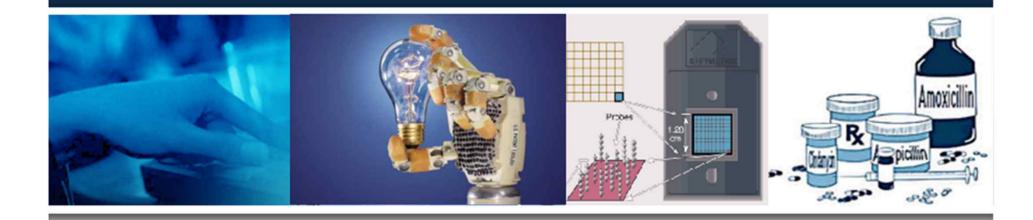
## Topic 10. Case Study

Patent Examination Practices in the National Phase



Jul 6, 2017

Weonhye Shin

Patent Examiner
Biotechnology Examination Div.
Korean Intellectual Property Office



## Criteria for Patentability

## **Patentability Criteria**

- Formality Examination
  - Documents required
  - Procedural requirements
- Substantive Examination
  - Unity of invention
  - Patent eligibility
  - Novelty
  - Inventive step (Non-obviousness)
  - Industrial applicability (Utility)
  - Sufficiency of disclosure
  - Prohibition of double patenting

### Patentable Subject Matter

- Invention must have a technical character
- Exclusions from Patentable Subject Matter
- Discoveries, mathematical theories
- Aesthetic creations
- Playing games, software, methods of doing business
- Surgery, therapeutic and diagnostic methods
- Inventions contrary to morality
- Plant or animal varieties
- Regional offices have differences in the extent of exclusions

## **Novelty**

- Novelty: an invention should not form a part of the prior art.
- Prior art: any knowledge made available to the public before the filing date of the relevant patent application
- "the invention is anticipated from the prior art"
  - → means not novel

PCT	EPC	35 USC	JPA	KPA
Art 33(2)	Art 54(1)	§ 102(a)	Art 29(1)	Art 29(1)

## **Inventive Step**

- Inventive Step: An invention involves an inventive step, If the invention is not obvious to a skilled person in the art having regard to the state of the art.
- ❖ Person skilled in the art should be presumed to be a skilled practitioner in the relevant field of technology, who possesses average knowledge and ability and is aware of common general knowledge in the art at the time of filing.

PCT	EPC	35 USC	JPA	KPA
Art 33(3)	Art 56	§ 103	Art 29(2)	Art 29(2)

## **Industrial Applicability**

- Industrial character: If the invention can be made or used in any kind of industry.
- not require that the invention is better than existing products or processes
- Utility: an invention is "useful" if it provides some identifiable benefit and is capable of use.
- prevents patenting of <u>hypothetical devices</u> such as <u>perpetual</u> motion machines and <u>medical methods(in some countries)</u>.

PCT	EPC	35 USC	JPA	KPA
Art 33(4)	Art 57	§ 101	Art 29(1) main para	Art 29(1) main para

## Sufficiency of Disclosure

- **Enablement**: an applicant must disclose the invention in a sufficiently clear and complete manner for the invention to be carried out by a person skilled in the art.
- Specification must provide sufficient information so that a person skilled in the art can, on the basis of the information disclosed in the application as filed and the common general knowledge in the art, perform the invention without "undue burden", "any inventive effort" or "undue experimentation".
- Reasonable amount of trial and error is generally acceptable.

PCT	EPC	35 USC	JPA	KPA
Art 5	Art 83	§ 112(a)	Art 36(4)(i)	Art 42(3)(i)

### Sufficiency of Disclosure

Enablement requirement is <u>not met</u>, when the description sets forth only a task and/or an assumption, or simply expresses a wish and/or a result, providing no technical means that a person skilled in the art can implement.

### <analysis>

- Working examples or prophetic examples?
- Experimental data?
- Reasonable association between an in vitro example and the alleged in vivo therapeutic efficacy(utility)?
- Post-filing date evidence as a support of the claimed therapeutic efficacy?

## **Support in Description**

- Support in Description: Claims shall be fully supported by an enabling disclosure.
- There must be a basis in the description for the subject-matter of every claim, and the scope of the claims must not be broader than what is justified by the extent of the description and drawings, and the contribution to the art.
- The extent to which an invention is <u>sufficiently disclosed</u> is also highly relevant to the issue of <u>support</u>.

PCT	EPC	35 USC	JPA	KPA
Art 6	Art 84	§ 112(a)	Art 36(6)(i)	Art 42(4)(i)

## Clarity – Claim scope

- Clarity: The claims shall define the matter for which protection is sought. They shall be clear and concise.
- The clarity of the claims is important in view of their function in defining the matter for which protection is sought.
- The wording of a claim must be <u>clear in itself</u>
- Objection of lack of Clarity ~ Indefiniteness objection

PCT	EPC	35 USC	JPA	KPA
Art 6	Art 84	§ 112(b)	Art 36(6)(ii)	Art 42(4)(ii)

## Case Study 1

❖ [Title] VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE ATTENUATION

KR Application No. 10-2011-7024968

WO Publication No. WO2010/124154
WO Application No. PCT/US2010/032149

### Claims

❖ Claim 1. An attenuated, avirulent *M bovis* bactermm stram, wherein the bacterium is passaged more than 110 times.

