Case studies for patenting and disclosure requirements of healthcare innovations

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WIPO
WORLD
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Contents

- Introduction – Best practices
- Case study vaccines - BiondVax
- Case study diagnostics - Mobidiag
- Case study biologic therapeutics – Noile Immune
- Q&A

Introduction

Objective – Guidelines of practices from real examples

Examples outside US, Western Europe.

Introduction

Global Dossier

Free patent database

Small molecule drugs – Pat-INFORMED

Commercial IP protection

Global Dossier

Global Dossier – “one-stop access to the dossier information of all applications that comprise a family and have been filed in participating offices” (IP5 + Australia and Canada).

IP5 offices - 2007 (EPO, JPO, KIPO, USPTO, CNIPA)

Global Dossier - access

https://globaldossier.uspto.gov/

☆ WO2009016639A2 MULTIMERIC MULTIEPITOPE INFLUENZA VACCINES

Bibliographic data | Description | Claims | Drawings | Original document | Citations | Legal eve

Register ↗ | Global Dossier ↗

Applicants: BIONDVAX PHARMACEUTICALS LTD [IL]; BEN-YEDIDIA TAMAR [IL]; SINGER YOSSI [I

Inventors: BEN-YEDIDIA TAMAR [IL]; SINGER YOSSI [IL] +

Classifications

IPC: ***C07K16/00;***

CPC: **A61K39/12 (EP,KR,US); A61K39/145 (EP,KR,US); A61P31/14 (EP); A61P31/16 (EP); C07K14/005 (KR,US);** A61K2039/53 (EP,US); A61K2039/55566 (EP,KR,US); A61K2039/57 (EP,US); A61K2039/645 (EP,US); C12N2760/16034 (US); C12N2760/16134 (EP,US); C12N2760/16234 (EP,US); Y02A50/30 (EP);

Priorities: US95349807P·2007-08-02

Application: IL2008001062W·2008-08-03

Publication: WO2009016639A2·2009-02-05

EPO Global Dossier: IL2008001062 Dossier alert: RSS Email

Dossier provided courtesy of IB of the WIPO

Date	Description	Pages
02.02.2010	International Preliminary Report on Patentability Chapter I	-
02.02.2010	Written Opinion of the International Search Authority	-
30.04.2009	Published International Application	-
05.02.2009	RO/101	-
05.02.2009	Seq List Tables	-
05.02.2009	Priority Document	-
05.02.2009	Published International Application	-
05.02.2009	Notification Concerning Submission Or Transmittal Of Priority Document	-

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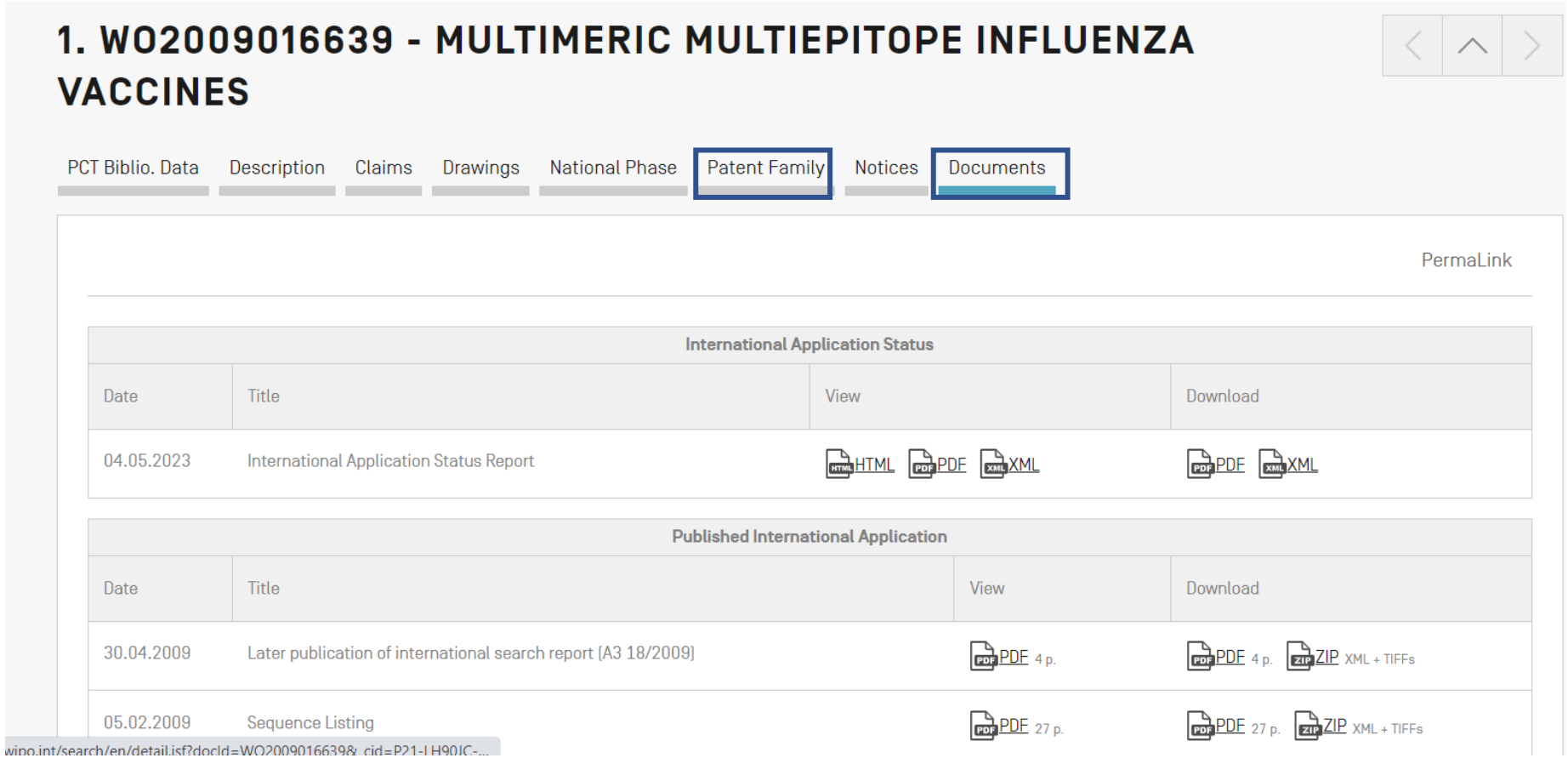
Global Dossier - access

Patentscope



Free patent databases

Patentscope, Espacenet, USPTO, Google Patents, Lens.org

Other patent searching platforms country specific (India, Japan, etc.)

PatSeq finder – Lens.org;

https://www.ebi.ac.uk/seqdb/confluence/display/JDSAT/Job+Dispatcher+Sequence+Analysis+Tools+Home

Pat-INFORMED

https://www.wipo.int/patinformed/

INN - International Non-proprietary Names

https://www.patentoppositions.org/en/home

(Example – abacavir – GSK)

Commercial IP protection

Patents

- Drug Compound
- Crystal forms/Salt forms
- Formulation
- Manufacturing process
- Methods of treatment
- Dosage regimens
- Delivery device

Trademark

- Roche name/logo
- Ocrevus name
- Delivery system name (if any)

Registered design

- The design of packaging
- The graphics on the packaging

Copyright

- Layout of packaging
- Patient information leaflet

Trade secret/Know-how

- Manufacturing process
- Purification method
- Scale-up

Vaccines - BiondVax

Vaccine protection avenues

Commercial name	Type of claim	1st claim	Patent number
BIOTHRAX	Formulation	1. A stable vaccine for stimulating an immune response to a Bacillus anthracis protective antigen comprising: a) a purified B. anthracis protective antigen protein; b) an alanine formulation buffer; and c) a pharmaceutically acceptable adjuvant.	U.S. Patent No. 8,778,359; Title: Stable anthrax vaccine formulations
RECOMBIVAX HB	Composition of matter	1. A DNA transfer vector comprising a yeast replication origin, a yeast promoter fragment and, in correct orientation with said promoter fragment, a DNA segment coding for the S-protein of Hepatitis B virus.	U.S. Patent No. 6,544,757; Title: Synthesis of human virus antigens by yeast
GARDASIL 9	Method of manufacture	1. A method of making a papillomavirus virus-like particle, which method comprises: constructing a recombinant DNA molecule that contains a sequence encoding a papillomavirus L1 protein; transfecting a host cell with the recombinant DNA molecule; expressing papillomavirus L1 protein in the host cell; and obtaining papillomavirus virus-like particles from the transfected host cell; wherein the papillomavirus is not HPV 16.	U.S. Patent No. 7,476,389; Title; Papillomavirus vaccines
N/a	Method of treatment	1. A method for treating a subject infected with H5N1 strain of avian influenza, wherein said method comprises diagnosing a subject as being infected with the H5N1 strain of avian influenza; and administering to the subject an effective amount of a salt of cysteamine.	U.S. Patent No. 9,283,198 ; Title: Materials and methods for treating viral infections

BiondVax – Case study

Founded in 2003 – Israel; Listed on Nasdaq – BVXV (2015)

BiondVax is developing a universal influenza vaccine. >20 years research carried at Weizmann Institute of Science, Israel.

CDMO (Contract Development and Manufacturing Organisation) services

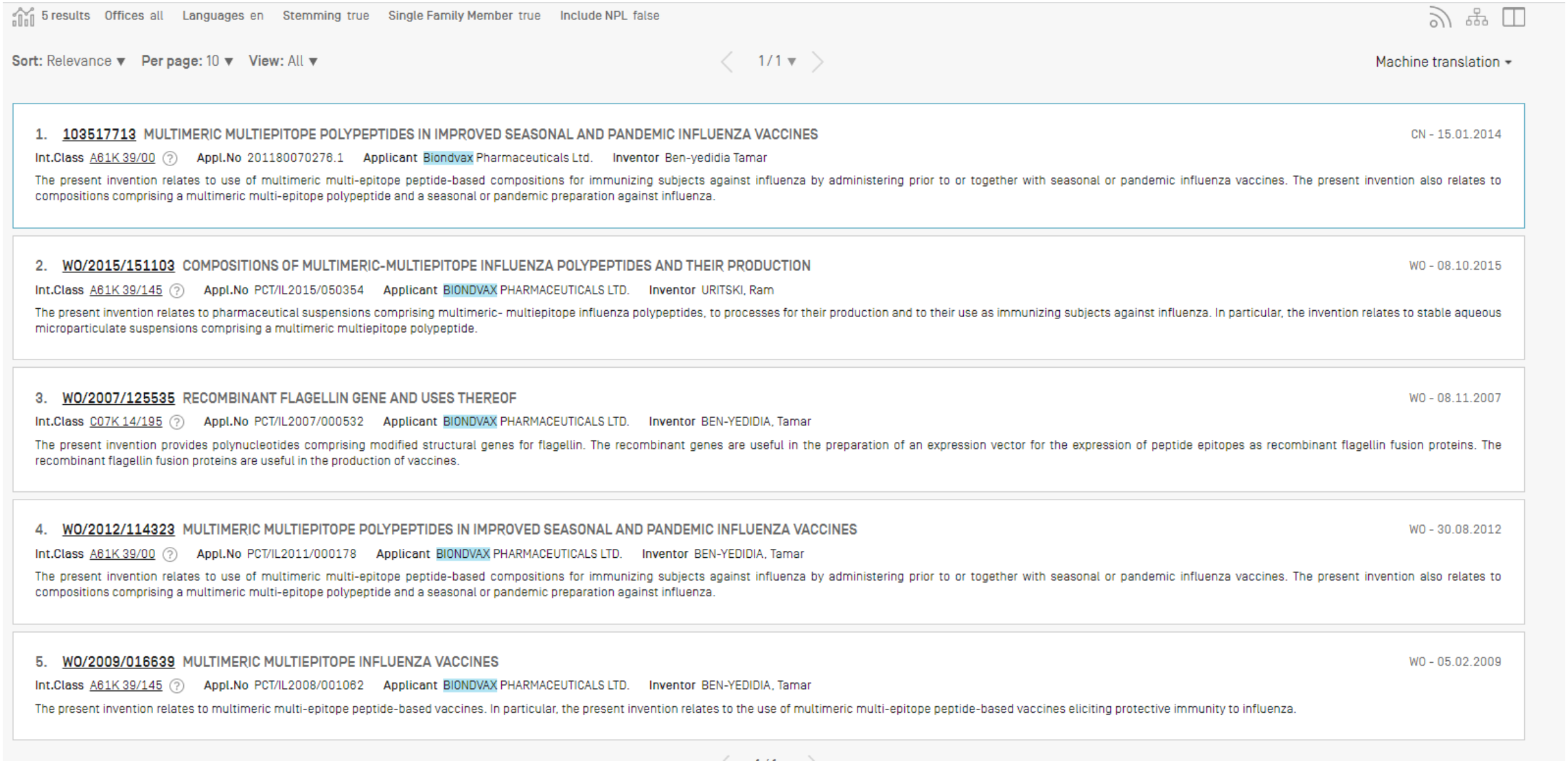
BiondVax – Case study

4 PatSnap families (44 total) | Custom Analysis | Landscape | Insights | Export | Set Email Alerts | Save

Change view | Set field display | Copy Query | Save Query | Application Date

	Publication Number	Title	Legal Status & Events	Standardized Current Assignee	Application Domain	Application Date
1	WO2007125535A1	Recombinant flagellin gene and uses thereof	Non-Entry PCT-NP	BIONDVAX PHARMA BEN YEDIDIA TAMAR ADAR YAAKOV	SsRNA viruses negative-sense Viral antigen ingredients Bacteria peptides +1	01 May 2007
2	BRPI0815008B8	MULTIMERIC vaccines with MULTIPLE EPITOPES AGAINST INFLUENZA	Granted	BIONDVAX PHARMA	SsRNA viruses negative-sense Viral antigen ingredients Virus peptides +4	03 Aug 2008
3	CA2828068C	Multimeric multiepitope polypeptides in improved seasonal and pandemic influenza vaccines	Granted	BIONDVAX PHARMA	SsRNA viruses negative-sense Viral antigen ingredients Virus peptides +3	22 Feb 2011
4	CA2944768C	Compositions of multimeric-multiepitope influenza polypeptides and their production	Granted	BIONDVAX PHARMA	SsRNA viruses negative-sense Viral antigen ingredients Virus peptides +4	01 Apr 2015

