is known from US 6 073 042.

Furthermore, the generation of local intravascular images in order to examine
10 a vascular system and to navigate within the vascular system is known. In this case, a catheter comprising a suitable probe (e.g. ultrasound probe) is pushed through a patient's vascular system, and two-dimensional sectional images of the interior of the vessels or of the surrounding tissue around the vessel are taken in each case at desired positions. The local intravascular images thus obtained are usually displayed on a separate monitor in real time.
15 Furthermore, the sectional images may be locally combined by image processing means to form a volume image.

Against this background, it is an object of the present invention to provide means for generating an image of a vascular system, said image comprising a large amount of information for the user.

20 This object is achieved by an apparatus having the features of claim 1 and by a method having the features of claim 8. Advantageous refinements are given in the dependent claims.

The apparatus according to the invention for generating an image of a vascular system comprises the following components:

25 a) an angiography device for producing an angiogram of the vascular system. As mentioned, an angiogram is an image in which the vessels of a body volume are shown on their own or emphasized with respect to the background. An angiogram may be either two-dimensional, for example as a section through the vascular system or a projection of the vascular system, or three-dimensional.

- b) a probe for generating local intravascular images from the vascular system. The intravascular images are usually two-dimensional (e.g. sectional images).
- c) a position determination unit for determining the spatial position (i.e. the position and preferably also the orientation) of the probe at the point in time at which the latter generates a local intravascular image.
- 5 d) a display unit which is designed to assign a local intravascular image of the type mentioned above to the associated position in the angiogram. By virtue of the assignment, in respect of each image point in the local intravascular image it is known to which image point in the angiogram it corresponds (in a geometrically and anatomically
- 10 correct manner) and vice versa. The display unit is furthermore designed to display the local intravascular image in an image together with the angiogram. This display may in principle be two-dimensional or three-dimensional, although in the present case the case of a three-dimensional display is preferred, it being possible for this display to take place in particular by means of a volume rendering. Moreover, the display preferably takes place by means of
- 15 an embedding of one image in the other, that is to say that image information from both images should be recognizable in the overlapping area.

The described invention has the advantage that it combines information from two high-performance imaging methods, namely the angiogram and the intravascular image, with one another and links them to one another by the assignment of the images together with

20 the joint display of the respective information. This is a considerable aid for the treating physician who can optimally use the information obtained in the respective imaging modes and supplement it with information from the other mode. Furthermore, the joint spatial display of intravascular image and angiogram provides a particularly clear and informative representation of the vascular system.

25 The angiography device may in principle be any imaging device suitable for producing an angiogram. In particular, the angiography device may be an X-ray apparatus that is customary in a catheter laboratory. X-ray apparatuses are widely used and are suitable for producing informative angiograms with the aid of contrast agents.

The probe may in particular be an ultrasound probe. Ultrasound probes for

30 generating local intravascular images that are integrated into the tip of a catheter are likewise known and available in many catheter laboratories. One advantage of ultrasound systems is that the generation of images essentially does not entail any side effects for the patient, so that local ultrasound recordings can be taken without any problems at a number of locations.

As the position determination unit for determining the position of the probe, use may in principle be made of any known locating system that is suitable for this purpose. In particular, use may be made of position determination units which can locate with the aid of electromagnetic fields. In this case, for example, there may be attached to the probe a
5 magnetic sensor which allows position determination in a magnetic field impressed on the space by means of a field generator.

There are various possibilities for the joint displaying of a local intravascular image and of the angiogram. According to a first variant, the display unit is designed to display at least one local intravascular image at the associated position of the angiogram.
10 This means that the angiogram and the local intravascular image are displayed (in an overlapping manner) in the same image, with the intravascular image being displayed at the geometrically and hence also anatomically correct position. This may be effected in particular in the form of an embedding or mixing, in which in the overlapping area image points from both images are taken into account in the representation so that one image does
15 not hide the other. The physician can therefore link the information from the local intravascular image and from the angiogram at a glance and in a particularly intuitive manner.

According to one embodiment of the apparatus, the latter may comprise a memory for storing a number of local intravascular images. Such a storing of intravascular
20 images is of use in particular in conjunction with the above-described display mode, since by using the memory it is possible not only for current images but also for earlier images and/or images which in spatial terms lie in an area of interest (e.g. an adjacent area) to be displayed, at the respectively associated positions of the angiogram.

According to an alternative embodiment, the display unit is designed to
25 display a local intravascular image together with the associated section of the angiogram. This means that the part of the angiogram in which the local intravascular image is situated is accordingly enlarged and superposed on the local intravascular image.