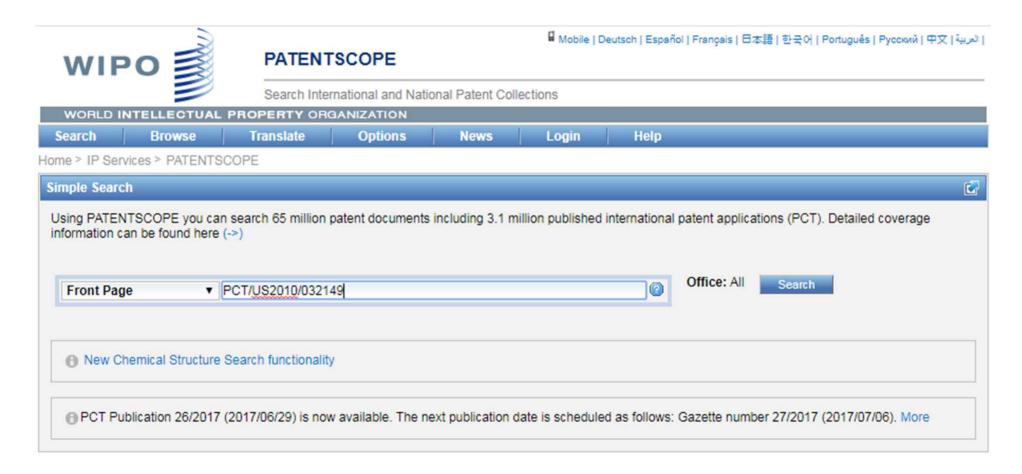
- ❖ Claim 7. A method of attenuating M. bovis, comprising,
- a . passaging *M. bovis* bacteria more than 110 times to produce a cultured *M. bovis* bacteria;
- b. obtaining the cultured *M. bovis* bacteria;
- c. testing the cultured *M. bovis* bacteria obtained under step b) for their pathogenicity and immunogenicity; and
- d . propagating the non-pathogenic, but immunogenic *M. bovis* bacteria to obtain the attenuated *M. bovis* bacteria.

### Using Publicly available websites

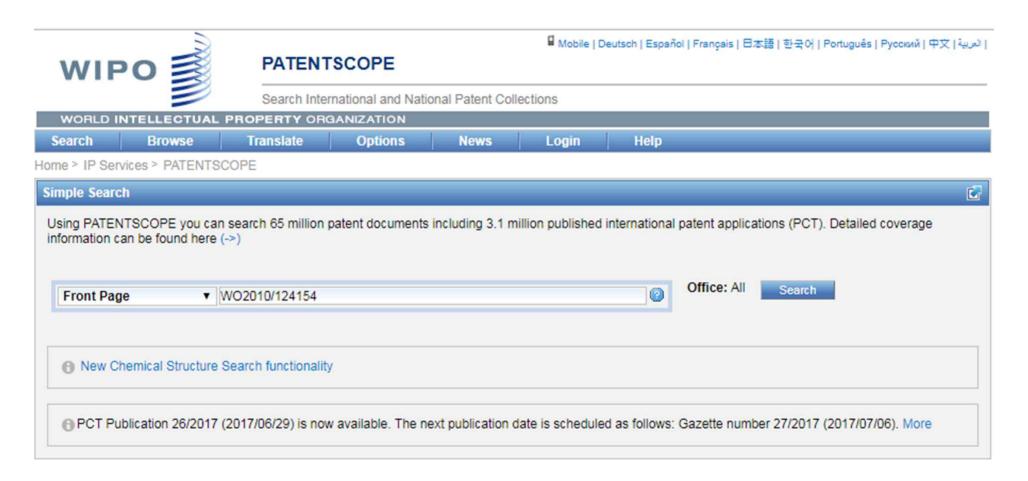
# Search the Examination Results from the International Phase

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### Search the International Pamphlet using Application Number



### Search the International Pamphlet using Publication Number





#### **PATENTSCOPE**

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Machine translation

1. (WO2010124154) VACCINES COMPRISING ATTENUATED MYCOPLASMA BOXIS STRAINS AND METHOD FOR THE ATTENUATION

PCT Biblio. Data Description Claims National Phase Notices Drawings Documents

Latest bibliographic data on file with the International Bureau

Pub. No.: WO/2010/124154 International Application No.: PCT/US2010/032149

Publication Date: 28.10.2010 International Filing Date: 23.04.2010

IPC: A61K 39/02 (2006.01)

Applicants: BOEHRINGER INGELHEIM VETMEDICA, INC. [US/US]; 2621 North Belt Highway St. Joseph, Missouri 64506-2002 (US) (For All

Designated States Except US).

BECK, Michael [US/US]; (US) (For US Only). KNITTEL, Jeffrey [US/US]; (US) (For US Only)

Inventors: BECK, Michael; (US).

**Designated States:** 

KNITTEL, Jeffrey; (US)

Agent: MORRIS, Michael, P.; Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877-0368

(US)

Priority Data: 61/172,543 24.04.2009 US

Title (EN) VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE ATTENUATION

(FR) VACCINS COMPRENANT DES SOUCHES DE MYCOPLASMA BOVIS ATTÉNUÉES ET PROCÉDÉ D'ATTÉNUATION

Abstract: (EN)The present invention relates to new attenuated mycroplasma bovis bacteria strains

passaged at least 110 times. Moreover, the present invention also provides immunogenic compositions comprising live bacteria of any of those attenuated M. bovis bacteria strain, their manufacture and use for the treatment and prophylaxis of M. bovis infections and combinations

with other veterinary vaccines or medicaments.

(FR)La présente invention porte sur de nouvelles souches bactériennes de mycoplasma bovis atténuées passées au moins 110 fois. De plus, la présente invention porte également sur des compositions immunogènes comprenant des bactéries vivantes de l'une quelconque de ces souches bactériennes de M. bovis atténuées, sur leur fabrication et leur utilisation pour le traitement et la prophylaxie d'infections par M. bovis et sur des combinaisons avec d'autres

vaccins ou médicaments vétérinaires.