BiondVax – Case study



BiondVax – Case study

Publication Number	Title	Application Date	Publication Date	Issue Date	Current Assignee
AU2008281384B2	Multimeric multiepitope influenza vaccines	2008-08-03	2012-02-16	2012-08-09	BIONDVAX PHARMACEUTICALS LTD.
AU2008281384C1	Multimeric multiepitope influenza vaccines	2008-08-03	2012-08-16	2012-08-09	BIONDVAX PHARMACEUTICALS LTD.
AU2008281384A1	Multimeric multiepitope influenza vaccines	2008-08-03	2010-02-25	-	BIONDVAX PHARMACEUTICALS LTD.
BRPI0815008A2	VACINAS MULTIMÉRICAS COM MÚLTIPLOS EPÍTOPOS CONTRA INFLUENZA	2008-08-03	2015-04-28	-	BIONDVAX PHARMACEUTICALS LTD.
BRPI0815008B1	VACINAS MULTIMÉRICAS COM MÚLTIPLOS EPÍTOPOS CONTRA INFLUENZA	2008-08-03	2019-11-19	2019-11-19	BIONDVAX PHARMACEUTICALS LTD.
BRPI0815008B8	VACINAS MULTIMÉRICAS COM MÚLTIPLOS EPÍTOPOS CONTRA INFLUENZA	2008-08-03	2021-05-25	2019-11-19	BIONDVAX PHARMACEUTICALS LTD.
CA2695399A1	Multimeric multiepitope influenza vaccines	2008-08-03	2009-02-05	-	BIONDVAX PHARMACEUTICALS LTD.
CA2695399C	Multimeric multiepitope influenza vaccines	2008-08-03	2017-10-17	2017-10-17	BIONDVAX PHARMACEUTICALS LTD.
CN101795709A	Multimeric multiepitope influenza vaccines	2008-08-03	2010-08-04	-	彼昂德瓦克斯医药有限公司
CN101795709B	Multimeric multiepitope influenza vaccines	2008-08-03	2013-07-17	2013-07-17	彼昂德瓦克斯医药有限公司
DE602008037345T2	MULTIMERE MULTIEPITOP-INFLUENZA-IMPFSTOFFE	2008-08-03	2015-03-25	2015-03-25	BIONDVAX PHARMACEUTICALS LTD.
DK2173376T3	Multimere multiepitop-influenzavacciner	2008-08-03	2015-06-29	2015-03-25	BIONDVAX PHARMACEUTICALS LTD.
EA201070219A1	ПОЛИМЕРНЫЕ МУЛЬТИЭПИТОПНЫЕ ВАКЦИНЫ ПРОТИВ ГРИППА	2008-08-03	2010-08-30	-	БАЙОНДВАКС ФАРМАСЬЮТИКАЛЗ ЛТД.
EA017887B1	Multimeric multiepitope influenza vaccines	2008-08-03	2014-07-30	2013-03-29	БАЙОНДВАКС ФАРМАСЬЮТИКАЛЗ ЛТД.
EP2173376B1	Multimeric multiepitope influenza vaccines	2008-08-03	2015-03-25	2015-03-25	BIONDVAX PHARMACEUTICALS LTD.
EP2173376A2	Multimeric multiepitope influenza vaccines	2008-08-03	2010-04-14	-	BIONDVAX PHARMACEUTICALS LTD.
ES2539818T3	Multimeric multiepitope influenza vaccines	2008-08-03	2015-07-06	2015-07-06	BIONDVAX PHARMACEUTICALS LTD.
HK1142809A	Multimeric multiepitope influenza vaccines	2010-09-28	2014-01-10	-	BIONDVAX PHARMACEUTICALS LTD.
HK1142809A1	Multimeric multiepitope influenza vaccines	2010-09-28	2014-01-10	2014-01-10	BIONDVAX PHARMACEUTICALS LTD.
HRP20150479T1	Multimeric multiepitope influenza vaccines	2015-05-04	2015-07-17	2015-07-17	BIONDVAX PHARMACEUTICALS LTD.
HUE025149T2	Multimeric multiepitope influenza vaccines	2008-08-03	2016-01-28	-	Biondvax Pharmaceuticals Ltd.
IL203508A	Multimeric multiepitope influenza vaccines	2008-08-03	2016-01-31	-	BIONDVAX PHARMACEUTICALS LTD.
IN670DELNP2010A	Multimeric multiepitope influenza vaccines	2010-01-29	2011-10-14	-	BIONDVAX PHARMACEUTICALS LTD
IN290866B	A synthetic or recombinant influenza multi-epitope polypeptide	2010-01-29	2017-12-20	2017-12-20	BIONDVAX PHARMACEUTICALS LTD
JP2010535026A	多量体マルチエピトープインフルエンザワクチン	2008-08-03	2010-11-18	-	ビオンドヴァックス ファーマシューティカルズ リミテッド
JP5654345B2	多量体マルチエピトープインフルエンザワクチン	2008-08-03	2015-01-14	2014-11-28	ビオンドヴァックス ファーマシューティカルズ リミテッド
JP2010535026A5	多量体マルチエピトープインフルエンザワクチン	2008-08-03	2011-09-15	-	ビオンドヴァックス ファーマシューティカルズ リミテッド
KR1020100045473A	Multimeric multiepitope influenza vaccines	2008-08-03	2010-05-03	-	BIONDVAX PHARMACEUTICALS, LTD.
KR101580660B1	Multimeric multiepitope influenza vaccines	2008-08-03	2015-12-28	2015-12-21	BIONDVAX PHARMACEUTICALS, LTD.
MX2010001284A	Multimeric multiepitope influenza vaccines.	2010-02-02	2010-08-31	-	BIONDVAX PHARMACEUTICALS LTD
MX302245B	VACUNAS CONTRA LA INFLUENZA CON MULTIEPITOPE MULTIMERICO.	2010-02-02	2012-09-19	2012-08-10	BIONDVAX PHARMACEUTICALS LTD
WO2009016639A2	Multimeric multiepitope influenza vaccines	2008-08-03	2009-02-05	-	BIONDVAX PHARMACEUTICALS LTD. |
WO2009016639A3	Multimeric multiepitope influenza vaccines	2008-08-03	2009-02-05	-	BIONDVAX PHARMACEUTICALS LTD. |
PL2173376T3	Multimeric multiepitope influenza vaccines	2008-08-03	2015-08-31	2015-08-31	Biondvax Pharmaceuticals Ltd.
PT2173376E	Multimeric multiepitope influenza vaccines	2008-08-03	2015-07-30	2015-07-30	BIONDVAX PHARMACEUTICALS LTD.
US20110182974A1	Multimeric multiepitope influenza vaccines	2008-08-03	2011-07-28	-	BIONDVAX PHARMACEUTICALS LTD.
US8747861B2	Multimeric multiepitope influenza vaccines	2008-08-03	2014-06-10	2014-06-10	BIONDVAX PHARMACEUTICALS LTD.
US20140286982A1	Multimeric multiepitope influenza vaccines	2014-04-28	2014-09-25	-	BIONDVAX PHARMACEUTICALS LTD.
US9353159B2	Multimeric multiepitope influenza vaccines	2014-04-28	2016-05-31	2016-05-31	BIONDVAX PHARMACEUTICALS LTD.

BiondVax – Case study

1. WO2009016639 - MULTIMERIC MULTIEPITOPE INFLUENZA VACCINES

PCT Biblio. Data | Description | Claims | Drawings | National Phase | Patent Family | Notices | Documents

PermaLink

International Application Status

Date	Title	View	Download
04.05.2023	International Application Status Report	HTML PDF XML	PDF XML

Published International Application

Date	Title	View	Download
30.04.2009	Later publication of international search report [A3 18/2009]	PDF 4 p.	PDF 4 p. ZIP XML + TIFFs
05.02.2009	Sequence Listing	PDF 27 p.	PDF 27 p. ZIP XML + TIFFs
05.02.2009	Initial Publication without ISR [A2 06/2009]	PDF 59 p.	PDF 59 p. ZIP XML + TIFFs

Search and Examination-Related Documents

Date	Title	View	Download
02.02.2010	[IB/373] International Preliminary Report on Patentability Chapter I	PDF 8 p.	PDF 8 p. ZIP XML + TIFFs
02.02.2010	[ISA/237] Written Opinion of the International Searching Authority	PDF 5 p.	PDF 5 p. ZIP XML + TIFFs

BiondVax – Case study

Applicant
BIONDVAX PHARMACEUTICALS LTD.

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

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

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

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

☒	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
☒	Box No. V	Reasoned statement under Article 35(2) 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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2008/001062

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

1. Statement

Novelty (N)	Yes:	Claims	1-38
	No:	Claims	
Inventive step (IS)	Yes:	Claims	9-17, 21, 22
	No:	Claims	1-8, 18-20, 23-38
Industrial applicability (IA)	Yes:	Claims	1-38
	No:	Claims	

BiondVax – Case study

Reference is made to the following documents:

D1 : WO 2006/128294 A (VARIATION BIOTECHNOLOGIES INC [CA]; TORRES JOSE VIDAL [US]) 7 December 2006 (2006-12-07)

D2 : CARO-AGUILAR ET AL: "Chimeric epitopes delivered by polymeric synthetic linear peptides induce protective immunity to malaria" MICROBES AND INFECTION, ELSEVIER, PARIS, FR, vol. 7, no. 13, 1 October 2005 (2005-10-01), pages 1324-1337, XP005158100 ISSN: 1286-4579

Article 33(3) PCT

The subject matter of claims 1-8, 18-20, 23-38 are not considered inventive (Article 33(3) PCT).

The subject matter of claims 9-17, 21 and 22 are considered to be inventive (Article 33(3) PCT)

The subject matter of claims 1-5, 18-20, 23-38 cannot be considered to be inventive (Article 33(3) PCT) as they refer to vaccines and epitopes for inclusion without defining structurally the epitopes of interest. As a result, the claims not only lack essential technical features (Article 6 PCT), but they also do not solve a technical problem and are thus not inventive (Article 33(3) PCT.

The closest prior art to claim 6 is D1 which discloses formulations comprising mixtures of influenza epitopes (from strains A and B) which can be used in the vaccination of humans and animals susceptible to influenza infection (see passages cited in search report).

The subject matter of claim 1 differs from the above disclosure in that it is directed towards a multiepitope polypeptide containing multiple copies of a plurality of influenza virus peptide epitopes.

There does not appear to be any difference arising from the difference.

BiondVax – Case study

EXAMPLES

Materials and methods

Multimeric multiepitope polypeptides: examples of multimeric multiepitope polypeptides comprising several repeats of the influenza virus peptide epitopes E1 to E9 listed in Table 1 are presented. The polypeptides include amino acids and short peptides

Vaccines: vaccines prepared from the multimeric multiepitope polypeptides presented in examples 1- 3 were used for immunization studies of various mouse strains.

Immunization studies: three strains of mice: an outbred strain (ICR), an inbred strain (BALB/c), and a strain transgenic for human HLA A*0201 molecules (HLA A*0201), were used for immunization studies as well as rabbits in some experiments.

Example 1: Multimeric polypeptide with five repeats of a unit containing nine different epitopes arranged in alternating sequential structure.

This is an example of a multimeric polypeptide comprising five repeats of nine influenza peptide epitopes arranged in the alternating sequential polymeric structure $[E1E2E3E4E5E6E7E8E9]_5$. The estimated molecular weight is 80 kD.

Example 2: Multimeric polypeptide with three repeats of each of nine different epitopes arranged in block copolymer structure.

In this example the DNA sequence of a polynucleotide construct used to prepare a multimeric peptide comprising three repeats of nine influenza peptide epitopes arranged in the block copolymer structure $[E1]_3$-$[E2]_3$-$[E3]_3$-$[E4]_3$-$[E5]_3$-$[E6]_3$-$[E7]_3$-$[E8]_3$-$[E9]_3$ is shown in Figure 2A and the corresponding amino acid sequence is shown in Figure 2B. The estimated molecular weight is 48 kD.

Example 3: Multimeric polypeptide with three repeats of a unit containing nine epitopes arranged in alternating sequential structure.

This is an example of a multimeric polypeptide comprising three repeats of nine influenza peptide epitopes arranged in the alternating sequential polymeric structure $[E1E2E3E4E5E6E7E8E9]_3$. The estimated molecular weight is 48 kD.

BiondVax – Case study

Example 4: Cellular immune response.

