(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 154 245 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
28.04.2010 Bulletin 2010/17

(43) Date of publication A2:
17.02.2010 Bulletin 2010/07

(21) Application number: **09177359.8**

(22) Date of filing: **01.09.2006**

(51) Int Cl.:
C12N 15/00 *(2006.01)* ***C12N 15/09*** *(2006.01)*
C12Q 1/68 *(2006.01)* ***G01N 33/53*** *(2006.01)*
G01N 33/574 *(2006.01)*

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **02.09.2005 JP 2005255499**
01.11.2005 JP 2005318589

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
06821799.1 / 1 930 426

(71) Applicants:
- **Toray Industries, Inc.**
  Tokyo 103-8666 (JP)
- **Kyoto University**
  Kyoto-shi
  Kyoto 606-8501 (JP)

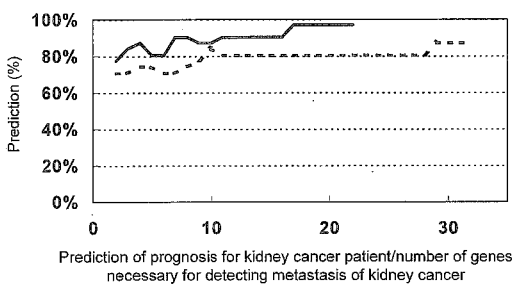
(72) Inventors:
- **Kozono, Satoko**
  Kamakura-shi, Kanagawa 248-8555 (JP)
- **Akiyama, Hideo**
  Fujisawa-shi Kanagawa 251-0033 (JP)
- **Myomoto, Akira**
  Kamakura-shi, Kanagawa 248-8555 (JP)
- **Tanaka, Yoshinori**
  Kamakura-shi Kanagawa 248-0036 (JP)
- **Jung, Giman**
  Kamakura-shi, Kanagawa 248-8555 (JP)
- **Nobumasa, Hitoshi**
  Otsu-shi Shiga 520-0043 (JP)
- **Nomura, Osamu**
  Kamakura-shi Kanagawa 248-0034 (JP)
- **Ogawa, Osamu**
  Kyoto-shi Kyoto 606-8501 (JP)
- **Nakamura, Eijiro**
  Kyoto-shi Kyoto 606-8501 (JP)
- **Tsujimoto, Gozoh**
  Kyoto-shi Kyoto 606-8501 (JP)

(74) Representative: **Prüfer & Partner GbR**
European Patent Attorneys
Sohnckestrasse 12
81479 München (DE)

(54) Composition and method for diagnosing kidney cancer and for predicting prognosis for kidney cancer patient

(57) This invention relates to a composition, kit, DNA chip, and use thereof for detecting, diagnosing, and predicting metastasis of kidney cancer and/or for predicting the prognosis for kidney cancer, comprising one or a plurality of polynucleotides selected from the group consisting of polynucleotides, mutants thereof or fragments thereof, the expression levels of which vary in kidney cancer cells from a patient with a poor prognosis when compared with that in kidney cancer cells from a patient with a good prognosis; or antibodies or fragments thereof that bind specifically to polypeptides, mutants thereof or fragments thereof, the expression levels of which vary in the similar manner.

Fig. 2



EP 2 154 245 A3

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 09 17 7359

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	VASSELLI JAMES R ET AL: "Predicting survival in patients with metastatic kidney cancer by gene-expression profiling in the primary tumor." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA 10 JUN 2003, vol. 100, no. 12, 10 June 2003 (2003-06-10), pages 6958-6963, XP002520165 ISSN: 0027-8424 * the whole document *	1-30	INV. C12N15/00 C12N15/09 C12Q1/68 G01N33/53 G01N33/574
X	TAKAHASHI MASAYUKI ET AL: "Gene expression profiling of clear cell renal cell carcinoma: Gene identification and prognostic classification" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, WASHINGTON, DC.; US, vol. 98, no. 17, 14 August 2001 (2001-08-14), pages 9754-9759, XP002318256 ISSN: 0027-8424 * the whole document *	1-30	TECHNICAL FIELDS SEARCHED (IPC) C12N
X	BOER JUDITH M ET AL: "Identification and classification of differentially expressed genes in renal cell carcinoma by expression profiling on a global human 31,500-element cDNA array" GENOME RESEARCH, COLD SPRING HARBOR LABORATORY PRESS, WOODBURY, NY, US, vol. 11, no. 11, 1 November 2001 (2001-11-01), pages 1861-1870, XP002215718 ISSN: 1088-9051 * the whole document *	1-30	