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC,

EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK,

SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Eurasian Patent Organization (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM)

European Patent Office (AT. BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL,

NO, PL, PT, RO, SE, SI, SK, SM, TR)

African Intellectual Property Organization (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publication Language: English (EN)
Filing Language: English (EN)

28.10.2010

28.10.2010

### WIPO PATENTSCOPE

PDF (243p.), ZIP(XML + TIFFs)

ZIP(XML + TIFFs)

#### 1. (WO2010124154) VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD F

PCT Biblio, Data Description Claims National Phase Notices Drawings Documents

Initial Publication with ISR (A1 43/2010)

Sequence Listings

	VI.32111-15-114-11-11-11-11-11-11-11-11-11-11-11-11						
International Application Status							
	Data		Title			Manuel	Download

05.07.2017	International Application Status Report	HTML, PDF, XML	PDF, XML	
	Published International Application			
Date	Title	View	Download	

PDF (243p.)

Search and Examination-Related Documents				
Date Title View Downlo				
25.10.2011	(IB/373) International Preliminary Report on Patentability Chapter I	PDF (7p.)	PDF (7p.), ZIP(XML + TIFFs)	
24.10.2011	Written Opinion of the International Search Authority	PDF (6p.)	PDF (6p.), ZIP(XML + TIFFs)	
28.10.2010	International Search Report	PDF (6p.)	PDF (6p.), ZIP(XML + TIFFs)	

Date	Title	View	Download
25.10.2011	(IB/326) Notification of Transmittal of Copies of International Preliminary Report on Patentability Chapter I	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
16.08.2011	(IB/308) Notice Informing the Applicant of the Communication of the International Application to the Designated Offices	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
17.11.2010	(IB/308) Notice Informing the Applicant of the Communication of the International Application to the Designated Offices	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
28.10.2010	US 61/172,543 24.04.2009 (Pr. Doc.)	PDF (67p.)	PDF (67p.), ZIP(XML + TIFFs)
28.10.2010	(IB/304) Notification Concerning Submission or Transmittal of Priority Document	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
28.10.2010	(IB/311) Notification Concerning Availability of Publication of the International Application	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
28.10.2010	(IB/301) Notification of receipt of record copy	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)
28.10.2010	Power of Attorney	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
28.10.2010	Application Body as Filed	PDF (240p.)	PDF (240p.), ZIP(XML + TIFFs)
28.10.2010	(RO/105) Notification of the International Application Number and of the International Filing Date	PDF (1p.)	PDF (1p.), ZIP(XML + TIFFs)
28.10.2010	(RO/101) Request form	PDF (5p.)	PDF (5p.), ZIP(XML + TIFFs)
8.10.2010	(RO/102) Notification Concerning Payment of Prescribed Fees	PDF (2p.)	PDF (2p.), ZIP(XML + TIFFs)

INTERNATIONAL SEARCH REPORT

nternational application No

International Search Report

- Use Examination Results from the International Phase

		P	CT/US201	0/032149	
A. CLASSI INV . ADD.	FICATION OF SUBJECT MATTER A61K39/02				
According to	o International Patent Classification (IPC) or to both national class	sification and IPC			
B. FIELDS SEARCHED					
Minimum do A61K	Minimum documentation searched (classification system followed by classification symbols)				
Documentat	Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  EPO-Internal , BIOSIS, CHEM ABS Data, WPI Data					
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where approprate, of the	relevant passages		Relevant to claim No	
x	THORNS C J BT AL: "EPFECT OF S PASSAGES THROUGH LIQUID MEDIUM VIRULENCE OF MYCOPLASMA-BOVIS F MOUSE MAMMARY GLAND" RESEARCH IN VETERINARY SCIENCE, vol. 29, no. 3, 1980, pages 328 XP008124597 ISSN: 0034-5288 table 1  US 2009/068231 A1 (XUMAR MAHESH AL) 12 March 2009 (2009-03-12) paragraph [0011] paragraph [0039]; claims 1, 11,	ON THE FOR THE 1-332, [US] ET		1-30	
"A" docume consid "E" earlier of filing d "L" docume which offatior "O" docume other i "P" docume "P" docume other i "P" docume	ent which may throw doubts on priority claim(s) or is ofted to establish the publication date of another no rother special reason (as specified) ent referring to an oral disclosure, use, exhibition or	"Y" document of particular cannot be considered document is combined	ed after the intent of in conflict with the principle or the conflict with the principle or the conflict of th	the application but soon underlying the stailmed invention be considered to oument is taken alone salmed invention ventifies step when the we other such docur- us to a person skilled	

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/032149

### International Search Report

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

B. FIELDS SEARCHED

- Use Examination Results from the International Phase

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

PO-Internal RICCIC CHEM ARS Data WET Dat

X

Further documents are listed in the continuation of Box C



See patent family annex

- Special categoπes of cited documents
- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "P" document published prior to the international filing date but later than the priority date claimed

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- "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