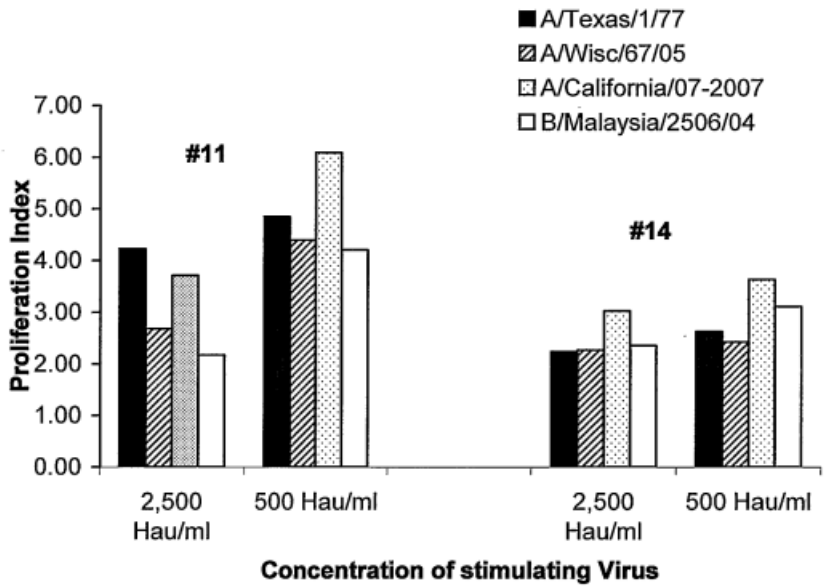
The cellular immune responses to two different concentrations of a stimulating influenza virus of the strains A/Texas/1/77, A/WisxWisc/67/05, A/California/07-2007, and B/Malaysia/2506/04, of were evaluated. Transgenic mice (transgenesys for HLA A*0201) mice were vaccinated once with two multimeric vaccines: #11 and #14, emulsified within IFA (Incomplete Freund's adjuvant). 7-10 days after the immunization, their spleen and

Example 5: Recognition of immunizing antigen and of viruses by immune serum

ICR mice were immunized with the multimeric multiepitope polypeptide comprising five repeats of nine epitopes arranged in the alternating sequential polymeric structure $[E1E2E3E4E5E6E7E8E9]_5$ (Multimeric #11), or with the multimeric

Example 6. Protection against a highly lethal challenge with H3N2 A/Texas/1/77

Groups of eight transgenic mice were immunized three times, at 3-week intervals, intramuscularly with the Multimeric-#14 vaccine or with PBS. A challenge infection with a highly lethal dose (300 LD_{50}) of H3N2 A/Texas/1/77 was given three weeks after the last boost. Mice were sacrificed five days post infection. A significant reduction of virus titer in mice lungs was observed, as described in Figure 5, despite of the large amount of virus used for infection.



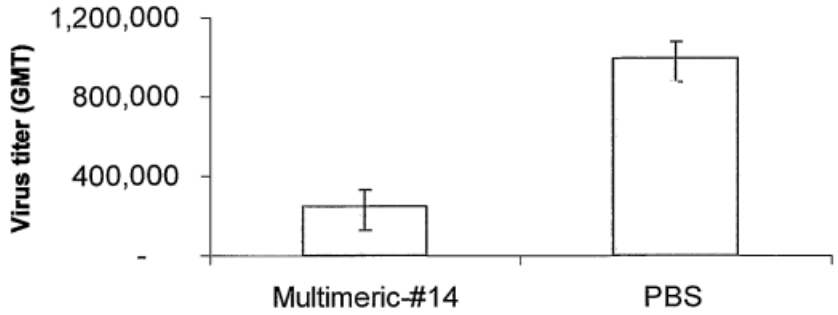


FIG. 5

BiondVax – Case study

Example 7: In vivo efficacy studies

Two vaccine versions have been evaluated in vivo: the multimeric polypeptide suspended in 50% Glycerol in PBS or in Incomplete Freund's adjuvant.

Example 8:

The efficacy of the vaccine was demonstrated in two preliminary studies using ICR and transgenic (HLA A*0201) mice. The mice were vaccinated intramuscularly three times with 3 weeks interval with a dose of 150 mcg/mouse of vaccines #11, #12 and #14 with and without adjuvant (IFA). Three to four weeks after the last immunization, the mice were infected with a 300 LD50 of a mouse adapted influenza virus H3N2 strain (A/Texas/1/77). Five days post infection, the survival rate was monitored. Treated and control groups immunized with 50% glycerol in PBS with and without IFA were compared.

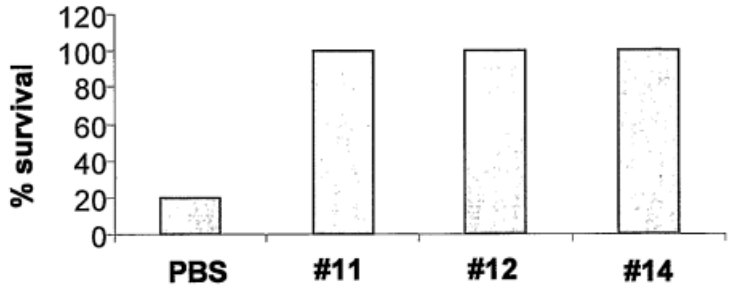


FIG. 6A

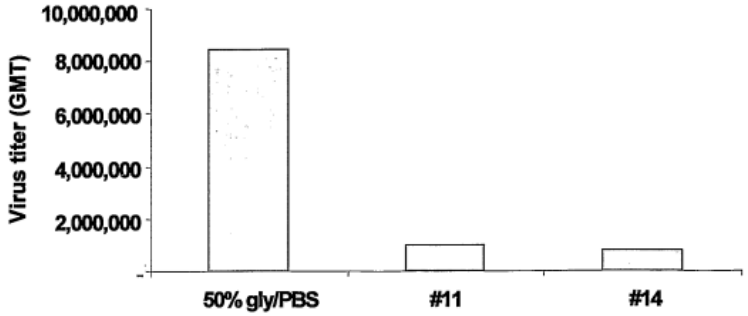


FIG. 6B

BiondVax – Case study

Example 9: Repeated dose toxicology

Repeated dose toxicology trials are performed with vaccine #14 (Multimeric vaccine in three block repeats suspended in 50% Glycerol in PBS or in Incomplete Freund's adjuvant, according a protocol based on: http://www3.niaid.nih.gov/daids/vaccine/Science/VRTT/06_SafetyTest.htm.

Example 10: Phase I/IIa clinical trial

The primary objective of this clinical study is to examine safety of the preventive anti-influenza vaccine after a single or double intramuscular administration. The study is conducted under controlled clinical settings among healthy volunteers aged from 18 years old to 49 years old. The secondary objective is to estimate the immunogenicity induced by administration of the multimeric vaccine. This phase I/II study assesses the most common acute adverse effects and examines the size of doses that patients can take safely without a high incidence of side effects.

Example 12. Peptide synthesis

Peptides and multimeric peptides were synthesized using typical solid phase peptide synthesis with the following materials: Protected amino acids, 9-fluorenylmethyloxycarbonyl- N-hydroxysuccinimide (Fmoc-OSu), bromo-tris-pyrrolidone-

43

Example 11: Anti viral response in mice sera immunized with commercial influenza vaccine followed by immunization with Multimeric vaccine

Transgenic mice for HLA A*0201 were immunized with the commercial inactivated influenza vaccine (split virion) BP Vaxigrip® three times, on days 0, 60, 81, or with Vaxigrip® once, on day 0, and 2 additional immunizations (on days 60 and 81) with the Multimeric vaccines #11, #12 and #14. Blood collection was performed before immunization (pre immune) and after the last immunization. Antibodies to several

Table 5A. H3N2

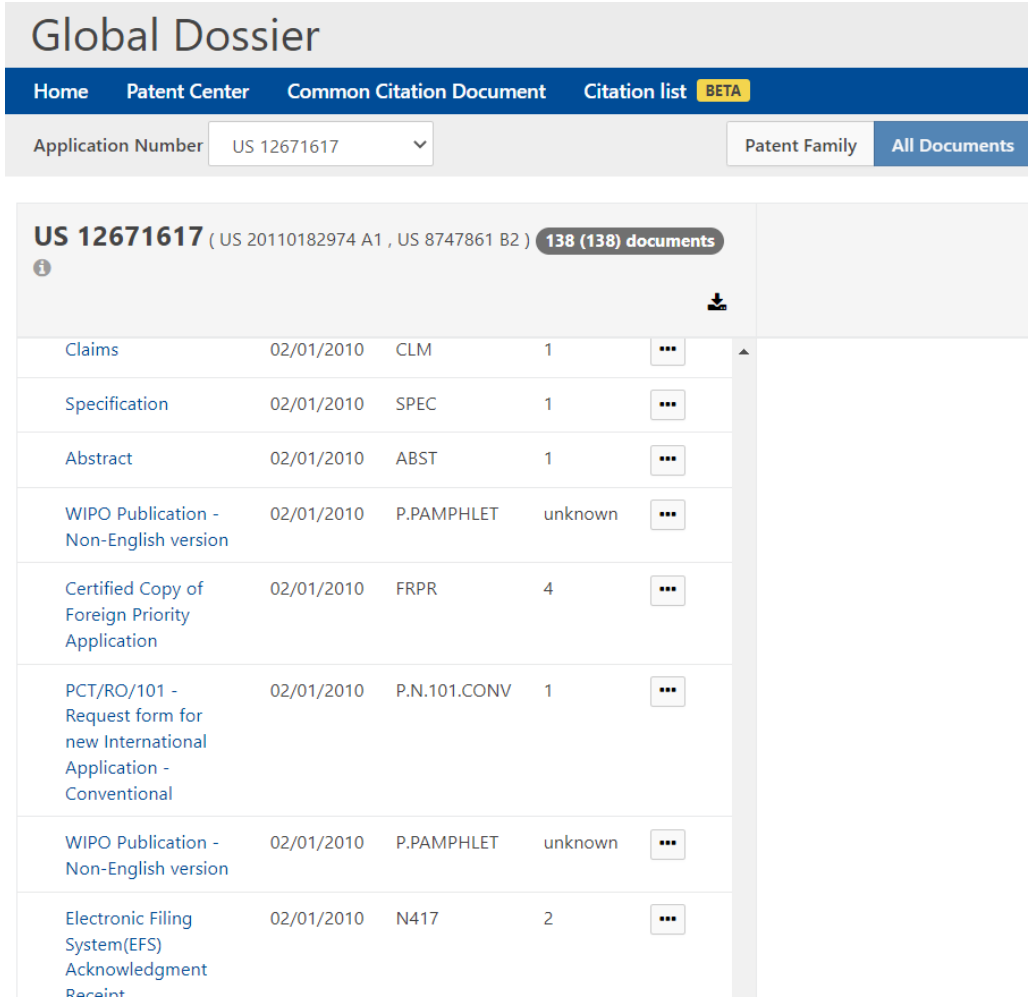
		WISC		Texas		Califor		Fujian		Moscow		Panama	
Treatment	immune	t	f	t	f	t	f	t	f	t	f	t	f
1xVaxigrip + 2x Multi #11	0	200		200		800		400		400		400	
	1	400	2	400	2	800	1	800	2	800	2	800	2
	2+	800	4	400	2	3200	4	800	2	800	2	1600	4
1xVaxigrip + 2x Multi #12	0	400		200		400		400		800		800	
	1	800	2	400	2	1600	4	400	1	800	1	800	1
	2+	800	2	400	2	3200	8	1600	4	1600	2	3200	4
1xVaxigrip + 2x Multi #14	0	200		200		800		400		400		800	
	1	800	4	400	2	1600	2	800	2	1600	4	3200	4
	2+	1600	8	1600	8	3200	4	1600	4	3200	8	6400	8
PBS	1	200		100		200		200		200		200	
	2+	200	1	100	1	200	1	200	1	200	1	400	2

t=titer, f=fold

BiondVax – Case study

Timeline

In Feb 2020 – submitted new claims for consideration
30/03/2011 – extra documents required for small entity status
28/12/2012 – Restriction requirement (Single inventive concept)
07/01/2013 – Election of group I – amendment of claims
11/04/2013 – Non final rejection
07/06/2013 – Further amendments of claims
26/09/2013 – Final rejection
30/09/2013 – Response and further amendments of claims (+further other amendments and arguments in October, and December)
03/02/2014 – Notice of allowance)



BiondVax – Case study

1. A synthetic or recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes arranged in a configuration selected from an alternating sequential polymeric structure $(X_1X_2X_3\ldots Xm)_n$ and a block copolymer structure $(X_1)_n(X_2)_n(X_3)_n\ldots(X_m)_n$.

39. (Currently Amended) A synthetic or recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes wherein the polypeptide is selected from the group consisting of:

i. $[[B]](X_1ZX_2Z\ldots X_m)_n[[B]]$; and

ii. $[[B]](X_1)_nZ(X_2)_nZ\ldots(X_m)_n[[B]]$;

wherein ~~B is an optional sequence of 1-4 amino acid residues;~~ n is at each occurrence independently an integer of 3-6~~2-50~~; m is an integer of 4-9~~3-50~~; each of X_1, $X_2\ldots X_m$ is an influenza peptide epitope selected from the group consisting of: HA 354-372 (E1, SEQ ID NO: 82), HA 91-108 (E2, SEQ ID NO: 48), M1 2-12 (E3, SEQ ID NO: 25), HA 150-159 (E4, SEQ ID NO: 52), HA 143-149 (E5, SEQ ID NO: 51), NP 206-229 (E6, SEQ ID NO: 64), HA 307-319 (E7, SEQ ID NO: 59), NP 335-350 (E8, SEQ ID NO: 69), and NP 380-393 (E9, SEQ ID NO: 70)~~consisting of 4-24 amino acid residues~~; Z at each occurrence is a bond or a spacer of a single amino acid or a short peptide~~1-4 amino acid residues; and wherein the maximal number of amino acid residues in the polypeptide is about 1000~~.

39. A synthetic or recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes wherein the polypeptide is selected from the group consisting of:

i. $B(X_1ZX_2Z\ldots X_m)_nB$; and

ii. $B(X_1)_nZ(X_2)_nZ\ldots(X_m)_nB$

wherein B is an optional sequence of 1-4 amino acid residues; n is at each occurrence independently an integer of 2-50; m is an integer of 3-50; each of $X_1, X_2\ldots X_m$ is an influenza peptide epitope consisting of 4-24 amino acid residues; Z at each occurrence is a bond or a spacer of 1-4 amino acid residues; and wherein the maximal number of amino acid residues in the polypeptide is about 1000.

