PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:	**PCT**
DANUBIA Patent and Law Office LLC Dr. SVINGOR Adam, Bajcsy-Zcilinszky Ut 16. H-1051 Budapest Hungary	NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty) (PCT Rule 71.1)
	Date of mailing (day/month/year) 31 October 2014 (31.10.2014)
Applicant's or agent's file reference P112603SG	**IMPORTANT NOTIFICATION**

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/HU 2013/000057	10 June 2013 (10.06.2013)	02 July 2012 (02.07.2012)

Applicant
UD-GENOMED MEDICAL GENOMIC TECHNOLOGIES

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT' Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the ISA/RU FGU FIPS Russia, 123995, Moscow, G-59, GSP-5, Berezhkovskaya nab., 30-1 Facsimile No.	Authorized officer O. Shanova Telephone No. (495)531-65-15

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P112603SG	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/HU 2013/000057	International filing date *(day/month/year)* 10 June 2013 (10.06.2013)	Priority date *(day/month/year)* 02 July 2012 (02.07.2012)
International Patent Classification (IPC) or national classification and IPC ***G01N 33/536*** *(2006.01)* ***C12N 15/11*** *(2006.01)* ***G01N 33/569*** *(2006.01)*		
Applicant UD-GENOMED MEDICAL GENOMIC TECHNOLOGIES		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      [X] sheets of the description, claims and/or drawings which have been amended and and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions).
      [ ] sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4*bis*, 70.2(e), 70.16 and 91.2).
      [ ] superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)).
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3*bis* of Annex C of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] 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
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step and 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

Date of submission of the demand 29 April 2014 (29.04.2014)	Date of completion of this report 27 October 2014 (27.10.2014)
Name and mailing address of the IPEA/RU FIPS Russia, 123995, Moscow, G-59, GSP-5, Berezhkovskaya nab., 30-1 Facsimile No.	Authorized officer M. Khudyaev Telephone No. (495) 531-65-15

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/HU 2013/000057

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] 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)).

[ ] publication of the international application (Rule 12.4(a)).

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a) and (b)).

2. With regard to the **elements** of the international application, this report is based on *(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)*:

[ ] the international application as originally filed/furnished

[X] the description:
pages 1-31 as originally filed/furnished.
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

[X] the claims:
pages _____ as originally filed/furnished.
pages* _____ as amended (together with any statement) under Article 19
pages* 32-33 received by this Authority on 07.07.2014
pages* _____ received by this Authority on _____

[X] the drawings:
pages 1/22-22/22 as originally filed/furnished.
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

[ ] a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages _____
[ ] the claims. Nos. _____
[ ] the drawings, sheets/figs _____
[ ] the sequence listing (specify): _____

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-*bis*)):

[ ] the description, pages _____
[ ] the claims. Nos. _____
[ ] the drawings, sheets/figs _____
[ ] the sequence listing *(specify)*: _____

5. [ ] This report has been established:

[ ] taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-*bis*) and 70.2(e)).

[ ] without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4*bis* and 70.2(e)).

6. [ ] Supplementary international search report(s) form Authority(ies) _____ has/have been received and taken into account in establishing this report (Rule 45*bis*.8(b) and (c)).

** If item 4 applies, some or all of those sheets may be marked "superseded".*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/HU 2013/000057

Box No. V Reasoned statement under Rule 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims		NO
Inventive Step (IS)	Claims	1-15	YES
	Claims		NO
Industrial Applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations (Rule 70.7):

D1: US 0006255462 B1 , 03.07.2001
D2: WO 2012/050963 A2 , 19.04.2012
D3: HARING M. et al. Plant Methods, 2007, 3:11, pp.1-16

D1 is the closest analogue with respect to the claimed inventions.

D1 (example 3) discloses that a virus, for example, the cowpox virus, may be used as a control in the immonoprecipitation reaction.

The invention of independent claim 1 differs from D1 in use of a virus or a virion, wherein a genetic material of the virus or virion comprises a traceable oligonucleotide segment in its genome encoding a peptide epitope, herein said epitope peptide is displayed by the virus or virion and recognized by said recognition molecule in the immonoprecipitation reaction.

Consequently, the invention of claims 1-5 meets the criterion of novelty.

Since above mentioned distinctive features of independent claim 1 are not known and are not obvious for a skilled person from the prior art and provide a positive control in the immonoprecipitation reaction, the invention of claim 1-5 meet the criterion of inventive step.

The inventions of claims 6-15 also meet the criteria of novelty and inventive step, since they comprise the features of claim 1.

The inventions meet the criterion of industrial applicability.