X Further documents are listed in the continuation of Box C

X See patent family annex

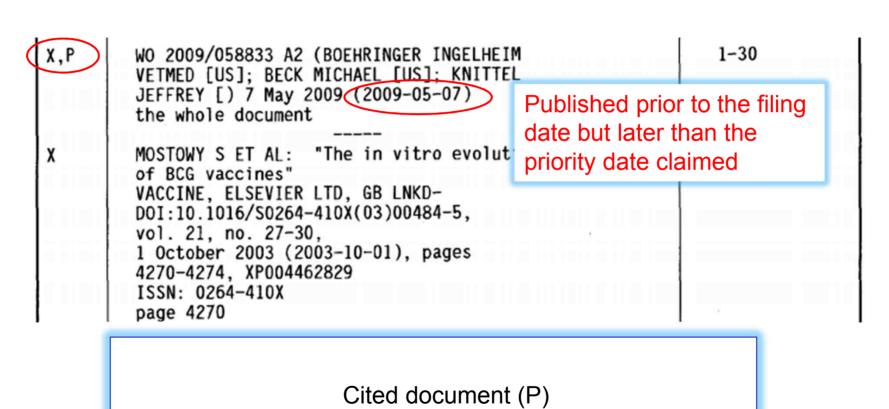
- Special categories of cited documents
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- "P" document published prior to the international filing date but later than the priority date claimed
- T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance, the claimed Invention cannot be considered to Involve an Inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
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Filing date

### International Search Report

- Use Examination Results from the International Phase

Priority date



### **Written Opinion of the ISA**: Report on Patentability

- Use Examination Results from the International Phase

	Box No. V Reasoned statemer industrial applicability; citations	nt und	er Rule 43 <i>b</i> explanations	is.1(a)(i) with regard to novelty, inventive step or supporting such statement
1.	Statement			
	Novelty (N)	Yes: No:	Claims Claims	<u>1-30</u>
	Inventive step (IS)	Yes: No:	Claims Claims	<u>1-30</u>
	Industrial applicability (IA)	Yes: No:	Claims Claims	1-30
2.	Citations and explanations			
	see separate sheet			

Reference is made to the following documents:

- D1 THORNS C J ET AL: "EFFECT OF SERIAL PASSAGES THROUGH LIQUID MEDIUM ON THE VIRULENCE OF MYCOPLASMA-BOVIS FOR THE MOUSE MAMMARY GLAND" RESEARCH IN VETERINARY SCIENCE, vol. 29, no. 3, 1980, pages 328-332, XP008124597 ISSN: 0034-5288
- D2 US 2009/068231 A1 (KUMAR MAHESH [US] ET AL) 12 March 2009 (2009-03-12)
- D3 WO 2009/058833 A2 (BOEHRINGER INGELHEIM VETMED [US]; BECK MICHAEL [US]; KNITTEL JEFFREY [) 7 May 2009 (2009-05-07)
- D4 MOSTOWY S ET AL: "The in vitro evolution of BCG vaccines" VACCINE, ELSEVIER LTD, GB LNKD- DOI:10.1016/S0264-410X(03)00484-5, vol. 21, no. 27-30, 1 October 2003 (2003-10-01), pages 4270-4274, XP004462829 ISSN: 0264-410X

### Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claims 21-30 relate to a subject-matter considered by this Authority to be covered by the provision of Rule 39.1(iv)/67.1(iv) PCT. The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for in a first or further medical treatment. (Although claims 21-30 are directed to a method of treatment of the human/

animal body, the search has been carried out and based on the alleged effects of the compound/composition).

Although D3 describes most of the content of the present application and its content falls within the scope of claims 1-30, the present opinion will be written in the assumption that the priority claimed is valid.

D1 discloses several avirulent *Mycoplasma bovis* strains which are attenuated by multiple serial passage (including one which is obtained by 138 passages). D4 discloses *M. bovis* strains which are attenuated by passaging them more than 110 times and maintain their immunogenicity.

In the view of the prior art, claims 1-6, 11, 19 and 21-23 lack novelty in the sense of Art. 33 (2) PCT, because they refer to any *M. bovis* strain which is attenuated by passaging more than 110 times and to features which are inherent to the strains (regardless of whether they are specifically mentioned in the prior art or not). This includes "having the same characteristics as the M. bovis bacteria strain deposited under accession number PTA-9666 (PTA9667)". Moreover, claims directed to products are only novel when the product is novel per se, the method by which the product was obtained does not render the product novel. This also applies to M. bovis strains being "any attenuated descendant M. bovis bacteria strains".

With respect to the method claims 7-10 there is nothing that makes them look novel with respect to the prior art except - once again- the enumeration of characteristics which are well known in the art.

Claims 12-18, 20 and 24-30 appear to be novel because they refer to products which have not been previously disclosed and, therefore, they comply with the requirements of Art. 33 (2) PCT. However, the person skilled in the art would not have needed inventive skill to arrive at the subject-matter of said claims departing from the teachings of the prior art and, consequently, they cannot be regarded as inventive.

D2 is regarded as the closest prior art because it also discloses attenuated *Mycoplasma* strains (also from the *bovis* species) which are obtained by mutiple serial passage.

The difference between the application and the closest prior art document D2 lies in the fact that ATTC Acc. No PTA-9666 is attenuated after a much higher number of passages.

The problem to be solved can be described as the further provision of attenuated *Mycoplasma bovis* strains.

The solution herein presented are ATTC Acc. No PTA-9666 and PTA-9667.

In the absence of any technical data regarding the attenuation and the immunogenicity of PTA-9667, this strain can only be regarded as an alternative solution lacking inventive step. On the contrary, in the view of the prior art the person skilled in the art would not have been prompted to attenuate *Mycoplasma bovis* with such a high number of passages, because he would have assumed that the bacteria would lose immunogenicity. However, in the absence of the essential technical feature *Mycoplasma bovis* ATTC Acc. No PTA-9666, the claims cannot be regarded as inventive (Art. 33(3) EPC), because for the same reason that this strain is inventive, any other strain attenuated by more than 110 passages cannot be regarded as sufficiently disclosed (Art. 5 PCT) and/ or as solving the technical problem (this includes PTA-9666 descendants).