-/--

1 ~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
Munich	21 December 2009	Roscoe, Richard

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 09 17 7359

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
L	MIYAKE H ET AL: "Introduction of basic fibroblast growth factor gene into mouse renal cell carcinoma cell line enhances its metastatic potential." CANCER RESEARCH 15 MAY 1996, vol. 56, no. 10, 15 May 1996 (1996-05-15), pages 2440-2445, XP002520166 ISSN: 0008-5472 L: Unity * the whole document * -----		
L	KITAGAWA ET AL: "EXPRESSION OF MESSENGER RNAS FOR MEMBRANE-TYPE 1, 2, AND 3 MATRIX METALLOPROTEINASES IN HUMAN RENAL CELL CARCINOMAS" JOURNAL OF UROLOGY, BALTIMORE, MD, US, vol. 162, no. 3, 1 September 1999 (1999-09-01), pages 905-909, XP005557829 ISSN: 0022-5347 L: Unity * the whole document * -----		TECHNICAL FIELDS SEARCHED (IPC)
L	FREEMAN M R ET AL: "Aberrant expression of epidermal growth factor receptor and HER-2 (erbB-2) messenger RNAs in human renal cancers." CANCER RESEARCH 15 NOV 1989, vol. 49, no. 22, 15 November 1989 (1989-11-15), pages 6221-6225, XP002520167 ISSN: 0008-5472 * the whole document * -----		
X	WO 2005/003776 A (PROGENIKA BIOPHARMA S A [ES]; GOMEZ ROMAN JOSE JAVIER [ES]; SAENZ JIME) 13 January 2005 (2005-01-13) * the whole document * ----- -/--	1-30	

1 ~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
Munich	21 December 2009	Roscoe, Richard

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 09 17 7359

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 98/45432 A (UNIV PITTSBURGH [US]; GETZENBERG ROBERT H [US]) 15 October 1998 (1998-10-15) * the whole document *	1-30	
X	WO 2004/032842 A (ANDEL INST VAN [US]; TEH BIN TEAN [US]; TAKAHASHI MASAYUKI [JP] ANDEL) 22 April 2004 (2004-04-22) * the whole document *	1-30	
X	WO 2005/036176 A (WYETH CORP [US]; LIU WEI [US]; WHITLEY MARYANN [US]; SLONIM DONNA [US]) 21 April 2005 (2005-04-21) * the whole document *	1-30	
A	US 2003/092616 A1 (MATSUDA AKIO [JP] ET AL) 15 May 2003 (2003-05-15) * the whole document *	1-30	
			TECHNICAL FIELDS SEARCHED (IPC)

1 ~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
Munich	21 December 2009	Roscoe, Richard

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Application Number
EP 09 17 7359

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-30 (all part)

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

Europäisches Patentamt
European Patent Office
Office européen des brevets

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 09 17 7359

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Invention 1: claims 1-30 (all part)

Subject.matter relating to the use of at least 2 probes including at least one based on the DNA seq. of Seq.ID No.1 for the determination or prediction of metastasis of kidney cancer. Includes kits, DNA chips and the use of the aforementioned probes in in vitro diagnostic methods.

