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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
100933-1 WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE 03/01978	17.12.2003	18.12.2002
International Patent Classification (IPC) or both national classification and IPC		
G01N33/58		
Applicant		
ASTRAZENECA AB et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.06.2004	02.09.2004
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/01978

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-22 as published

Claims, Numbers

1-36 as published

Drawings, Sheets

1/7-7/7 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. 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. 20-28

   because:

   ☒ the said international application, or the said claims Nos. 20-28 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 said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-36
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-19,29-36
	No:	Claims	20-28

2. Citations and explanations

see separate sheet

item III

Claims 20-28 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT (the subject-matter of said claims embraces diagnostic methods carried out "in vivo", therefore involving the treatment of the living human or animal body). Consequently, no report will be issued with respect to the industrial applicability of the subject-matter of these claims (Article 34 (4) (a) (I) PCT).

For the assessment of the present claims 20-28 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims (in this particular case, an according to the EPO practice, it would suffice to direct the claims to methods that are to be carried out "in vitro").

item V

1.) Reference is made to the following documents:

D1: US-A-5,225,349
D2: M. J. Berridge et al (1982) Biochem. J. 206, 587-595
D3: L. Andersson & J. Porath (1986) Anal. Biochem. 154, 250-254
D4: S. Li & C. Dass (1999) Anal. Biochem. 270, 9-14
D5: J. J. Liu et al (2003) Anal. Biochem. 318, 91-99

2.) The subject-matter of claims 1-36 is considered to be novel and inventive within the sense of Art. 33 (2) and (3) PCT, for the following reasons:

D1 (closest state of the art) discloses a chromatographic method for separating/ detecting inositol phosphates in a sample by feeding the sample into a column containing a solid non-polar phase and eluting the inositol phosphates with an organic solvent (examples 1 and 2).

D2 discloses a chromatographic method for separating/detecting inositol phosphates in a sample by feeding the sample into an anion-exchange column (Dowex) and eluting the inositol phosphates with a buffer containing an organic acid (p. 1982).

D3 discloses the use of immobilized metal ion affinity chromatography (IMAC) for the separation/detection of phosphoproteins and phosphoamino acids (see abstract). D4

discloses the use of immobilized metal ion affinity chromatography (IMAC) for the separation/detection of synthetic phosphopeptides (see abstract).

The skilled person equipped with the teaching of D1-D4 would not be motivated to modify the method of D1 by using the chromatographic method of D3-D4, thus arriving at a method as claimed in claims 1 (and 2-7 as dependent thereon), with the purpose to provide an improved method for detecting/measuring inositol phosphates which can be used in drug screening studies in vitro and in vivo. Analogous arguments apply for the subject-matter of claims 8-36.

3.) In case of an invalid priority date, D5 may be considered relevant for assessing novelty and inventive step of the subject-matter claimed when the application enters the regional phase.