#### Re Item VIII

### Certain observations on the international application

An independent claim must specify clearly all the essential technical features necessary to define the invention. In the present case *Mycoplasma bovis* ATTC Acc. No PTA-9666 is considered an essential technical feature which allows the clear and unambiguous characterisation of the products concerned and, moreover, it is a feature upon which the patentability of the present application may be found to be acknowledged. In the absence of the feature of ATTC Acc. No PTA-9666 in the independent claims, the requirements of clarity according to Article 6 PCT cannot be considered to be satisfied. The complete name of the genus is necessary in the independent claims in order to avoid confusion with other "*M. bovis*" (like, for ex. *Mycobacterium bovis*).

The expression "having the same characteristics as..." is not a true characterization, because such characteristics have not been previously defined, so it could simply be the characteristic of the attenuation, for example. Claim 2 is therefore unclear.

The terms "at least" and "more than" render the scope of the claims extremely broad and unclear (Art. 6 PCT).

In the view of the fact that claims 1-6 do not refer to any antigen, but to whole cells, claim 28 (and, consequently, its dependent claims) is unclear.

Drawing sheets 1-13 are not numbered (only the corresponding figures are numbered). However, from sheet 14 to the end they are all numbered. The numbering therefore contravenes the requirements of Art. 6 PCT.

The expresion "hereby incorporated by reference" and similar ones (for ex. page 13, I. 1) result in lack of clarity (Article 6 EPC).

### **Confirm Priority Documents**

## Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US2010/032149

International filing date: 23 April 2010 (23.04.2010)

Document type: Certified copy of priority document

Document details: Country/Office: US

Number: 61/172,543

Filing date: 24 April 2009 (24.04.2009)

Date of receipt at the International Bureau: 14 May 2010 (14.05.2010)

Remark: Priority document submitted or transmitted to the International Bureau in

compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse ✓ Important where "X, P" document is cited





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### 1. (WO2010124154) VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE ATTENUATION

Office	Entry Date	National Number	National Status
Australia	10.10.2011	2010238689	
Canada	13.10.2011	2758733	
China	23.04.2010	201080028660.0	
European Patent Office	10.11.2011	2010717367	Published: 29.02.2012 Granted: 05.04.2017
India	08.11.2011	8637/DELNP/2011	
Japan	21.10.2011	2012507405	
New Zealand	21.10.2011	595914	
Philippines		12011502165	Granted: 24.09.2015



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#### ← About European Patent Register Other EPO online services ▼ Register Alert login Advanced search About this file: EP2421556 EP2421556 European procedure Refine search 🔸 ST36 (2) Show history 🤻 Espacenet 🛱 Submit observations Print About this file Legal status EP2421556 - VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE ATTENUATION [Right-click to bookmark this link] Federated register Event history Status The patent has been granted Citations Status updated on 03.03.2017 Database last updated on 29.06.2017 Patent family Most recent event i 03.03.2017 published All documents (Expected) grant on 05.04.2017 > [2017/14] Applicant(s) For all designated states Quick help Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway → What happens if I click on the St. Joseph, MO 64506-2002 / US "XML" or "ST36" buttons? → What kind of information can be [2012/09] found if I click on the "Show history" button? 01 / BECK, Michael Inventor(s) → What kind of information can be Boehringer Ingelheim Vetmedica Inc. found under "Status"? 2621 North Belt Highway → What do the digits in square St. Joseph Missouri 64506 / US brackets refer to? → What does N/P stand for? 02 / KNITTEL, Jeffrey → What does the letter in square Boehringer Ingelheim Vetmedica Inc. brackets stand for in the 2621 North Belt Highway "Documents cited" part? St. Joseph Missouri 64506 / US → Is it possible to navigate in the A [2012/09] → What kind of information can be found under "Lapses during Representative(s) Simon, Elke Anna Maria, et al opposition"? Boehringer Ingelheim GmbH → What are validation states? Binger Strasse 173 → What are extension states? 55216 Ingelheim am Rhein / DE Maintenance news + [2012/40] News flashes Application number, filing date 10717367.6 23.04.2010 [2017/14] Related links + WO2010US32149 Priority number, date US20090172543P 24.04.2009 Original published format: US 172543 P [2012/09]

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https://register.epo.org/regviewer

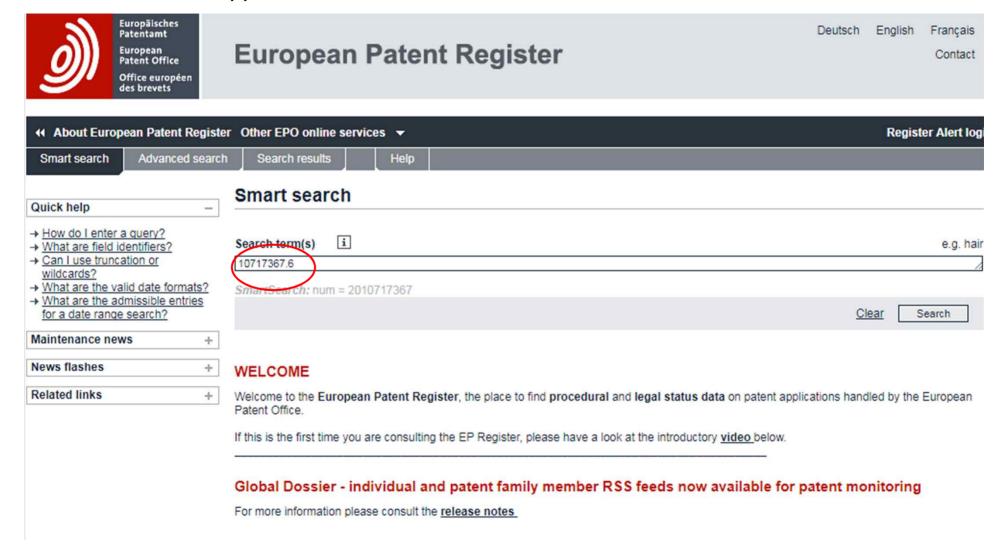
(Application No. 10717367.6 or Publication No. 2421556)