BiondVax – Case study

39. (Currently Amended) A synthetic or recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes wherein the polypeptide is selected from the group consisting of:

i. $(X_1ZX_2Z \ldots X_m)_n$; and

ii. $(X_1)_nZ(X_2)_nZ\ldots(X_m)_n$;

wherein n is at each occurrence independently an integer of 3-6; m is ~~an integer of 4-~~9; ~~each of~~ X_1, $X_2\ldots X_m$ ~~is an~~ are influenza peptide epitopes ~~selected from the group~~ consisting of HA 354-372 (E1, SEQ ID NO: 82), HA 91-108 (E2, SEQ ID NO: 48), M1 2-12 (E3, SEQ ID NO: 25), HA 150-159 (E4, SEQ ID NO: 52), HA 143-149 (E5, SEQ ID NO: 51), NP 206-229 (E6, SEQ ID NO: 64), HA 307-319 (E7, SEQ ID NO: 59), NP 335-350 (E8, SEQ ID NO: 69), and NP 380-393 (E9, SEQ ID NO: 70); Z at each occurrence is a bond or a spacer of ~~a single amino acid or a short peptide~~ 1 to 4 neutral amino acid residues.

39. (Currently Amended) A synthetic or a recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes wherein the polypeptide is selected from the group consisting of:

i. $(X_1ZX_2Z \ldots X_m)_n$; and

ii. $(X_1)_nZ(X_2)_nZ\ldots(X_m)_n$;

wherein n is at each occurrence independently an integer of 3-6; m is 9; X_1, $X_2\ldots X_m$ are influenza peptide epitopes consisting of HA 354-372 (E1, SEQ ID NO: 82), HA 91-108 (E2, SEQ ID NO: 48), M1 2-12 (E3, SEQ ID NO: 25), HA 150-159 (E4, SEQ ID NO: 52), HA 143-149 (E5, SEQ ID NO: 51), NP 206-229 (E6, SEQ ID NO: 64), HA 307-319 (E7, SEQ ID NO: 59), NP 335-350 (E8, SEQ ID NO: 69), and NP 380-393 (E9, SEQ ID NO: 70); Z at each occurrence is a bond or a spacer of 1 to 4 neutral amino acid residues.

BiondVax – Case study

PCT Rule 26 bis3

(i) occurred in spite of due care required by the circumstances having been taken; or

(ii) was unintentional.

BiondVax – Case study

Office	Entry Date	National Number	National Status
China	03.08.2008	200880101581.0	
European Patent Office	25.01.2010	2008789738	Published 14.04.2010 Granted 25.03.2015
Israel	25.01.2010	208508	
Japan	27.01.2010	2010518815	
India	29.01.2010	870/DELNP/2010	
Australia	02.02.2010	2008281384	Published 25.02.2010
Canada	02.02.2010	2695399	
Mexico	02.02.2010	MX/a/2010/001284	Published 10.09.2010 Granted 10.08.2012
Republic of Korea	18.02.2010	1020107003351	Published 03.05.2010 Granted 02.11.2015
Eurasian Patent Organization	01.03.2010	201070219	Published 30.08.2010 Granted 29.03.2013
United States of America	01.04.2011	12871817	Published 28.07.2011 Granted 10.08.2014
Republic of Korea	25.09.2015	1020157026782	Refused 18.12.2015

Diagnostics - Mobidiag

Patenting diagnostics

USA – Mayo vs Prometheus 2012 – correlation of metabolites in the blood with drug dosage – law of nature (not patentable)

Investment in diagnostics fell by $9.3bn – 2012-2016

Strategies

- Measuring new biomarker without diagnostic step
- Isolating a new biomarker from a sample
- Method of treatment linked to a diagnostic test

Patenting diagnostics

Europe – diagnostic methods can be patented so long as the method is “not practiced on a human or animal body”

Just obtaining information (data) from a living human or animal body (e.g., X-ray investigations, MRI studies, etc.) - not excluded from patentability

Similar for Japan

Strategies

- Measuring a certain marker in a body sample
- Improved method of measuring/isolating a biomarker from a sample
- Kit or device for the diagnostic

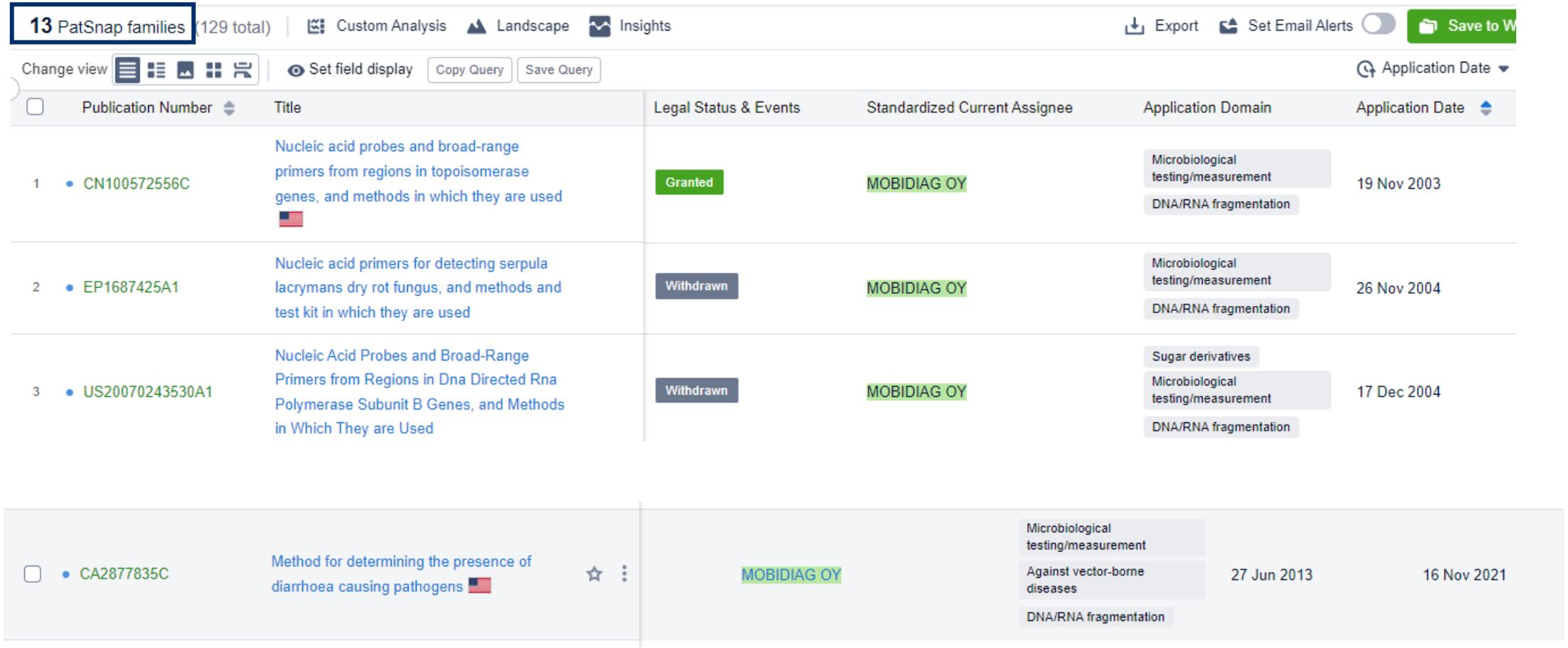
Mobidiag – case study

Founded in 2000 – Finland; Acquired by Hologic in 2021 for €668m

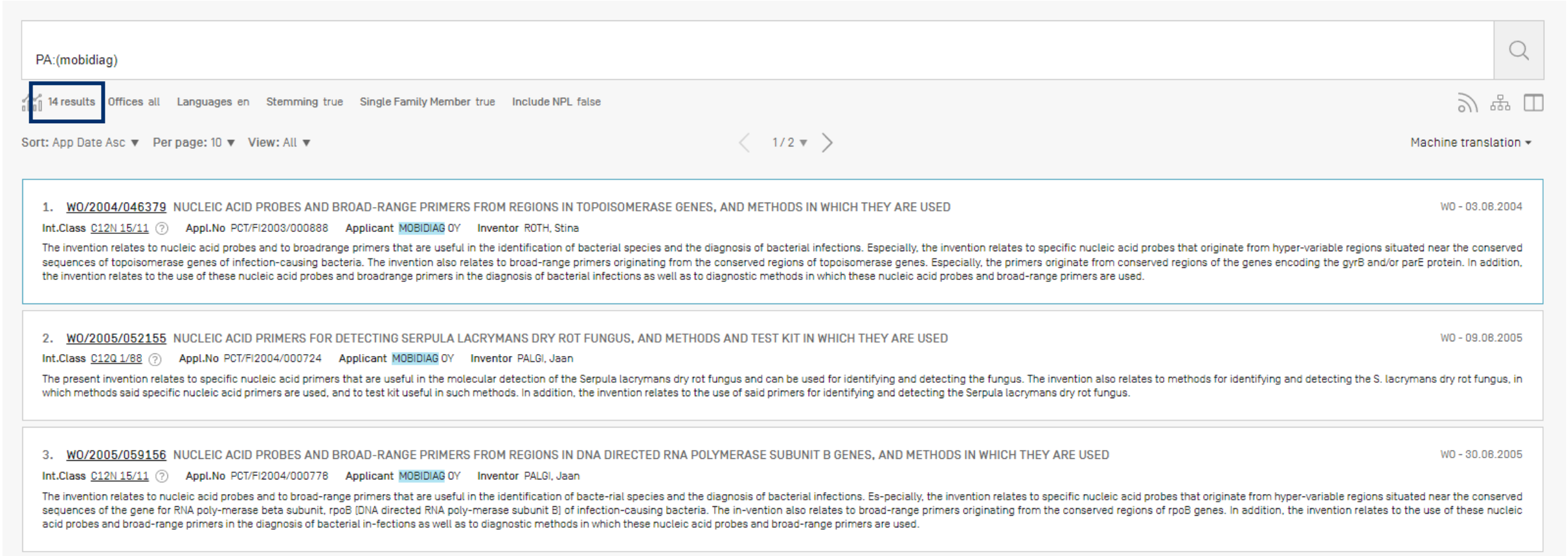
Innovative molecular diagnostic solutions for gastrointestinal infection, antimicrobial resistance management, healthcare associated infections (HAIs), respiratory infections and sepsis

“differentiated platform”; “differentiated, highly competitive solution”

Mobidiag – case study



Mobidiag – case study



Mobidiag – case study

Publication Number	Title	Application Date	Publication Date	Issue Date	Inventor Name	Current Assignee
AU2013283152A1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2015-02-12	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
AU2013283152B2	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2019-04-18	2019-07-30	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
CA2877835A1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2014-01-03	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
CA2877835C	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2021-11-16	2021-11-16	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
CN104662167A	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2015-05-27	-	J.安蒂凯南 | J.柯维斯卡里	莫比蒂亚戈公司
CN104662167B	确定致腹泻病原体的存在的方法	2013-06-27	2020-06-16	2020-06-16	J.安蒂凯南 | J.柯维斯卡里	莫比蒂亚戈公司
DE602013048521T2	VERFAHREN ZUR BESTIMMUNG DES VORHANDENSEINS VON DIARRHÖE-ERZEUGENDEN KRANKHEITSERREGERN	2013-06-27	2018-12-19	2018-12-19	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
DK2867372T3	FREMGANGSMÅDE TIL AT BESTEMME TILSTEDEVÆRELSEN AF DIARRÉFREMKALDENDE PATOGENER	2013-06-27	2019-04-08	2018-12-19	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
EP2867372A1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2015-05-06	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
EP2867372A4	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2016-04-13	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
EP2867372B1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2018-12-19	2018-12-19	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
ES2716575T3	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2019-06-13	2019-06-13	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
JP2015522271A	下痢性病原体の存在を検出するための方法	2013-06-27	2015-08-06	-	アンティカイネン,ヤェンニ | キルヴェスカリ,ユハ	モビディアグ オイ
JP6498115B2	下痢性病原体の存在を検出するための方法	2013-06-27	2019-04-10	2019-03-22	アンティカイネン,ヤェンニ | キルヴェスカリ,ユハ	モビディアグ オイ
JP2015522271A5	下痢性病原体の存在を検出するための方法	2013-06-27	2016-08-12	-	アンティカイネン,ヤェンニ | キルヴェスカリ,ユハ	モビディアグ オイ
NO2867372B1	METHOD FOR DETERMINING THE PRESENCE OF DIARRHOEA CAUSING PATHOGENS	2013-06-27	2015-05-06	2019-05-20	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
WO2014001648A1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2014-01-03	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
PL2867372T3	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2019-06-28	2019-06-28	ANTIKAINEN JENNI | KIRVESKARI JUHA	Mobidiag Oy
TR201903763T4	Diyareye sebep olan patojenlerin mevcudiyetinin belirlenmesine yönelikyöntem.	2013-06-27	2019-04-22	2019-04-22	JENNI ANTIKAINEN | JUHA KIRVESKARI	MOBIDIAG OY
US20150299774A1	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2015-10-22	-	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY
US10724106B2	Method for determining the presence of diarrhoea causing pathogens	2013-06-27	2020-07-28	2020-07-28	ANTIKAINEN, JENNI | KIRVESKARI, JUHA	MOBIDIAG OY

Mobidiag – case study

1. WO2009016639 - MULTIMERIC MULTIEPITOPE INFLUENZA VACCINES

PCT Biblio. Data | Description | Claims | Drawings | National Phase | Patent Family | Notices | Documents

PermaLink

International Application Status			
Date	Title	View	Download
05.05.2023	International Application Status Report	HTML PDF XML	PDF XML

Published International Application			
Date	Title	View	Download
30.04.2009	Later publication of international search report [A3 18/2009]	PDF 4 p.	PDF 4 p. ZIP XML + TIFFs
05.02.2009	Sequence Listing	PDF 27 p.	PDF 27 p. ZIP XML + TIFFs
05.02.2009	Initial Publication without ISR [A2 08/2009]	PDF 59 p.	PDF 59 p. ZIP XML + TIFFs

Search and Examination-Related Documents			
Date	Title	View	Download
02.02.2010	[IB/373] International Preliminary Report on Patentability Chapter I	PDF 8 p.	PDF 8 p. ZIP XML + TIFFs
02.02.2010	[ISA/237] Written Opinion of the International Searching Authority	PDF 5 p.	PDF 5 p. ZIP XML + TIFFs

Mobidiag – case study

Iso Roobertinkatu 4-6 A
FI-00120 Helsinki
Finland

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	25-11-2013
Applicant's or agent's file reference 51991	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/FI2013/050716	27-06-2013	27-06-2012

International Patent Classification (IPC) or both national classification and IPC
See Supplemental Box

Applicant
MOBIDIAG OY

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 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

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant data (Rules 43*bis*.1 and 64.1) is the claimed priority date.