The invention furthermore relates to a method of generating an image of a vascular system, said method comprising the following steps:

- 30 a) recording an angiogram of the vascular system, where the angiogram may be two-dimensional or three-dimensional.
- b) recording at least one local intravascular image from the vascular system.
- c) determining the spatial position of the abovementioned local intravascular image.

d) assigning the abovementioned local intravascular image to the geometrically associated position in the angiogram and displaying it together with the angiogram. This display may in principle be two-dimensional or three-dimensional, although in the present case the case of a three-dimensional display (in particular in the form of a volume rendering) is preferred.

As has been mentioned in connection with the above-described apparatus, such a method combines the information from a local intravascular image and an angiogram by means of geometric association and joint display, thus producing a considerable synergistic effect

If the angiogram is two-dimensional, for example an X-ray projection of the vascular system, it is preferably embedded in a three-dimensional display space prior to being displayed together with the local intravascular image. In said three-dimensional space, the geometrically and anatomically correct assignment and joint displaying of the angiogram and of the at least one local intravascular image may then take place, with it being possible for the latter to be either two-dimensional or three-dimensional.

According to a preferred embodiment of the method, a number of local intravascular images are displayed at the same time together with the angiogram. In this way it is possible for the information obtained during an examination, said information coming from a number of local intravascular images, to be retained or stored and embedded jointly in the angiogram. In this case, it is optionally possible for recordings taken only recently to be emphasized to a greater extent in the representation and for older recordings to be diminished – e.g. by virtue of a greater transparency.

The invention will be further described with reference to an example of embodiment shown in the drawing to which, however, the invention is not restricted.

The single figure schematically shows an apparatus according to the invention for generating a combined image of a vascular system.

A section of the vascular system 2 of a patient is shown symbolically in the upper part of the figure. A catheter 1 can also be seen, which catheter is pushed into the vascular system 2 up to a defined position. The catheter 1 has, at its tip, an ultrasound probe 4 by means of which two-dimensional sectional images can be generated, it being possible, for

example, for a local intravascular image of a volume 5 around the ultrasound probe 4 to be generated by virtue of a succession of such sectional images. The recording data of the ultrasound probe 4 are passed via the catheter 1 to a data processing unit 8, where image processing takes place in a known manner. Using the intravascular image, representations of the inside of the vessel wall or volumetric information from the surrounding tissue in the area 5 can be obtained. The generation of local intravascular images may be repeated step by step at as many points in the vessel tree 2 as desired, in order in this way to obtain volumetric data about the surrounding tissue of the entire vessel or vessel tree.

The figure also shows an X-ray apparatus comprising an X-ray radiation source 3 and an X-ray detector 7, which are likewise connected to the data processing unit 8. Using the X-ray apparatus 3, 7 it is possible to generate an X-ray projection image of the vascular system 2. If a contrast agent is injected into the vascular system it is thereby possible to generate an emphasized representation of the vessel (angiogram). The angiogram may be two-dimensional (e.g. an X-ray projection) or three-dimensional, depending on the type of X-ray apparatus and on the image generation thus carried out.

In known examination systems, the local intravascular images of the ultrasound probe 4 are displayed two-dimensionally on a separate, special display device. This display takes place in real time, that is to say an image is displayed directly at the time of its generation. The display is thus restricted to showing the last local sectional image without any correlation with the location at which the image was taken in the vessel structure under examination.

By contrast, in the apparatus shown in the figure there is a combined three-dimensional display of the local intravascular image and of the angiogram. In order to be able to carry this out, a position determination unit (not shown) is provided at the catheter tip and coupled to the data processing unit 8, by means of which it is possible for the spatial position of the ultrasound probe 4 and hence also the position of the locally imaged area 5 to be determined. Various methods of locating visually hidden objects may be used for the position determination system, e.g. a location using an external magnetic field 6 measured on the ultrasound probe 4. Alternatively, it is also possible to make use of image processing methods in order to evaluate the (e.g. two-dimensional) angiogram or another current image of the vascular system with respect to the position of the ultrasound probe 4 as the intravascular image is being taken.

By knowing the spatial position of the local volume 5, it is possible to assign this in a geometrically/anatomically correct manner to the angiogram of the vascular system

2. This means that the position of the recorded local volume 5 in the angiogram can be determined. The known assignment can then be used on a monitor 9, which is coupled to the data processing unit 8, for a joint three-dimensional display 13 of the angiogram 12 and of the current intravascular image 11. For this purpose, the volumetric data provided by the
5 ultrasound system 4 are subjected to a local volume rendering in the data processing unit 8, so that they can be displayed together with the angiogram 12, which is either two-dimensional or three-dimensional. In a volume rendering (e.g. by contrast to surface rendering), each point of a volume is taken into account in the representation in accordance with the characteristic properties assigned to it (cf. Richard A. Robb, "Three-Dimensional
10 Biomedical Imaging", Chapter 4.4). Typically, an image is generated with the aid of virtual beams sent through the volume.