alternatively

https://worldwide.espacenet.com/singleLineSearch?locale=en\_EP

### https://register.epo.org/regviewer

Application No. 10717367.6





### **European Patent Register**

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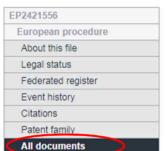
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P2421556	About this file: EP2	2421556			
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About this file	Refine search ↓ ST36	Show history > E	spacenet 🙋 Subm	t observations II Report error	Print
Legal status	EP 2421556 - VACCIN	JES COMPRISING AT	TENUATED MYC	OPLASMA BOVIS STRA	INS AND
Federated register	METHOD FOR THE AT			OI ENGINA BOVIO OTTO	INO AIND
Event history	Status				
Citations	Status	The patent has been gra Status updated on 03.03.201			
Patent family		Database last updated on 29.	06.2017		
All documents	Most recent event i	03.03.2017	(Expected) gran		ublished n 05.04.2017 > [2017/14
wick help – What happens if I click on the "XML" or "ST36" buttons?	Applicant(s)	For all designated states Boehringer Ingelheim Ve 2621 North Belt Highway St. Joseph, MO 64506-2	tmedica, Inc.		
What kind of information can be found if I click on the "Show		[2012/09]			
history" button? What kind of information can be found under "Status"? What do the digits in square brackets refer to?	Inventor(s)	01 / BECK, Michael Boehringer Ingelheim Ve 2621 North Belt Highway St. Joseph Missouri 645			
What does N/P stand for? What does the letter in square brackets stand for in the "Documents cited" part? Is it possible to navigate in the		02 / KNITTEL, Jeffrey Boehringer Ingelheim Ve 2621 North Belt Highway St. Joseph Missouri 645	C.		
result list?		> [2012/09]			
What kind of information can be found under "Lapses during opposition"? What are validation states? What are extension states?	Representative(s)	Simon, Elke Anna Maria Boehringer Ingelheim Gr Binger Strasse 173 55216 Ingelheim am Rhe	Hdm		
Maintenance news +		[2012/40]			
ews flashes +	Application number, filing date	9 10717367.6	23.04.2010		
elated links +		[2017/14]			
		WO2010US32149			
	Priority number, date	US20090172543P	24.04.2009	Original published format: US 172	543 P
	i nong namon, auto	5520000 1720401	27.07.2003	Original published format. GO 172	V-1-V-1

	Examination procedure	24.11.2011	Examination requested [2012/09]			
	5	18.06.2012	Amendment by applicant (claims and/or description)			
		02.10.2014	Despatch of a communication from the examining division (Time limit: MOR			
		27.03.2015	Reply to a communication from the examining division			
		24.04.2015	Despatch of a communication from the examining division (Time limit: M04			
		21.08.2015	Reply to a communication from the examining division			
		29.09.2016	Cancellation of oral proceeding that was planned for 04.11.2016			
		28.10.2016	Communication of intention to grant the patent			
		04.11.2016	Date of oral proceedings (cancelled)			
		20.02.2017	Fee for grant paid			
		20.02.2017	Fee for publishing/printing paid			
		20.02.2017	Receipt of the translation of the claim(s)			
	Divisional application(s)	The date of the Examining Division's first communication in respect of the earliest application for which a communication has been issued is 02.10.2014				
	Fees paid	Renewal fee				
		02.05.2012	Renewal fee patent year 03			
Get prior art		02.05.2013	Renewal fee patent year 04			
•		14.03.2014	Renewal fee patent year 05			
documents cited -		30.04.2015	Renewal fee patent year 06			
in the ISR		02.05,2016	Renewal fee patent year 07			
	Cited in	International search	[I] > US2009068231 (KUMAR MAHESH [US], et al) [I] 1-30 * paragraph [0011] * * paragraph [0039]; claims 1, 11, 38, 41 *;			
			[PX] MO2009058833 (BOEHRINGER INGELHEIM VETMED [US], et al [PX] 1-30 * the whole document *;			
			[XI] - THORNS C J ET AL, "EFFECT OF SERIAL PASSAGES THROUGH LIQUID MEDIUM ON THE VIRULENCE OF MYCOPLASMA-BOVIS FOR THE MOUSE MAMMARY GLAND", RESEARCH IN VETERINARY SCIENCE, (1980), vol. 29, no. 3, ISSN 0034-5288, pages 328 - 332, XP008124597 [X] 1 * table 1 * [I] 2-30			
			[XI] - MOSTOWY S ET AL, "The in vitro evolution of BCG vaccines", VACCINE, ELSEVIER LTD, GB LNKD- DOI:10.1016/S0264- 410X(03)00484-5, (20031001), vol. 21, no. 27-30, ISSN 0264-410X, page 4270 - 4274, XP004462829 [X] 1-6,11,19,21-23 * page 4270 * [I] 7-10,12- 18 20 24-30			

18,20,24-30

DOI: > http://dx.doi.org/10.1016/S0264-410X(03)00484-5

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		27.09.2016	Amended description with annotations	Search / examination	132
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### Annex to the Communication

New Matter in the Amendment?

