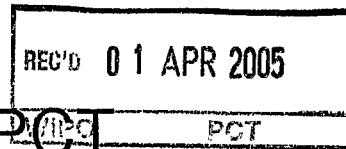


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/NO2004/000372	International filing date (day/month/year) 03.12.2004	Priority date (day/month/year) 04.12.2003
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International Patent Classification (IPC) or both national classification and IPC
A61B8/00

Applicant
AMERSHAM HEALTH AS

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

<p>Name and mailing address of the ISA:</p> <p>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</p>	<p>Authorized Officer</p> <p>Telephone No. +49 89 2399-</p>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/NO2004/000372

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/NO2004/000372

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,
- claims Nos. 1-26

because:

- the said international application, or the said claims Nos. 1-26 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for the whole application or for said claims Nos.
- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form has not been furnished
 - does not comply with the standard
 - the computer readable form has not been furnished
 - does not comply with the standard
- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- See separate sheet for further details

Re Item III

- 1 **Claims 1-26** relate to methods for treatment of the human or animal body by surgery (Rule 67.1(iv) PCT). The reasons are as follows.

The methods claimed in independent **claims 1** and **26** implicitly and explicitly, respectively, require the administration of an ultrasound contrast agent to the living human or animal body. The administration of an ultrasound contrast agents is generally performed by way of injection or infusion. For the claimed methods, non-intravascular injections, for instance intramuscular or percutaneous injections or injections directly in a lymphatic vessel or in a tumour are preferred (see p. 10, l. 14-17, p. 11, l. 1-6). The administration of the ultrasound contrast agent is, therefore, considered a surgical step, by means of which the claimed methods as a whole are considered to be methods for treatment by surgery.

- 2 At the same time, **claims 1-26** relate to diagnostic methods practised on the human or animal body (Rule 67.1(iv) PCT). The reasons are as follows.

Claims 23-25, which are dependent on **claim 1**, explicitly contain steps to characterize the lymph nodes as being normal or malignant. Independent **claim 26** is directly related to a method of characterizing lymph nodes as being normal or malignant lymph nodes. Accordingly, all claimed methods are implicitly or explicitly directed to the determination of a condition which differs from the normal healthy condition, i.e. to the determination of a disease, and, consequently, to the establishment of a diagnosis.

Further, since the claimed methods implicitly or explicitly comprise surgical steps (see above), they are practiced on the human or animal body.

- 3 Therefore, an opinion with respect to novelty, inventive step and industrial applicability is not established for **claims 1-26** (Art. 34(4)(a)(i) PCT).