If the angiogram 12 is two-dimensional, it is embedded beforehand in the three-dimensional display space. This may be effected, for example, through a surface bearing the image data. The locally volume-rendered information about the surrounding
15 tissue is then placed in the angiogram 12 at the position at which it was obtained. In the case of a three-dimensional angiogram 12, the locally volume-rendered information 11 is placed in the vessel or vascular tree at the position at which it was obtained, as shown in the figure on the schematic monitor display 13. Upon embedding, the image information both of the intravascular images and of the angiogram remains recognizable in the overlapping area,
20 since the corresponding volumes are displayed with a certain transparency.

With the above-described embedding of the local intravascular image 11 in the angiogram 12, it is possible for a number or all of the local intravascular images obtained up to now to be displayed in the angiogram 12 at the same time. In the figure this is shown for an earlier local intravascular image 10. Optionally, the representation of earlier and/or
25 remoter images 10 may be weaker than that of more recent and/or nearer images (or of the last image 10) in order to emphasize the current position.

Alternatively, the joint displaying of angiogram and intravascular image could also be effected in that the last intravascular image 11 obtained is assigned to the position at which it was obtained and is displayed in the vessel or vascular tree of the angiogram 12 at
30 the same time with the position at which it was obtained.

By means of the apparatus described, it is possible for local volumetric information from an intravascular imaging device to be displayed in a two-dimensional or three-dimensional angiogram. In this way, new and improved methods for diagnosis and treatment planning can be pursued since characteristics of the surrounding vascular tissue can

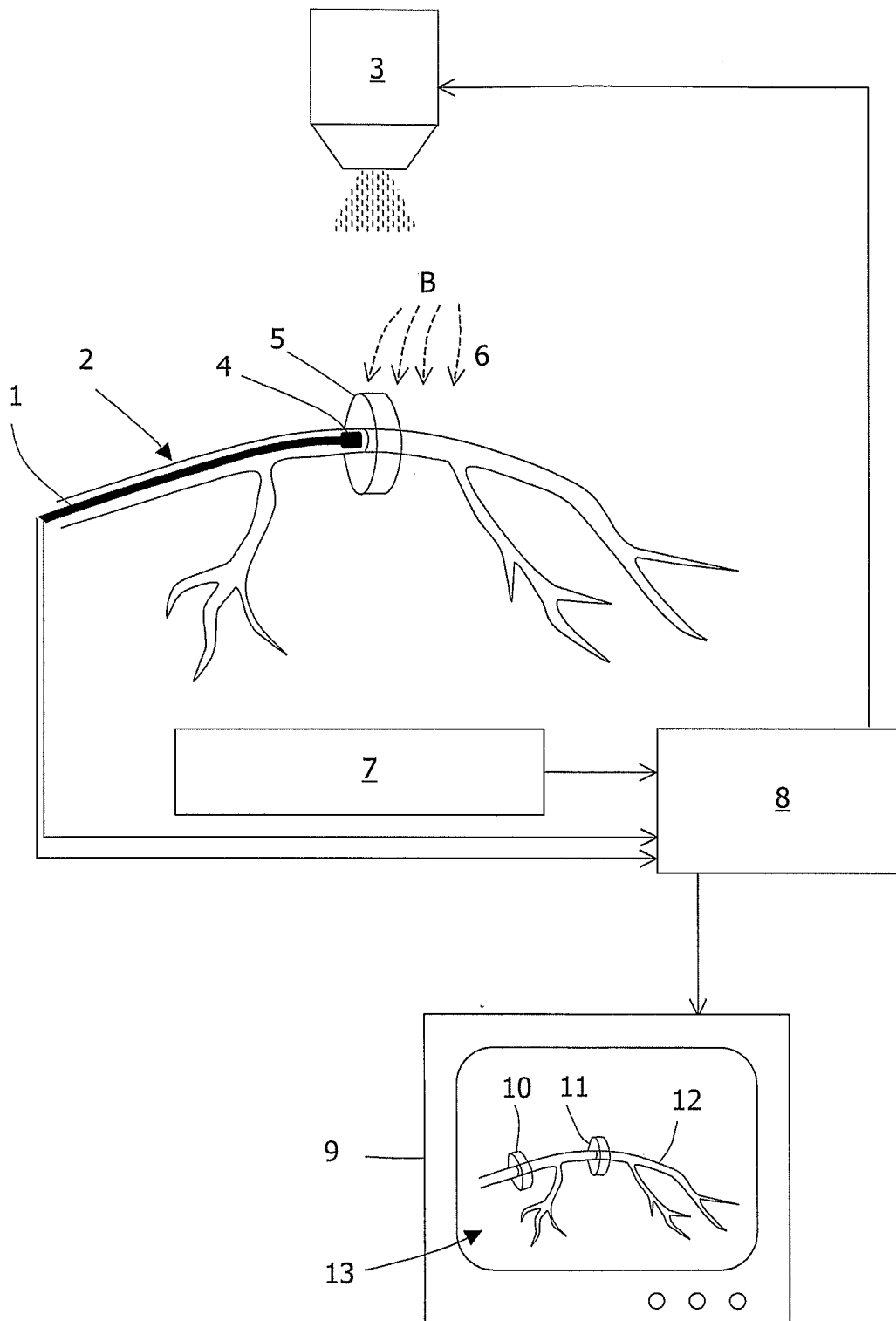
be correlated with the anatomical location at which the image was obtained and with the local anatomical situation in the vessel or vascular structure. The apparatus may be used in particular in a catheter laboratory and in the case of targeted medication in which the distribution of the medicament in a vascular tree or vascular structure can be visualized.