#### Art. 123(2) EPC

- The amendments to the claims comply with Art. 123(2) EPC except for the following:
- 1.1 Page 2 and page 93 of the description as filed provide basis for an attenuated, avirulent *M. bovis* strain for use in a method of treatment and/or prophylaxis of infections cause by *M. bovis*. However, no basis was found for the wording "for use as a vaccine or as medicament" and, in consequence, claim 1 contravenes the provisions of Art. 123(2) EPC.
- 1.2 The application as filed does not provide basis for the text of claim 7 "for use in a method for the treatment or prophylaxis of infections caused by Mycoplasma bovis or for reducing the incidence and/or severity of clinical symptoms of Mycoplasma bovis infection". According to page 10 of the description, the text should read "for use in a method for the treatment or prophylaxis of infections caused by Mycoplasma bovis consisting of reducing the incidence and/or severity of clinical symptoms of Mycoplasma bovis infection". Moreover, the passages cited by the Applicant do not provide basis for "for use in the reduction of the incidence of euthanasia".

### **EP Register**

#### Annex to the Communication

#### Exceptions to patentability (Art. 53 [c] EPC)

- Claim 6(c) is directed to subject-matter covered by the provisions of Art. 53 (c) EPC and is therefore not patentable.
- 6. A method of attenuating Mycoplasma bovis, comprising,
  - c. testing the cultured Mycoplasma bovis bacteria obtained under step b) for their pathogenicity and immunogenicity, wherein the immunogenic testing comprises:
    - A) infecting cattle with the passaged Mycoplasma bovis bacteria; and

      B) monitoring the development of the humoral antibody response against

      Mycoplasma bovis in the infected cattle; and

#### Novelty (Art. 54 EPC)

- 3 Claims 1-5 and 7-20 are novel in the sense of Art. 54 EPC.
- 3.1 Claim 6 is not regarded as novel over D1, since the latter also discloses a method for attenuating *Mycoplasma bovis* consisting of passaging the bacterial strains more than 110 times.

### **EP Register**

Inventive step (Art. 56 EPC) and sufficiency of disclosure (Art. 83 EPC)

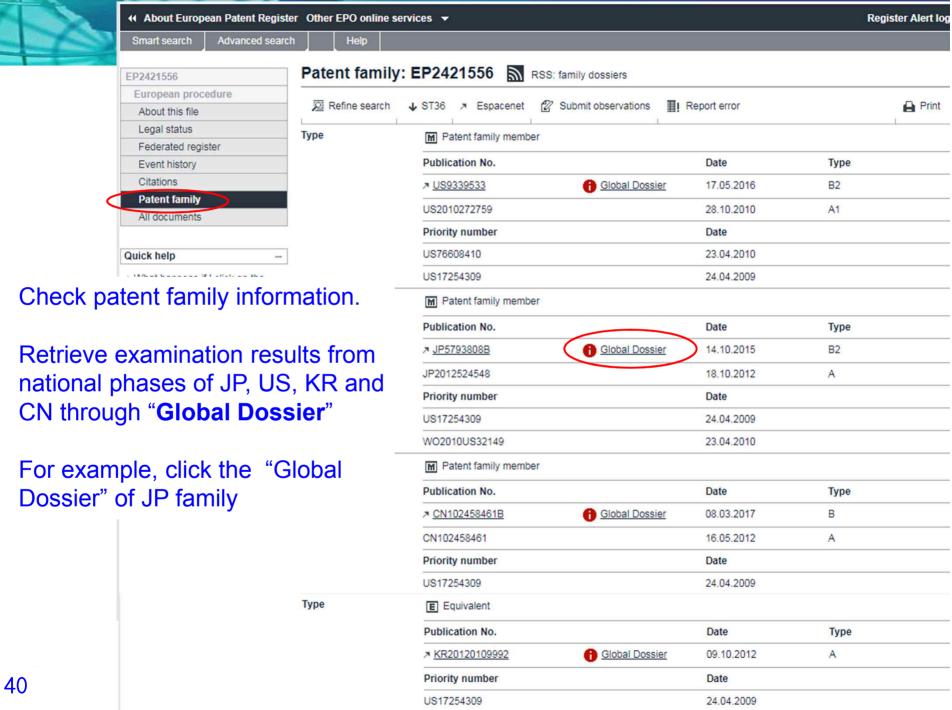
- Annex to the Communication
- As already stated in the WOISA, the prior art teaches away from using an attenuated *Mycoplasma bovis* obtained by more than 110 passages for a method of prevention and/or therapy of *Mycoplasma bovis* infection. Consequently, the subject-matter of claims 1-5 and 7-20 is not obvious over the prior art. However, following the same reasoning it cannot be stated that any *Mycoplasma bovis* strain attenuated by more than 110 passages will retain its immunogenicity and, therefore, the claims cannot be regarded as solving the problem over their entire scope (Art. 56 EPC) nor as sufficiently disclosed (Art. 83 EPC). This reasoning also applies (would apply) to claims directed to the strain PTA-9667 because of the absence of technical data showing the attenuation and the immunogenicity of said strain.
- 4.1 Therefore, the Applicant is kindly requested to restrict the claims to the attenuated *Mycoplasma bovis* strain PTA-9666 in order to obtain a set of claims allowable under articles 56 and 83 EPC.
- In addition to the above, claims 2-4, 7 and 18 refer to reduction of euthanization rate or reduction of incidence of euthanasia. Given that euthanasia is a man-controlled process, no immunogenic composition can be regarded as solving such a problem, because it cannot be asserted that if a vaccine is successful the number of euthanised animals will decrease. It is current practice to euthanasize laboratory animals that have been used for a particular test even if they have survived a challenge and, therefore, the rate of euthanasization -unlike the mortality rate- cannot be regarded as something that is directly linked with a successful or unsuccessful vaccination. This subject-matter should therefore be removed in order to fulfil the requirements of Art. 56 EPC.