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest and, where applicable, the protest fee.
   - ☐ paid additional fees under protest but the applicable protest fee was not paid.
   - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
   - ☐ complied with.
   - ☒ not complied with for the following reasons:

The following separate inventions were identified:

1: Claims 1-16, 17-18 (partly), 19, 20-28 (partly) and 29 directed to a method for determining the presence of diarrhoea causing pathogens in a biological sample comprising a multiplex PCR assay comprising two or more separate PCR reactions, involving primer pairs amplifying each of the enterotoxigenic E. coli (ETEC) amplicons as defined by SEQ ID NOS: 61-63 at least partly. The invention is further directed to use/nucleotide primer/nucleotide primer pair/nucleotide probe/kit/method related to SEQ ID NOS: 13-18 and 43-45.

2: Claims 17-18 (partly), 20-26 (partly) and 28 (partly) directed to use/nucleotide primer/nucleotide primer pair/nucleotide probe/kit/method related to SEQ ID NOS: 1-4 and 37-38, which are useful in the detection of EHEC amplicons defined by SEQ ID NOS: 55 and 56.

Mobidiag – case study

The present application has been considered to contain 12 inventions which are not linked such that they form a single general inventive concept, as required by Rule 13 PCT for the following reasons:

The single general concept of the present application is the teaching that a multiplex PCR assay comprising two or more separate PCR reactions can be used for determining the presence of diarrhoea causing pathogens in a biological sample.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/FI2013/050716

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-19, 21, 25-26 and 28-29	YES
	Claims	20, 22-24 and 27	NO
Inventive step (IS)	Claims	1-19, 21 and 28-29	YES
	Claims	20 and 22-27	NO
Industrial applicability (IA)	Claims	1-29	YES
	Claims		NO

2. Citations and explanations

Interpretation of the claims having an effect on the examination:
Claim 23 is examined as if it refers to claims 20-21 instead of claims 17-19 (see also Box VIII).

The invention claimed in claims 1-16, 17-18 (partly), 19, 20-28 (partly) and 29
The claimed invention relates to a method for determining the presence of diarrhoea causing pathogens in a biological sample comprising a multiplex PCR assay involving primer pairs amplifying each of the enterotoxigenic E. coli (ETEC) amplicons as defined in SEQ ID NOS: 61-63 at least partly. Furthermore, the claimed invention relates to use/nucleotide primer/nucleotide primer pair/nucleotide probe/kit/method involving primer sequences SEQ ID NOS: 13-18 and probe sequences SEQ ID NOS: 43-45.

Reference is made to the following documents:
D1: West D.M et al., "Rapid detection of Escherichia coli virulence factor genes using multiplex real-time TaqMan PCR assays", Veterinary Microbiology, 2007, 122, pages 323-331
D2: Zhang H. et al., "Taqman triplex real-time PCR assay for rapid detection of diarrheagenic Escherichia coli in raw milk", Journal of Northeast Agricultural University, 2010, Vol. 41, pages 108-115
D3: Fujioka M. et al., "Direct detection of diarrheagenic Escherichia coli in patient stool specimens by developed Multiplex PCRs. For the establishment of surveillance system of diarrheagenic Escherichia coli", Igaku Kensa, 2008, Vol. 57, pages 1041-1046
D4: Fukushima H. et al., "Duplex real-time SYBR green PCR assays for detection of 17 species of food- or waterborne pathogens in stools", Journal of Clinical Microbiology, 2003, Vol. 41, pages 5134-5146

Summary
The subject matter of claims 20, 22-24 and 27 lacks novelty and an inventive step. The subject matter of claims 25-26 is novel, but is not considered to involve an inventive step. The subject matter of claims 1-19, 21 and 28-29 is novel and is considered to involve an inventive step. The subject matter of all the claims is industrially applicable.

Mobidiag – case study

EXAMPLE

Materials and methods

Patient samples. Control stool samples were cultured at HUSLAB for *Salmonella, Yersinia, Shigella, Campylobacter* and EHEC with standard biochemical methods. A total of 146 travellers were recruited in Travel Clinic (Medicity, Helsinki, Finland) to participate in this study during six month period. The age ranged from 1 to 72 (mean 39.2 years); 84 (57.5%) were females and 62 (42.5%) were males. The travel destinations were Europe in 7.5%, Asia in 32.9%, Africa in 44.5%, Australia in 1.4% and America in 13.7% of cases.

Total nucleic acids were purified from the stool samples with NucliSENS kit using easyMAG platform as described in Antikainen et al., 2009. Briefly, stool swabs were suspended to 100 µl of Tris-EDTA buffer and purified by the general method of easyMAG platform and eluted to the volume of 25 µl. Eluate (0.5 µl) was used as a template in PCR.

REFERENCES

Allos, B.M. (2001). Campylobacter jejuni Infections: update on emerging issues and trends. Clin. Infect. Dis. 32, 1201-1206.

Antikainen, J., Tarkka, E., Haukka, K., Siitonen, A., Vaara, M., and Kirveskari, J. (2009). New 16-plex PCR method for rapid detection of diarrhoeagenic Escherichia coli directly from stool samples. Eur. J. Clin. Microbiol. Infect. Dis. 28, 899-908.

Identification of the isolates. *Design of the Real-Time-PCR.*

Specificity of the PCR. *Analytical sensitivity of the PCR.* *Clinical sensitivity and specificity.*

Results

Validation of the Real-Time-PCR method. The Real-Time PCR assay was optimized and validated using the reference strains including 249 positive strains and 243 strains belonging to other major genera (Table 5). All positive control strains were correctly identified and no false positive amplification was obtained. Thus, the assay achieved 100% analytical specificity.

Discussion

This is the first systematic follow-up study analyzing all major pathogens associated with traveller's diarrhoea using the new molecular methods. The study design allowed the inventors to follow the consequences of travelling to the tropical countries case by case as a normal sample prior to the trip was available. The most important achievement of the study was that all the major pathogens within the patient group were able to be identified using straight-forward modern methods, which eliminates inherent biases in comparison to results from different studies. As expected in high hygiene countries, such as Finland, there

Mobidiag – case study

Table 5. A summary of known positive control strains and samples.

	PCR positive	Total
Pure control strains		
Positive control strains	246	246
Negative control strains	0	243
Total		489
Feacal control samples		
Positive		
Campylobacter	52	53
Salmonella	50	50
Yersinia	5	5
Shigella	6	6
EHEC	9	9
Negative	0	65

		Oligonucleotide pairs amplifying the target (strain/patient sample		
		ST variant 1	ST variant 2	Heat labile toxin (LT)
Strain name	Origin	est_005 (SEQ ID NOS:13 and 14)	estlab_004 (SEQ ID NOS:15 and 16)	elt_001 (SEQ ID NOS:17 and 18)
JA4	Reference strain THL	-	+	+
JA24	Reference strain THL	-	-	+
JA25	Reference strain THL	-	-	+
JA26	Reference strain THL	-	-	+
JA27	Reference strain THL	-	-	+
JA28	Reference strain THL	-	-	+
JA32	Reference strain THL	-	+	-
JA35	Control species, Germany	+	-	+
JA36	Control species, Germany	+	-	+
JA48	Patient sample	-	+	+
JA50	Patient sample	+	-	-
JA53	Patient sample	-	+	-
JA58	Patient sample	+	-	-
JA61	Patient sample	+	-	-
JA64	Patient sample	-	+	+
JA85	Patient sample	+	-	-
JA88	Patient sample	-	+	-
JA122	Patient sample	+	-	-
JA124	Patient sample	-	+	+
mixB	control DNA mixture	+	+	+

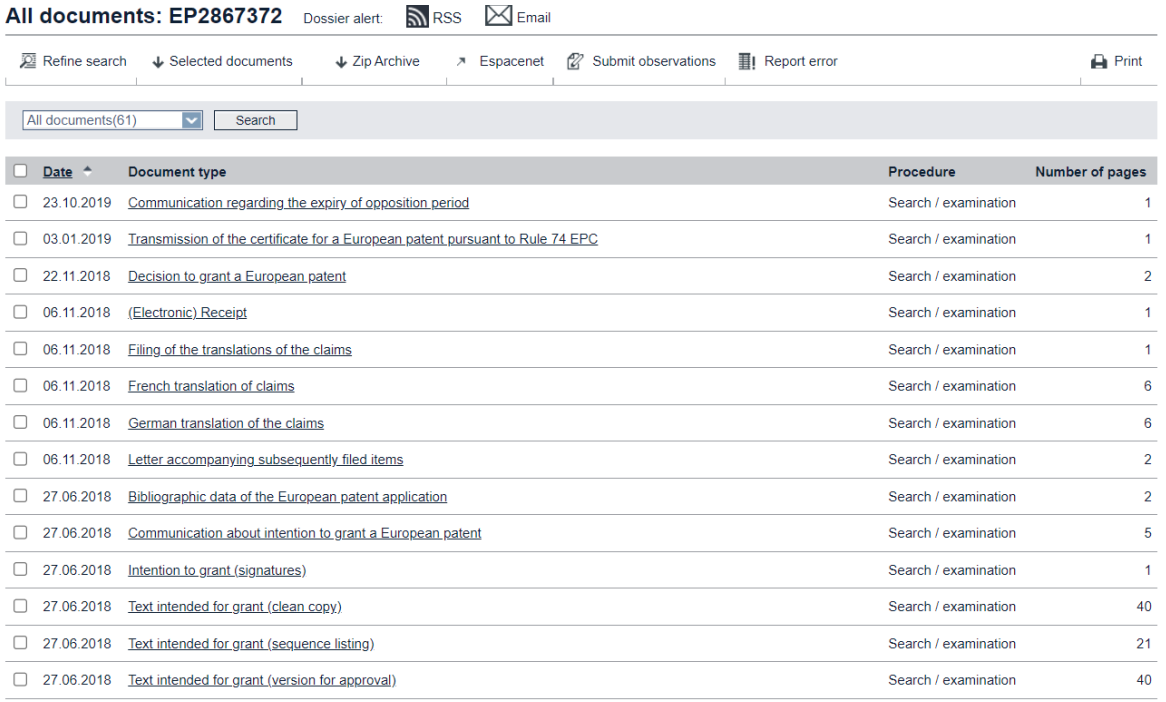
A Quantitative Polymerase Chain Reaction Assay for Rapid Detection of 9 Pathogens Directly From Stools of Travelers With Diarrhea - https://doi.org/10.1016/j.cgh.2013.03.037 (Published May 2013)

Bacterial, viral and parasitic pathogens analysed by qPCR: Findings from a prospective study of travellers' diarrhoea - https://doi.org/10.1016/j.tmaid.2020.101957 (Published April 2021)

Mobidiag – case study

Timeline

15/01/2015 – Entry European phase (SME reduction of fees)
06/03/2015 – First communication (R161/2 EPC)
16/09/2015 – First Amendment of Claims (compressed to 15 claims)
04/04/2016 – Further communication with extra search report
14/10/2016 – Further amendments of claims
03/01/2018 – Text intended for grant
11/05/2018 – Request for correction/amendment of text
27/06/2018 – Text intended for grant
06/11/2018 – Filing of translation of claims & grant fee
22/11/2018 – Decision to grant (19/12/2018)
23/10/2019 – Expiry of the opposition window (9 months)



All documents: EP2867372 Dossier alert: RSS Email

Refine search | Selected documents | Zip Archive | Espacenet | Submit observations | Report error | Print

All documents(61) Search

Date	Document type	Procedure	Number of pages
23.10.2019	Communication regarding the expiry of opposition period	Search / examination	1
03.01.2019	Transmission of the certificate for a European patent pursuant to Rule 74 EPC	Search / examination	1
22.11.2018	Decision to grant a European patent	Search / examination	2
06.11.2018	(Electronic) Receipt	Search / examination	1
06.11.2018	Filing of the translations of the claims	Search / examination	1
06.11.2018	French translation of claims	Search / examination	6
06.11.2018	German translation of the claims	Search / examination	6
06.11.2018	Letter accompanying subsequently filed items	Search / examination	2
27.06.2018	Bibliographic data of the European patent application	Search / examination	2
27.06.2018	Communication about intention to grant a European patent	Search / examination	5
27.06.2018	Intention to grant (signatures)	Search / examination	1
27.06.2018	Text intended for grant (clean copy)	Search / examination	40
27.06.2018	Text intended for grant (sequence listing)	Search / examination	21
27.06.2018	Text intended for grant (version for approval)	Search / examination	40

Mobidiag – case study

CLAIMS

1. Method for determining the presence of diarrhoea causing pathogens in a biological sample comprising the steps of:

i) contacting the sample or nucleic acid isolated therefrom with primer pairs in a multiplex PCR assay comprising two or more separate PCR reactions, wherein the primers of said primer pairs amplify each of the ETEC amplicons as defined by SEQ ID NOS:61-63 at least partly;

ii) performing a polymerase chain reaction with reaction mixes obtained from step i) so that the target sequences of diarrhoea causing pathogens are specifically amplified, if said sequences are present in the sample; and

iii) detecting the presence of amplified target sequences in the reaction mix, wherein the presence of any of the target sequences is indicative of the presence of diarrhoea causing pathogens in the sample.