Invention 2-45: claims 1-30 (part)

Subject.matter relating to the use of at least 2 probes including at least one based on the DNA seq. of Seq.ID No.2-10, 12-20, 22-47 (1 of these per invention group) for the determination or prediction of metastasis of kidney cancer. Includes kits, DNA chips and the use of the aforementioned probes in in vitro diagnostic methods.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 09 17 7359

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

21-12-2009

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005003776 A	13-01-2005	EP 1642133 A2	05-04-2006
		ES 2297953 A1	01-05-2008
		US 2008274968 A1	06-11-2008
		US 2008015143 A1	17-01-2008
WO 9845432 A	15-10-1998	AU 6789598 A	30-10-1998
		CA 2287778 A1	15-10-1998
		EP 0973894 A1	26-01-2000
		JP 2001523087 T	20-11-2001
WO 2004032842 A	22-04-2004	AU 2003288918 A1	04-05-2004
		CA 2501131 A1	22-04-2004
		EP 1570078 A2	07-09-2005
		JP 2006501849 T	19-01-2006
		US 2006183120 A1	17-08-2006
WO 2005036176 A	21-04-2005	US 2005282168 A1	22-12-2005
US 2003092616 A1	15-05-2003	NONE	

EPO FORM P0459

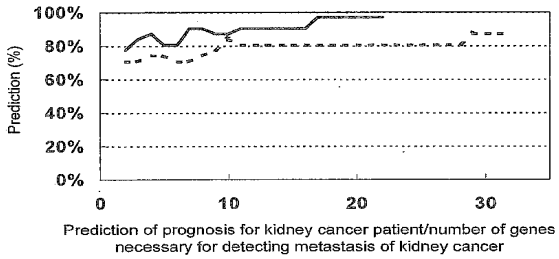
For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

专利名称(译)	用于诊断肾癌和预测肾癌患者预后的组合物和方法		
公开(公告)号	EP2154245A3	公开(公告)日	2010-04-28
申请号	EP2009177359	申请日	2006-09-01
[标]申请(专利权)人(译)	东丽株式会社 国立大学法人京都大学		
申请(专利权)人(译)	TORAY INDUSTRIES，INC. 京都大学		
当前申请(专利权)人(译)	TORAY INDUSTRIES，INC. 京都大学		
[标]发明人	KOZONO SATOKO AKIYAMA HIDEO MYOMOTO AKIRA TANAKA YOSHINORI JUNG GIMAN NOBUMASA HITOSHI NOMURA OSAMU OGAWA OSAMU NAKAMURA EIJIRO TSUJIMOTO GOZOH		
发明人	KOZONO, SATOKO AKIYAMA, HIDEO MYOMOTO, AKIRA TANAKA, YOSHINORI JUNG, GIMAN NOBUMASA, HITOSHI NOMURA, OSAMU OGAWA, OSAMU NAKAMURA, EIJIRO TSUJIMOTO, GOZOH		
IPC分类号	C12N15/00 C12N15/09 C12Q1/68 G01N33/53 G01N33/574		
CPC分类号	G01N33/57438 C12Q1/6837 C12Q1/6886 C12Q2600/112 C12Q2600/118		
优先权	2005255499 2005-09-02 JP 2005318589 2005-11-01 JP		
其他公开文献	EP2154245A2 EP2154245B1		
外部链接	Espacenet		

摘要(译)

本发明涉及用于检测，诊断和预测肾癌转移和/或预测肾癌预后的组合物，试剂盒，DNA芯片及其用途，其包含一种或多种选自下组的多核苷酸：多核苷酸，其突变体或其片段，其表达水平在来自预后不良的患者的肾癌细胞中与来自具有良好预后的患者的肾癌细胞中的表达水平不同;或者与多肽，其突变体或其片段特异性结合的抗体或其片段，其表达水平以相似的方式变化。

Fig. 2


100%
80%
60%
40%
20%
0%
Prediction (%)
0
10
20
30
Prediction of prognosis for kidney cancer patient/number of genes necessary for detecting metastasis of kidney cancer