CLAIMS

1. Use of a virus or virion for providing control in an immunoprecipitation reaction carried out with a recognition molecule, wherein the genetic material of the virus or virion comprises a traceable oligonucleotide segment in its genome encoding an epitope peptide, wherein said epitope peptide is displayed by the virus or virion and recognized by said recognition molecule in the immunoprecipitation reaction.
2. The use according to claim 1 wherein the control is a positive control.
3. The use according to claim 1 or 2 wherein the virus is a virion.
. The use according to any of claims 1 to 3 wherein the virus or virion is a bacteriophage.
5. The use according to any of claims 1 to 4 wherein the immunoprecipitation reaction is nucleic acid immunoprecipitation selected from
   - a direct nucleic acid immunoprecipitation and
   - immunoprecipitation of a complex containing a nucleic acid, preferably chromatin immunoprecipitation.
6. An immunoprecipitation kit, said kit comprising
   - a recognition molecule recognizing an antigen epitope for use in immunoprecipitation,
   - a positive control nanoparticle, said nanoparticle comprising a nucleic acid and a polypeptide carrying an epitope, wherein the nucleic acid comprises a traceable oligonucleotide segment

   and optionally
   - a negative control nanoparticle lacking said oligonucleotide and epitope but preferably having a nucleic acid and a polypeptide (preferably a negative control bacteriophage lacking said oligonucleotide and epitope,)
   - means for detecting the binding of said recognition molecule to said antigen epitope, preferably means for amplification of said positive control bacteriophage and optionally said negative control bacteriophage,
   - support or carrier for binding said recognition molecule, preferably beads.

   wherein said nanoparticle is a virus or a virion as defined in claim 1.
7. The immunoprecipitation kit of claim 6 for use in a nucleic acid immunoprecipitation, wherein the virus or virion is a bacteriophage, said kit comprising as a means for amplification oligonucleotide primers, preferably QPCR primers for amplification of displayed epitope coding sequence, and/or QPCR primers for amplification of the bacteriophage sequence.
8. An immunoprecipitation method said method comprising the steps of
   - providing a set of samples comprising an antigen or a target protein carrying an epitope,
   - adding a recognition molecule recognizing an epitope of said antigen (antigen epitope) to one or more samples from the set of samples,
   - adding a positive control nanoparticle, said nanoparticle comprising a nucleic acid and a polypeptide carrying an epitope, wherein the nucleic acid comprises a traceable oligonucleotide segment,

- optionally adding a negative control nanoparticle lacking said epitope to one or more samples from the set of samples,
- adding the recognition molecule to the set of samples
- carrying out the immunoprecipitation reaction,
- detecting the binding of the recognition molecule to the displayed epitope,

wherein said nanoparticle is a virus or a virion as defined in claim 1.

9. The immunoprecipitation method according to claim 8 wherein immunoprecipitation is a nucleic acid - protein complex immunoprecipitation, preferably chromatin immunoprecipitation said method further comprising fragmenting the nucleic acid - protein complex, and binding the antigen and thereby those fragments bound by the antigen to the recognition molecule, wherein preferably the recognition molecule is bound to a support or carrier.
10. The method according to any of claims 8 to 9 wherein the detection of the binding of the recognition molecule to the displayed epitope is carried out by
    - amplifying a region coding the displayed epitope from the traceable nucleic acid from the nanoparticle, and/or
    - adding the nucleic acid fragments bound by the antigen to a chip comprising a multiplicity of nucleic acid sequences wherein preferably at least one of them is complementary to a sequence of the nucleic acid, preferably to the sequence encoding the epitope region, and/or
    - sequencing the nucleic acid fragment bound by the antigen.
11. The use of a multiplicity of virions as a control in an immunoprecipitation reaction, said multiplicity of virions comprising an oligonucleotide segment in their genome said segment encoding a peptide, wherein said peptide is displayed by said virions and comprises an epitope or an immunogenic portion, wherein the epitope or the immunogenic portion is 5-20, preferably 7 or 8 amino acids long and wherein said peptide is capable of binding to a recognition molecule bound to a carrier, wherein preferably the carrier comprises protein A or protein G or any combination thereof.
12. The use according to claim 11 wherein the multiplicity of virions is used as a positive control.
13. The use according to any of claims 11 to 12 wherein a further multiplicity of virions are used as a negative control in said immunoprecipitation reaction said further multiplicity of virions comprising an oligonucleotide segment in their genome said segment encoding a further peptide, said further peptide lacking said epitope or immunogenic portion.
14. The use according to any of claims 11 to 13 wherein the virions are bacteriophages.
15. The use according to any of claims 11 to 14 wherein the immunoprecipitation is chromatin immunoprecipitation.