CLAIMS:

1. An apparatus for generating an image (13) of a vascular system (2), said apparatus comprising:
 - a) an angiography device (3, 7) for producing an angiogram (12) of the vascular system (2);
 - 5 b) a probe (4) for generating local intravascular images (10, 11) from the vascular system (2);
 - c) a position determination unit for determining the spatial position of the probe (4) while a local intravascular image is being generated;
 - d) a display unit (8, 9) which is designed to assign a local intravascular image
10 (10, 11) to the associated position in the angiogram (12) and to display it in a preferably three-dimensional image (13) together with the angiogram.
2. An apparatus as claimed in claim 1, characterized in that the angiography device comprises an X-ray apparatus (3, 7).
15
3. An apparatus as claimed in claim 1, characterized in that the probe is an ultrasound probe (4).
4. An apparatus as claimed in claim 1, characterized in that the position
20 determination unit is designed to locate with the aid of electromagnetic fields.
5. An apparatus as claimed in claim 1, characterized in that the display unit (8, 9) is designed to display at least one local intravascular image (10, 11) at the associated position of the angiogram (12).
25
6. An apparatus as claimed in claim 1, characterized in that it comprises a memory for storing local intravascular images (10, 11).

7. An apparatus as claimed in claim 1, characterized in that the display unit is designed to display a local intravascular image together with the associated section of the angiogram.
- 5 8. A method of generating an image (13) of a vascular system (2), said method comprising the following steps:
- a) recording an angiogram (12) of the vascular system (2);
 - b) recording at least one local intravascular image (10, 11) from the vascular system (2);
 - 10 c) determining the spatial position of the local intravascular image (10, 11);
 - d) assigning the local intravascular image (10, 11) to the associated position in the angiogram (12) and displaying it, preferably three-dimensionally, together with the angiogram (12).
- 15 9. A method as claimed in claim 8, characterized in that the angiogram is two-dimensional and is embedded in a three-dimensional display area prior to being displayed together with the local intravascular image.
10. A method as claimed in claim 8, characterized in that a number of local
20 intravascular images (10, 11) are displayed at the same time together with the angiogram (12).

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2004/050433

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B6/00 A61B8/12

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 7 A61B

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, WPI Data, PAJ, COMPENDEX, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/115931 A1 (GHAZAROSSIAN VARTAN ET AL) 22 August 2002 (2002-08-22) paragraphs '0046!, '0047!, '0052!, '0071!	1-3,5-7
X	YOCK PAUL G ET AL: "Intravascular ultrasound: State of the art and future directions" AMERICAN JOURNAL OF CARDIOLOGY, vol. 81, no. 7A, 9 April 1998 (1998-04-09), pages 27E-32E, XP002292690 ISSN: 0002-9149 page 29E, section "3-Dimensional Reconstruction" figure caption of figure 7	1-3,5,6

Further documents are listed in the continuation of box C.

Patent family members are listed in 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 document 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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

17 August 2004

Date of mailing of the international search report

30/08/2004

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INTERNATIONAL SEARCH REPORT

Intern: Application No

PCT/IB2004/050433

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>TAMURA SHINICHI ET AL: "Intrabody three-dimensional position sensor for an ultrasound endoscope" IEEE TRANS. BIOMED. ENG.; IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING OCT 1 2002, vol. 49, no. 10, 1 October 2002 (2002-10-01), pages 1187-1194, XP002292600 page 1187, section "Introduction", first paragraph page 1193, section "Conclusion", second and third paragaph -----</p>	1,3,4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2004/050433

Box 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.: 8-10
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2004/050433

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 2002115931 A1 22-08-2002 NONE
