PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference P08130P	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2009/007051	21.12.2009	22.12.2008

International Patent Classification (IPC) or both national classification and IPC

Applicant
FUJITA HEALTH UNIVERSITY

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 43*bis*.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 be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that 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 66.1*bis*(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 3 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.

Name and mailing address of the ISA/JP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. I Basis of this 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

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. 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

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) 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.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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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**

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 2007-504863 A (AFFiRiS Forschungs- und Entwicklungs GmbH), 08 March 2007, paragraphs [0001], [0004], [0005], [0011], [0014], [0024], [0041] and [0050]-[0054]

Document 2: JP 1-135533 A (Kaneka Corp.), 29 May 1989, claims 1, 2 and 11, page 2, upper right column, lines 8-10; page 2, lower left column, line 5-page 3, upper left column, line 15; page 4, upper left column, line 5-lower left column, line 14; page 5, lower left column, line 15-page 6, upper left column, lowest line

Document 3: JP 2008-69346 A (Kaneka Corporation), 27 March 2008, paragraphs [0003] and [0004]

The invention as in claims 1-6 and 9-12 does not involve an inventive step in the light of documents 1 and 2 cited in the ISR. Document 1 discloses the invention of an extracorporeal circulation blood processing device (hereinafter, referred to as "cited invention 1") provided with an Aβ-remover for efficiently removing an amyloid β protein (hereinafter, referred to as "Aβ") from a body fluid

such as blood for the treatment of Alzheimer disease, wherein said remover has an immunoadsorption column with an anti-Aβ antibody or the like fixed on a carrier comprising silica or the like or a carrier having an alkyl group on the surface thereof.

The invention as in claims 1-6 and 9-12 differs from cited invention 1 in terms of adsorbing Aβ by the affinity of the surface of a carrier, not by immunoadsorption.

Document 2 discloses a serum amyloid A adsorbent for an extracorporeal circulation treatment, wherein for cost reduction, the carrier of the adsorbent is a water-insoluble carrier comprising cellulose, silica, polyvinyl alcohol, or the like and has an alkyl group at least in part of the surface of a carrier.

In view of the foregoing, for cost reduction, a person skilled in the art could easily conceive of applying the feature of document 2 to the carrier of the remover of cited invention 1 so as to obtain a carrier for capturing a target substance by chemoaffinity.

In addition, document 2 discloses the feature wherein a functional group of a silanol group or the like used for an immobilization reaction has been found on the surface of an inorganic carrier.

The invention as in claims 7 and 8 does not involve an inventive step in the light of documents 1-3 cited in the ISR. Document 3 discloses an adsorbent for processing extracorporeal circulation blood, wherein the surface of activated carbon of a carrier has been processed through a poly-HEMA having a good blood compatibility and a ligand does

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not have to be fixed.

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Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Regarding the wording "アミロイドβタンパク除去材" [amyloid β protein remover] of claim 1, it is not clear whether the wording merely means a remover having a specific property/function or a device limited to the use for removing an amyloid β protein.