CLAIMS DRAFT (additions are double underlined, deletions are crossed out)

1. Method for determining the presence of diarrhoea causing pathogens in a biological sample comprising the steps of:

i) contacting the sample or nucleic acid isolated therefrom with primer pairs in a multiplex PCR assay comprising two or more separate PCR reactions, wherein the primers of said primer pairs amplify each of the ETEC amplicons as defined by SEQ ID NOS:61-63 ~~at least partly~~, wherein at least 20 nucleotides long sequence of each of the target amplicons are amplified;

ii) performing a polymerase chain reaction with reaction mixes obtained from step i) so that the target sequences of diarrhoea causing pathogens are specifically amplified, if said sequences are present in the sample; and

iii) detecting the presence of amplified target sequences in the reaction mix, wherein the presence of any of the target sequences is indicative of the presence of diarrhoea causing pathogens in the sample.

Mobidiag – case study

1. Method for determining the presence of diarrhoea causing pathogens in a biological sample comprising the steps of:

i) contacting the sample or nucleic acid isolated therefrom with primer pairs in a multiplex PCR assay comprising ~~two~~ three ~~two~~ or more separate PCR reactions, wherein the primers of said primer pairs amplify each of the ETEC amplicons as defined by SEQ ID NOS:61-63, wherein at least 20 nucleotides long sequence of each of the target amplicons are amplified;

ii) performing a polymerase chain reaction with reaction mixes obtained from step i) so that the target sequences of diarrhoea causing pathogens are specifically amplified, if said sequences are present in the sample; and

iii) detecting the presence of amplified target sequences in the reaction mix, wherein the presence of any of the target sequences is indicative of the presence of diarrhoea causing pathogens in the sample.

CLAIMS

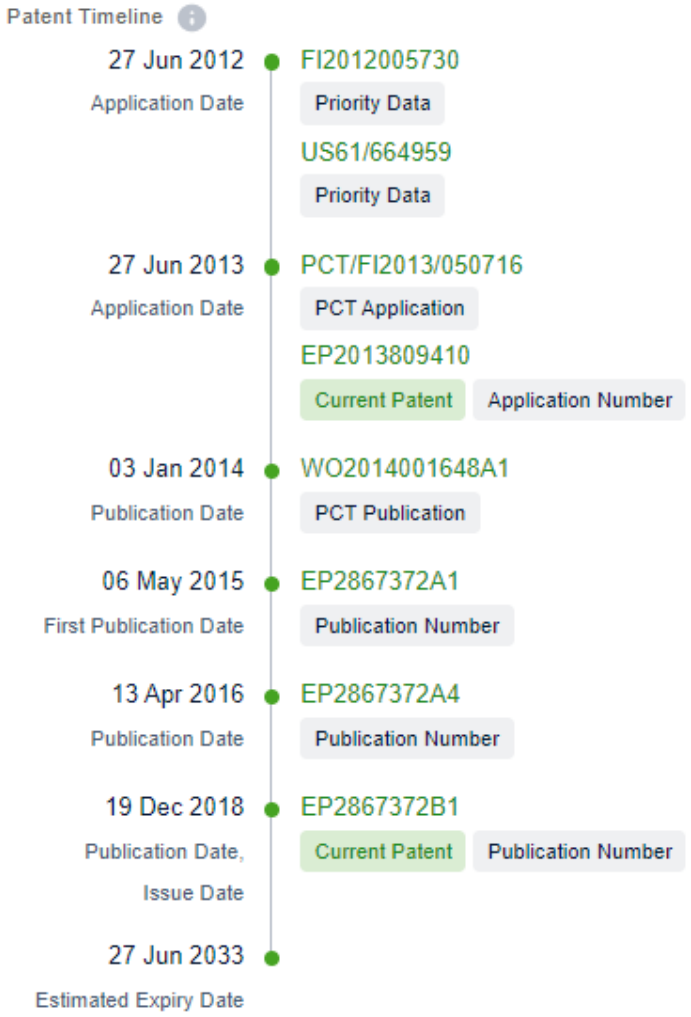
1. Method for determining the presence of diarrhoea causing pathogens in a biological sample comprising the steps of:

i) contacting the sample or nucleic acid isolated therefrom with primer pairs in a multiplex PCR assay comprising two or more separate PCR reactions, wherein the primers of said primer pairs amplify each of the ETEC amplicons as defined by SEQ ID NOS:61-63, wherein at least 20 nucleotides long sequence of each of the target amplicons are amplified;

ii) performing a polymerase chain reaction with reaction mixes obtained from step i) so that the target sequences of diarrhoea causing pathogens are specifically amplified, if said sequences are present in the sample; and

iii) detecting the presence of amplified target sequences in the reaction mix, wherein the presence of any of the target sequences is indicative of the presence of diarrhoea causing pathogens in the sample.

Mobidiag – case study



Mobidiag – case study

1. WO2014001648 - METHOD FOR DETERMINING THE PRESENCE OF DIARRHOEA CAUSING PATHOGENS

PCT Biblio. Data | Description | Claims | National Phase | Patent Family | Notices | Documents

PermaLink

Available information on National Phase entries [more information]

Office	Entry Date	National Number	National Status
Canada	23.12.2014	2877835	Granted 16.11.2021
United States of America	24.12.2014	14411170	Published 22.10.2015
Japan	26.12.2014	2015519268	
European Patent Office	15.01.2015	2913809410	Published 06.05.2015 Granted 19.12.2018
Australia	22.01.2015	2013283152	Published 12.02.2015 Granted 22.08.2019
China	03.02.2015	201380041290.8	Granted 16.06.2020

Biologic Therapeutics – Noile Immune

Patenting therapeutics

Therapeutics – Biologics (Cell & Gene Therapy; mAb) + Small molecule drugs

Juno Therapeutics vs Kite Pharma & *Amgen vs Sanofi* – Outlines importance good written description & sufficient exemplification

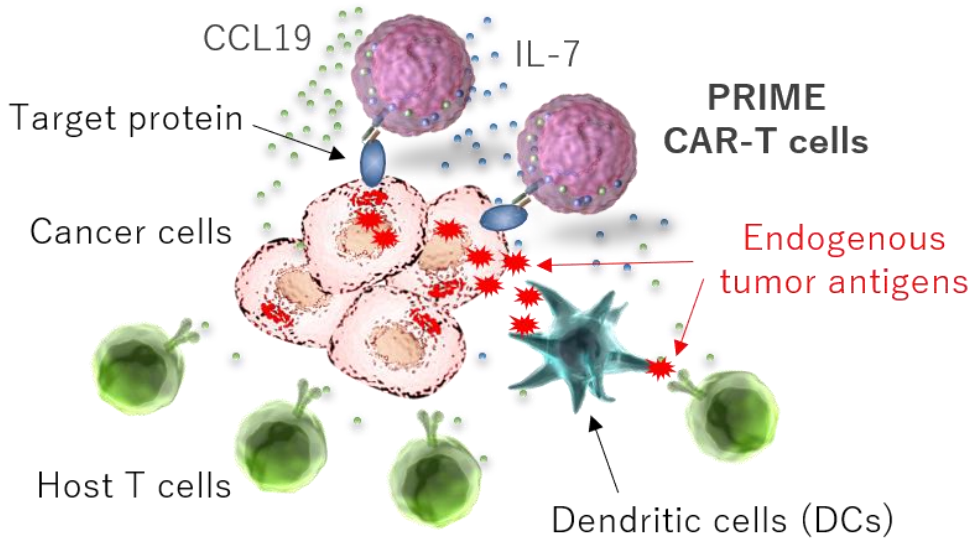
EPO – more stringent with broadness of claims (https://new.epo.org/en/legal/guidelines-epc/2023/g_ii_5_6.html - extensive guideline for antibodies)

Noile – Immune case study

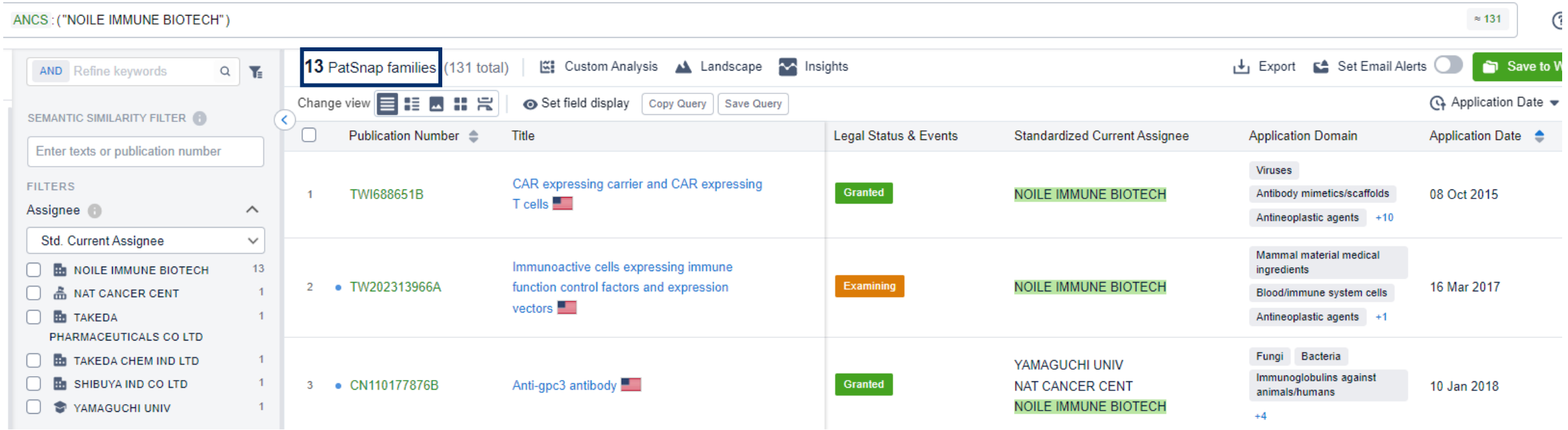
Founded in April 2015 – Japan; Prof. Koji Tamada - Yamaguchi University Graduate School of Medicine

PRIME technology is a platform designed to enhance the function of immune cells through the expression of the cytokine interleukin (IL)-7 and the chemokine CCL19 from CAR-T cells, exerting anti-tumor effects. Pre-clinical studies (mouse, in vivo) have shown that the PRIME technology increases the expression of IL-7 and CCL19 and boosts the proliferation and migration into solid tumors of both CAR-T cells as well as the patient's own immune cells.

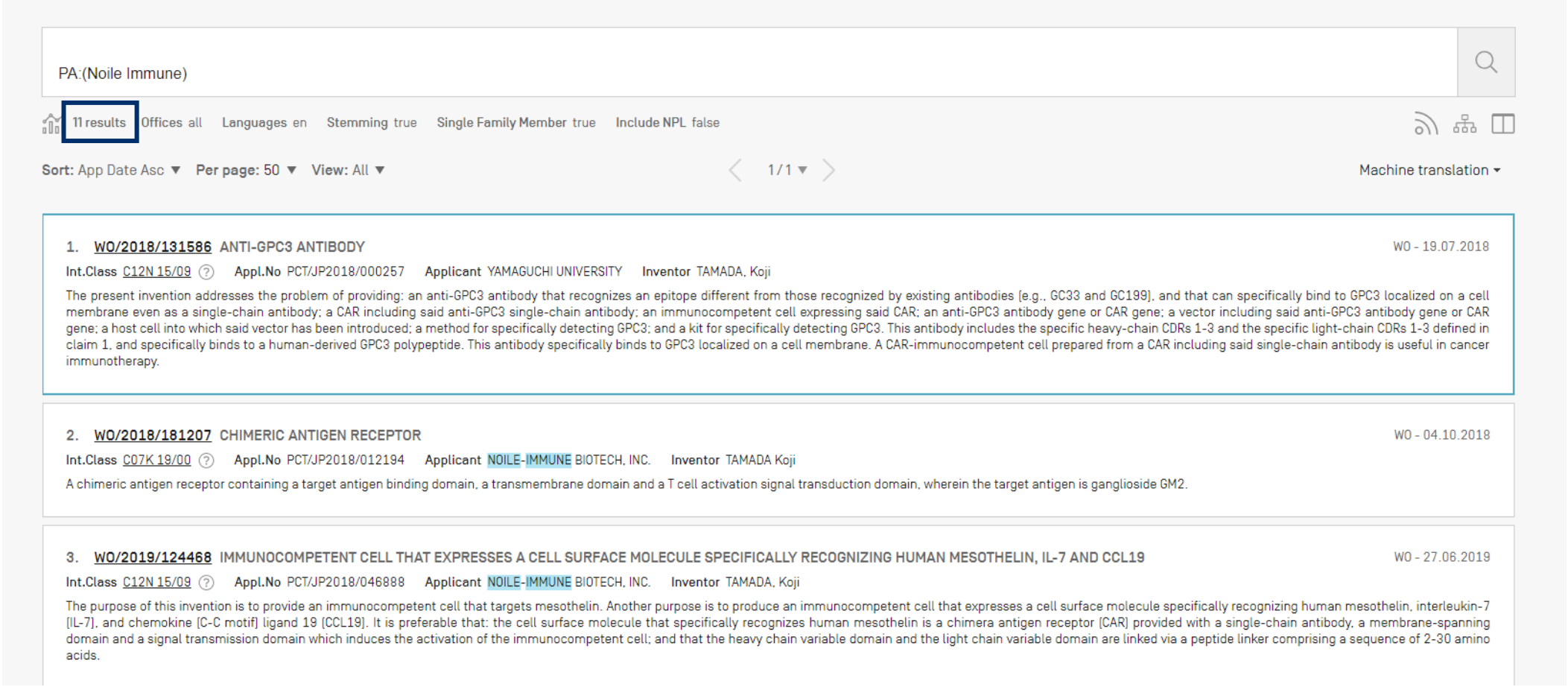
PRIME CAR-T cell therapy (CAR-T expressing IL-7 and CCL19)



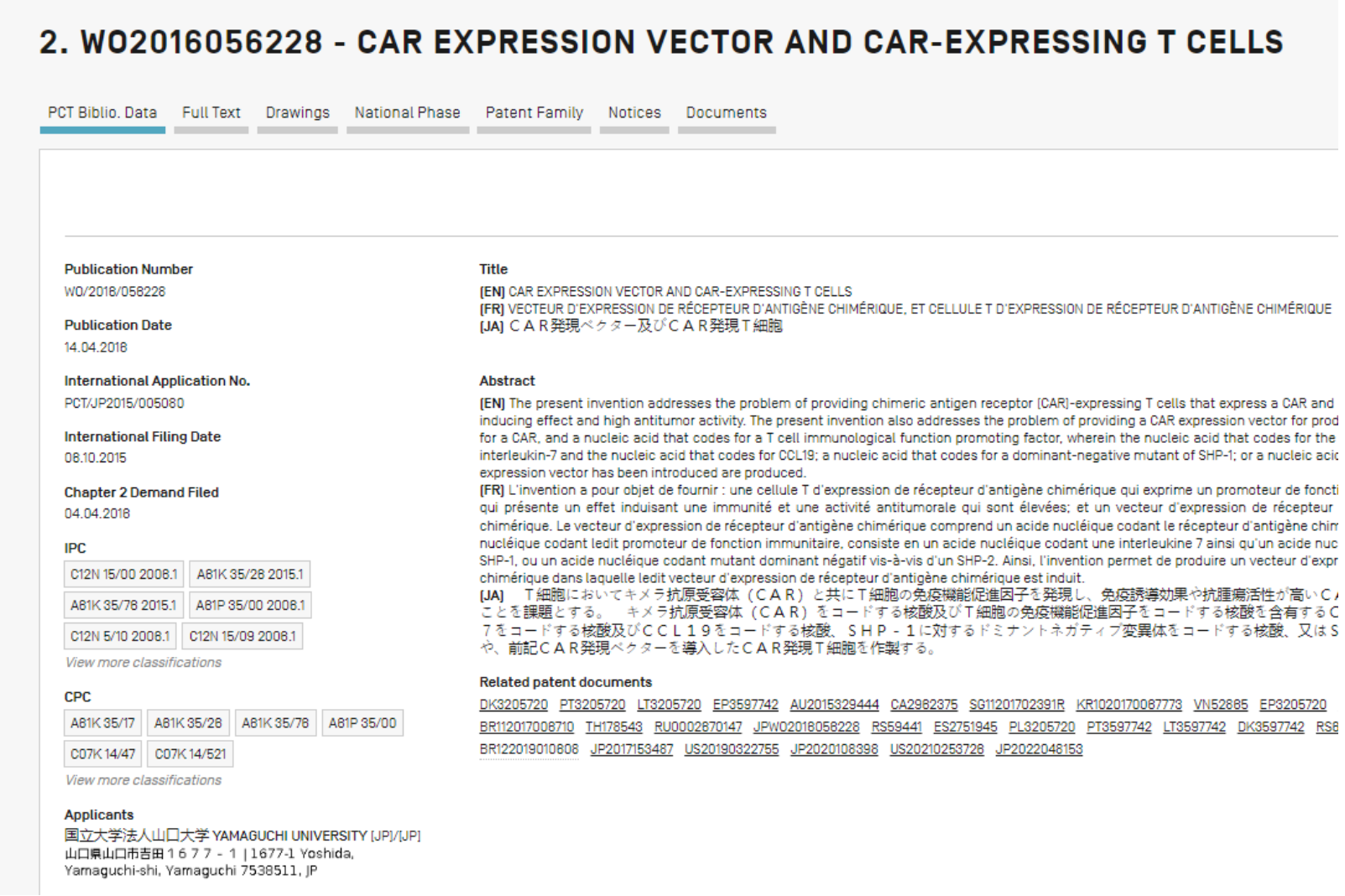
Noile – Immune case study



Noile – Immune case study



Noile – Immune case study



2. WO2016056228 - CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS

PCT Biblio. Data | Full Text | Drawings | National Phase | Patent Family | Notices | Documents

Publication Number
WO/2016/056228

Publication Date
14.04.2016

International Application No.
PCT/JP2015/005080

International Filing Date
08.10.2015

Chapter 2 Demand Filed
04.04.2016

IPC
C12N 15/00 2006.1 | A61K 35/28 2015.1 | A61K 35/76 2015.1 | A61P 35/00 2006.1 | C12N 5/10 2006.1 | C12N 15/09 2006.1
View more classifications

CPC
A61K 35/17 | A61K 35/28 | A61K 35/76 | A61P 35/00 | C07K 14/47 | C07K 14/521
View more classifications

Applicants
国立大学法人山口大学 YAMAGUCHI UNIVERSITY [JP]/[JP]
山口県山口市吉田１６７７－１ | 1677-1 Yoshida, Yamaguchi-shi, Yamaguchi 7538511, JP

Title
[EN] CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS
[FR] VECTEUR D'EXPRESSION DE RÉCEPTEUR D'ANTIGÈNE CHIMÉRIQUE, ET CELLULE T D'EXPRESSION DE RÉCEPTEUR D'ANTIGÈNE CHIMÉRIQUE
[JA] ＣＡＲ発現ベクター及びＣＡＲ発現Ｔ細胞

Abstract
[EN] The present invention addresses the problem of providing chimeric antigen receptor [CAR]-expressing T cells that express a CAR and inducing effect and high antitumor activity. The present invention also addresses the problem of providing a CAR expression vector for prod for a CAR, and a nucleic acid that codes for a T cell immunological function promoting factor, wherein the nucleic acid that codes for the interleukin-7 and the nucleic acid that codes for CCL19; a nucleic acid that codes for a dominant-negative mutant of SHP-1; or a nucleic acic expression vector has been introduced are produced.
[FR] L'invention a pour objet de fournir : une cellule T d'expression de récepteur d'antigène chimérique qui exprime un promoteur de fonct qui présente un effet induisant une immunité et une activité antitumorale qui sont élevées; et un vecteur d'expression de récepteur chimérique. Le vecteur d'expression de récepteur d'antigène chimérique comprend un acide nucléique codant le récepteur d'antigène chim nucléique codant ledit promoteur de fonction immunitaire, consiste en un acide nucléique codant une interleukine 7 ainsi qu'un acide nuc SHP-1, ou un acide nucléique codant mutant dominant négatif vis-à-vis d'un SHP-2. Ainsi, l'invention permet de produire un vecteur d'expr chimérique dans laquelle ledit vecteur d'expression de récepteur d'antigène chimérique est induit.
[JA] Ｔ細胞においてキメラ抗原受容体（ＣＡＲ）と共にＴ細胞の免疫機能促進因子を発現し、免疫誘導効果や抗腫瘍活性が高いＣＡ ことを課題とする。 キメラ抗原受容体（ＣＡＲ）をコードする核酸及びＴ細胞の免疫機能促進因子をコードする核酸を含有するＣ ７をコードする核酸及びＣＣＬ１９をコードする核酸、ＳＨＰ－１に対するドミナントネガティブ変異体をコードする核酸、又はＳ や、前記ＣＡＲ発現ベクターを導入したＣＡＲ発現Ｔ細胞を作製する。

Related patent documents
DK3205720 PT3205720 LT3205720 EP3597742 AU2015329444 CA2962375 SG11201702391R KR1020170067773 VN52685 EP3205720 BR112017006710 TH178543 RU0002670147 JPWO2016056228 RS59441 ES2751945 PL3205720 PT3597742 LT3597742 DK3597742 RS8 BR122019010808 JP2017153487 US20190322755 JP2020106398 US20210253726 JP2022046153

Noile – Immune case study

Publication Number	Title	Application Date	Publication Date	Issue Date	Inventor Name	Current Assignee
AU2015329444B2	CAR expression vector and CAR-expressing T cells	2015-10-06	2017-11-23	2018-03-08	SAKODA, YUKIMI | ADACHI, KEISHI | TAMADA, KOJI	YAMAGUCHI UNIVERSITY
AU2015329444A1	CAR expression vector and CAR-expressing T cells	2015-10-06	2017-04-13	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
BR112017006710A2	VETOR DE EXPRESSÃO DE CAR E CÉLULAS T EXPRESSANDO CAR	2015-10-06	2017-12-12	-	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
BR112017006710B1	VETOR DE EXPRESSÃO DE UM RECEPTOR DE ANTÍGENO QUIMÉRICO E AGENTE ANTICANCERÍGENO	2015-10-06	2020-01-21	2020-01-21	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
CA2962375A1	Car expression vector and car-expressing t cells	2015-10-06	2016-04-14	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
CA2962375C	Car expression vector and car-expressing t cells	2015-10-06	2020-07-14	2020-07-14	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
CN107109421A	Car expression vector and car-expressing t cells	2015-10-06	2017-08-29	-	玉田耕治 | 佐古田幸美 | 安达圭志	国立大学法人山口大学
CN107109421B	CAR表达载体及CAR表达T细胞	2015-10-06	2018-09-25	2018-09-25	玉田耕治 | 佐古田幸美 | 安达圭志	国立大学法人山口大学
CY1122324T1	ΔΙΑΒΙΒΑΣΤΗΣ ΕΚΦΡΑΣΗΣ CAR ΚΑΙ T-ΚΥΤΤΑΡΑ ΕΚΦΡΑΣΗΣ CAR	2019-11-26	2021-01-27	-	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	YAMAGUCHI UNIVERSITY
DE602015037985T2	CAR-EXPRESSIONS-VEKTOR UND CAR-EXPRIMIERENDE T-ZELLEN	2015-10-06	2019-09-11	2019-09-11	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
DE602015079895T2	CAR-EXPRESSIONS-VEKTOR UND CAR-EXPRIMIERENDE T-ZELLEN	2015-10-06	2022-07-13	2022-07-13	TAMADA, KOJI, UBE-SHI | SAKODA, YUKIMI, UBE-SHI | ADACHI, KEISHI, UBE-SHI	YAMAGUCHI UNIVERSITY
DK3205720T3	CAR-EKSPRIMERINGSVEKTOR OG CAR-EKSPRIMERENDE T-CELLER	2015-10-06	2019-10-07	2019-09-11	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
DK3597742T3	CAR-UDTRYKKENDE VEKTOR OG CAR-UDTRYKKENDE T-CELLER	2015-10-06	2022-10-03	2022-10-03	SAKODA Yukimi | ADACHI Keishi | TAMADA Koji	Yamaguchi University
EP3205720A1	Car expression vector and car-expressing t cells	2015-10-06	2017-08-16	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
EP3205720A4	Car expression vector and car-expressing t cells	2015-10-06	2018-07-04	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
EP3205720B1	Car expression vector and car-expressing t cells	2015-10-06	2019-09-11	2019-09-11	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
EP3597742A1	Car expression vector and car-expressing t cells	2015-10-06	2020-01-22	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
EP3597742B1	Car expression vector and car-expressing t cells	2015-10-06	2022-07-13	2022-07-13	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
ES2751945T3	Vector de expresión de un RAQ y células T que expresan un RAQ	2015-10-06	2020-04-02	2020-04-02	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
ES2927366T3	Vector de expresión de CAR y células T que expresan CAR	2015-10-06	2022-11-04	2022-11-04	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
HK1235426A	Car expression vector and car-expressing t cells	2017-09-06	2018-03-09	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
HK1235426A1	Car expression vector and car-expressing t cells	2017-09-06	2020-05-15	2020-05-15	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
HRP20191839T1	Car expression vector and car-expressing t cells	2019-10-11	2020-01-24	2020-01-24	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
HRP20221211T1	Car expression vector and car-expressing t cells	2022-10-03	2022-12-09	2022-12-09	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
HUE060047T2	Car expression vector and car-expressing t cells	2015-10-06	2023-01-28	-	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
HUE046710T2	Car expression vector and car-expressing t cells	2015-10-06	2020-03-30	-	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
ID201800205A	Car expression vector and car-expressing t cells	2017-04-27	2018-01-12	-	KEISHI ADACHI | KOJI TAMADA | YUKIMI SAKODA	YAMAGUCHI UNIVERSITY
IDP000068541B	VEKTOR EKSPRESI CAR DAN SEL-SEL T PENGEKSPRESI-CAR	2017-04-27	2020-04-22	2020-04-22	KEISHI ADACHI | KOJI TAMADA | YUKIMI SAKODA	YAMAGUCHI UNIVERSITY
IL251504A	Car expression vector and car-expressing t cells	2015-10-06	2020-03-31	-	-	YAMAGUCHI UNIVERSITY
IN201747010172A	Car expression vector and car expressing t cells	2017-03-23	2017-04-14	-	TAMADA KOJI | SAKODA YUKIMI | ADACHI KEISHI	YAMAGUCHI UNIVERSITY
IN402684B	Car expression vector and car expressing t cells	2017-03-23	2017-04-14	2022-07-29	TAMADA KOJI | SAKODA YUKIMI | ADACHI KEISHI	YAMAGUCHI UNIVERSITY
IT202200063606T2	VETTORE DI ESPRESSIONE CAR E CELLULE T CHE ESPRIMONO CAR	2015-10-06	2022-07-13	2022-07-13	-	YAMAGUCHI UNIVERSITY
JPWO2016056228A1	CAR発現ベクター及びCAR発現T細胞	2015-10-06	2017-06-01	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP6161098B2	CAR発現ベクター及びCAR発現T細胞	2015-10-06	2017-07-12	2017-06-23	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP2017153487A	Car expression vector and car expressing t cell	2017-06-06	2017-09-07	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP6683990B2	CAR発現ベクター及びCAR発現T細胞	2017-06-06	2020-04-22	2020-03-31	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学

Noile – Immune case study

JP2020108398A	Car expression vector and car expressing t cell	2020-03-19	2020-07-16	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP2020108398A5	Car expression vector and car expressing t cell	2020-03-19	2021-02-12	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP7008350B2	CAR発現ベクター及びCAR発現T細胞	2020-03-19	2022-02-10	2022-01-13	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP2022048153A	Car expression vector and car expression t cells	2021-12-28	2022-03-25	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
JP2022048153A5	Car expression vector and car expression t cells	2021-12-28	2022-09-20	-	玉田 耕治 | 佐古田 幸美 | 安達 圭志	国立大学法人山口大学
KR1020170067773A	Car expression vector and car-expressing t cells	2015-10-06	2017-06-16	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
KR101890638B1	Car expression vector and car-expressing t cells	2015-10-06	2018-08-22	2018-08-16	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
LT3205720T	Car expression vector and car-expressing t cells	2015-10-06	2019-12-10	2019-12-10	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
LT3597742T	Car expression vector and car-expressing t cells	2015-10-06	2022-09-12	2022-09-12	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
MOJ003500C	CAR表達載體及CAR表達T細胞。	2018-12-27	2019-04-03	2019-03-11	玉田耕治 | 佐古田幸美 | 安達圭志	YAMAGUCHI UNIVERSITY
MX2017004393A	Car expression vector and car-expressing t cells.	2017-04-04	2017-06-22	-	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
MX358472B	Car expression vector and car-expressing t cells.	2017-04-04	2018-08-21	2018-08-21	KEISHI ADACHI | KOJI TAMADA | YUKIMI SAKODA	YAMAGUCHI UNIVERSITY
MY167722A	Car expression vector and car-expressing t cells	2015-10-06	2018-09-21	2018-09-21	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
MYPI2017701137A0	Car expression vector and car-expressing t cells	2015-10-06	2016-04-09	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
NO3205720B1	CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS	2015-10-06	2017-08-16	2019-11-18	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
NO3597742B1	CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS	2015-10-06	2020-01-22	2022-10-03	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
NZ730382A	Car expression vector and car-expressing t cells	2015-10-06	2019-01-25	-	ADACHI, KEISHI | SAKODA, YUKIMI | TAMADA, KOJI	YAMAGUCHI UNIVERSITY
NZ730382B	Car expression vector and car-expressing t cells	2015-10-06	2019-04-30	2019-04-30	ADACHI, KEISHI | SAKODA, YUKIMI | TAMADA, KOJI	YAMAGUCHI UNIVERSITY
WO2016056228A1	Car expression vector and car-expressing t cells	2015-10-06	2016-04-14	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
PH12017500596A1	Car expression vector and car-expressing t cells	2015-10-06	2017-08-30	-	ADACHI, KEISHI | TAMADA, KOJI | SAKODA, YUKIMI	YAMAGUCHI UNIVERSITY
PH12017500596B1	Car expression vector and car-expressing t cells	2015-10-06	2018-06-06	2018-06-06	ADACHI, KEISHI | TAMADA, KOJI | SAKODA, YUKIMI	YAMAGUCHI UNIVERSITY
PL3205720T3	Car expression vector and car-expressing t cells	2015-10-06	2020-02-28	2020-02-28	TAMADA KOJI | SAKODA YUKIMI | ADACHI KEISHI	Yamaguchi University
PL3597742T3	Car expression vector and car-expressing t cells	2015-10-06	2022-11-14	2022-11-14	TAMADA KOJI | SAKODA YUKIMI | ADACHI KEISHI	Yamaguchi University
PT3205720T	Car expression vector and car-expressing t cells	2015-10-06	2019-10-28	2019-10-28	KOJI TAMADA | YUKIMI SAKODA | KEISHI ADACHI	YAMAGUCHI UNIVERSITY
PT3597742T	Car expression vector and car-expressing t cells	2015-10-06	2022-08-30	2022-08-30	-	YAMAGUCHI UNIVERSITY
RS59441B1	Car expression vector and car-expressing t cells	2015-10-06	2019-11-29	2019-11-29	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
RS63601B1	Car expression vector and car-expressing t cells	2015-10-06	2022-10-31	2022-10-31	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
RU2670147C1	CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS	2015-10-06	2018-10-18	2018-10-18	TAMADA KOJI | SAKODA YUKIMI | ADACHI KEISHI	YAMAGUCHI UNIVERSITY
SG11201702391RA	Car expression vector and car-expressing t cells	2015-10-06	2017-04-27	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
SG11201702391RB	Car expression vector and car-expressing t cells	2015-10-06	2019-03-13	2019-03-13	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
SI3205720T1	Car expression vector and car-expressing t cells	2015-10-06	2020-01-31	-	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
SI3597742T1	Car expression vector and car-expressing t cells	2015-10-06	2022-11-30	-	TAMADA Koji | SAKODA Yukimi | ADACHI Keishi	Yamaguchi University
TH178543A	เวกเตอร์การแสดงออกของ CAR และ T เซลล์ที่แสดง CAR ออกมา	2015-10-06	2018-08-02	-	นายโคจิ ทามาดะ | นายยูกิมิ ซากาดะ | นายเคอิชิอะดาชิ	ยามากูชิ ยูนิเวอร์ซิตี้
TW201619377A	Car expression vector and car-expressing t cells	2015-10-08	2016-06-01	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	NOILE-IMMUNE BIOTECH INC.
TWI688651B	ＣＡＲ表現載體及ＣＡＲ表現Ｔ細胞	2015-10-08	2020-03-21	2020-03-21	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	NOILE-IMMUNE BIOTECH INC.
US20170291953A1	Car expression vector and car-expressing t cells	2015-10-06	2017-10-12	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
US10316102B2	Car expression vector and car-expressing T cells	2015-10-06	2019-06-11	2019-06-11	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
US20190322755A1	Car expression vector and car-expressing t cells	2019-05-06	2019-10-24	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
US10906984B2	CAR expression vector and CAR-expressing T cells	2019-05-06	2021-02-02	2021-02-02	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
US20210253726A1	Car expression vector and car-expressing t cells	2020-12-23	2021-08-19	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
VN52865A	VECTƠ BIỂU HIỆN THỤ THỂ CỦA KHÁNG NGUYÊN KHẢM (CAR) VÀ TẾ BÀO T BIỂU HIỆN CAR	2015-10-06	2017-06-26	-	ADACHI, KEISHI | TAMADA, KOJI | SAKODA, YUKIMI	YAMAGUCHI UNIVERSITY
VN10021834B	VECTƠ BIỂU HIỆN THỤ THỂ CỦA KHÁNG NGUYÊN KHẢM (CAR) VÀ TẾ BÀO T BIỂU HIỆN THỤ THỂ CỦA KHÁNG NGUYÊN KHẢM NÀY	2015-10-06	2019-10-25	2019-08-26	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
ZA201701968B	Car expression vector and car-expressing t cells	2017-03-22	2019-06-26	2019-06-26	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY
ZA201701968A	Car expression vector and car-expressing t cells	2017-03-22	2017-03-29	-	TAMADA, KOJI | SAKODA, YUKIMI | ADACHI, KEISHI	YAMAGUCHI UNIVERSITY

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2. WO2016056228 - CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS

PCT Biblio. Data | Full Text | Drawings | National Phase | Patent Family | Notices | Documents

PermaLink

International Application Status

Date	Title	View	Download
05.05.2023	International Application Status Report		

Date	Title
14.04.2016	Initial Publication with ISR (A1 15/2016
14.04.2016	Sequence Listing

（ＰＣＴ実施細則附属書Ｃ第３の３段落参照）

４．この国際予備審査報告は、次の内容を含む。

- ☑ 第Ⅰ欄　国際予備審査報告の基礎
- ☐ 第Ⅱ欄　優先権
- ☐ 第Ⅲ欄　新規性、進歩性又は産業上の利用可能性についての国際予備審査報告の不作成
- ☐ 第Ⅳ欄　発明の単一性の欠如
- ☑ 第Ⅴ欄　ＰＣＴ35条(2)に規定する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるための文献及び説明
- ☐ 第Ⅵ欄　ある種の引用文献
- ☐ 第Ⅶ欄　国際出願の欠陥
- ☐ 第Ⅷ欄　国際出願についての意見

Date	Title	View	Download
02.03.2017	[IPEA/409] English Translation of International Preliminary Report on Patentability Chapter II	PDF 7 p.	PDF 7 p. ZIP XML + TIFFs
20.07.2016	[IPEA/409] International Preliminary Report on Patentability Chapter II	PDF 10 p.	PDF 10 p. ZIP XML + TIFFs

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1. EP3205720 - CAR EXPRESSION VECTOR AND CAR-EXPRESSING T CELLS

National Biblio. Data | Description | Claims | Drawings | Patent Family | Documents

PermaLink

Published Application

		Download
EP15849416B1	EP20190911	XML ZIP XML+TIFFS
EP15849416A1	EP20170816	XML ZIP XML+TIFFS

Other Available Documents

Title	View	Download
Original EP document	PDF	

Global Dossier

Legal date	Description	Download
14.04.2016	Converted Sequence Listing	PDF (13 pages)
14.04.2016	Copy of the international search report	PDF (2 pages)
14.04.2016	Copy of the translated international search report	PDF (2 pages)
18.04.2017	Translation of the international preliminary examination report	PDF (7 pages)

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TRANSLATION

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	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
FH26-030WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2015/005080	**06.10.2015**	**09.10.2014**

International Patent Classification (IPC) or national classification and IPC
C12N15/00(2006.01)i, A61K35/26(2015.01)i, A61K35/76(2015.01)i, A61P C12N15/09(2006.01)i, C07K14/47(2006.01)n, C07K14/54(2006.01)n, C07K

Applicant
YAMAGUCHI UNIVERSITY

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

☒	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
☒	Box No. V	Reasoned statement under Article 35(2) 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

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> However, none of the documents describe preparing a chimeric antigen receptor (CAR) expression vector that contains nucleic acid that codes for a CAR and nucleic acid that codes for each of the T cell immune function promoters interleukin 7 and CCL19. The documents also do not set forth that CAR-expressing T cells into which such an expression vector had been introduced would exhibit therapeutic effects against tumors. Furthermore, even a person skilled in the art could not easily conceive of said features/effects.

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Example section has 12 examples – very specific

Preparation of T cells expressing IL -7 and CCL-19; (Preparation of the CAR expression vectors, retrovirus with CAR expression vectors for transduction, transduction of mouse cells); CAR expression assay flow cytometry, Secretion of IL-7 and CCL-19; Cell number – survival rate of CAR expressing cells

T – cell migration test; Therapeutic effect in mouse tumor models; Effect of infiltrating into tumor tissues; Therapeutic effect brought about by the combination.

Key – the breadth of claims are supported totally by the examples and their figures.

Noile – Imr

17/02/2017

of claims (d

06/04/2017

(discounted

08/05/2017

Use in Pate

faster grant

European Patent Office
D-80298 Munich
Germany

22 November 2017

Dear Sirs

RE: European Patent Application No. 15849416.1
Applicant: YAMAGUCHI UNIVERSITY
Our File: P5821EP21

This letter is in response to the Communication pursuant to Rules 161(2) and 162 EPC dated 16 June 2017.

We hereby file a request for participation in the PPH pilot programme. Request form EPA/EPO/OEB 1009 is submitted herewith.

In support of the PPH request we also file herewith:

- an English translation of the claims granted on the corresponding Japanese Patent
- the decision of the JPO to grant together with an English translation (which constitutes all of the office actions)

No office action was issued before the decision to grant and no references were cited by the JPO Examiner during prosecution of the corresponding Japanese patent application upon which this request is based.

Applicant hereby requests allowance of the same claims granted in respect of the corresponding Japanese Patent.

Do not hesitate to contact me if you require any further information.

Yours faithfully,

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Office	Entry Date	National Number	National Status
Japan	17.02.2017	2016552830	
European Patent Office	21.03.2017	2015849416	
Australia	22.03.2017	2015329444	Published 13.04.2017 Granted 22.03.2018
New Zealand	22.03.2017	730382	Published 31.03.2017 Granted 30.04.2019
Canada	23.03.2017	2962375	Granted 14.07.2020
United States of America	23.03.2017	15513870	Published 12.10.2017 Granted 11.06.2019
Philippines	31.03.2017	12017500596	Granted 04.05.2018
Israel	02.04.2017	251504	Published 29.05.2017 Granted 01.07.2020
Mexico	04.04.2017	MX/a/2017/004393	Published 11.07.2017 Granted 21.08.2018
Thailand	05.04.2017	1701001909	
Brazil	11.04.2017	122019010608	Divisional 02.07.2019 Refused 11.02.2020
Russian Federation	10.05.2017	2017114545	Granted 18.10.2018
Serbia	10.10.2019	P-2019/1315	Granted 29.11.2019
India		201747010172	Granted 05.08.2022
Republic of Korea		1020177009895	Published 16.06.2017
Singapore		11201702391R	Granted 13.03.2019

Conclusions

Not all is lost with a missed – most of the times, there are solutions (only if necessary!)

Speed of process can be modulated (depending on the needs)

Broad claims are becoming rare in life sciences (be intentional!)

Understanding all the tools/levers in the process can help with a smaller budget

There is not just one best strategy – many potential strategies

Thank you for your attention!

Dsava@mathys-squire.com
0044 7721025759

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