### **EP** Register

#### Clarity (Art. 84 EPC)

#### Annex to the Communication

- Guidelines FIV, 4.5.2, state that an independent claim must specify clearly all the essential technical features necessary to define the invention. In the present case the attenuated *Mycoplasma bovis* strain PTA-9666 is considered to be an essential technical feature upon which the patentability of the present application may be found to be acknowledged. Accordingly, said feature must be incorporated into the independent claims in order to satisfy the requirements of clarity according to Article 84 and Rule 43(1) EPC and to allow the clear and unambiguous characterisation of the products concerned.
- 5.1 Claim 1 is no longer a product claim but a claim directed to a "product for use". Claims 2-5 and 7-20 should be amended to recite "for use" for consistency (for ex. claim 2 should read "The attenuated, avirulent Mycoplasma bovis bacterium strain for use according to claim 1".
- The above reasoning applies to claims which depend on and/or refer to claim7.
- 5.3 Claim 17 appears redundant in the view of the preceding claims.
- 5.4 Claim 19 appears redundant in the view of the preceding claims.
- 5.5 The term preferably (claim 8) is not limiting and, moreover, it introduces ambigüity regarding the actual scope of the claim.
- 5.6 Claim 17 refers to the reduction of signs of Mycoplasma bovis infection and to the reduction of the severity of or incidence of clinical signs of Mycoplasma bovis infection. Given that one comprises the other (the reduction of the severity of or incidence of clinical signs is comprised in the reduction of signs), the fact that both features are recited in the claim results in lack of clarity.



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25.08.2014	Notification of Reasons for Refusal (TRANSLATED)	-1
16.04.2013	Request for Examination (ORIGINAL)	-1





Application number: Patent Application No. 2012-507405

Date of Drafting: Heisei 26(2014) August 19 Patent examiner: KODA, Toshiki 4671 4N00

Representative/Applicant: TSUJII, Koichi (and 6 others) Applied Provisions: Article 29(1), Article 29(2), Article 36

This application should be refused for the reason that the following Reason. If the applicant has any argument against the reason, please submit a Written Argument within three months after the day of dispatch of this notification.

Reason

## Reasons for Refusal by JPO examiner

Reason 1 The claimed invention(s) in the each claim listed below of this patent application should not be granted a patent under the provision of Patent Law Article 29 (1)(iii) for the reason that the claimed invention(s) has/have been deemed to be identical with the invention(s) described in the distributed publication(s) listed below or made available to the public through electric telecommunication lines in Japan or other foreign countries prior to the filing of the patent application.

Reason 2 The claimed invention(s) in the each claim listed below of this patent application should not be granted a patent under the provision of Patent Law Article 29 (2) for the reason that the claimed invention(s) could have easily been made by persons who have common knowledge in the technical field to which the claimed invention(s) pertains, on the basis of the invention(s) described in the distributed publication(s) listed below or made available to the public through electric telecommunication lines in Japan or other foreign countries prior to the filling of the patent application. Reason 3 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(4)(i) in terms of the item(s) listed below regarding the statement of the detailed explanation of the invention.

Reason 4 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(6)(i) in terms of the item(s) listed below regarding the statement of the scope of claims.

Reason 5 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(6)(ii) in terms of the item(s) listed below regarding the statement of the scope of claims.

Note (See the list of cited documents etc., below.)

- Reason: 1, 2

- Claim: 1-3, 7-8, 11, 14-16, 19-21, 26 - Cited Documents: 1

## Reasons for Refusal by JPO examiner

#### 1. Novelty

#### - Remarks:

The place which inoculated into the mouse mammary gland the inoculation material which contains in cited document 1 stock 10 6.1 \*\* which carried out the 138-generation \*\* cost of the Mycoplasma bovis stock five M192 to E culture medium of 0.1mL, A systemic reaction (Systemic response) is that a neutrophil response (Neutrophil response) is shown although not shown. [ that the stock by which \*\* cost was carried out by the liquid medium repeatedly loses the susceptibility over a mouse mammary gland, and the stock which lost the susceptibility concerned 1 M. It is described that it may lead to the elucidation of the onset-of-a-disease mechanism of a bovis mastitis, and may be connected with the stable vaccine against a mastitis by extension (especially). Refer to the 328th page 'Mouse inoculation' column, 329th page TABLE 1, the 332nd page right column lines 9-11, and the 332nd page right column lines 28-32. . Although susceptibility is lost by \*\* cost having been carried out 110 times or more, here, [ the M. bovis stock described in cited document 1 ] In that it is maintaining, immunogenicity has the same characteristics as the stock deposited by accession number PTA-9666 and PTA-9667, and cannot distinguish them from a posterity attenuation [ of these deposition stock ] M. BOBISU bacteria stock. Therefore, the invention concerning Claims 1-3 and 7-8, 11, 14-16, 19-21, and 26 could have been invented by a person skilled in the art on the basis of the well-known art in the description of cited document 1, and the field concerned even if it cannot distinguish from the invention described in cited document 1 and there is a distinguishable part.

#### Reasons for Refusal by JPO examiner

#### 2. Inventive Step

Reason: 2Claim: 1-30

- Cited Documents: 1-2

Remarks:

The contents described in cited document 1 are as above-mentioned. The Mycoplasma bovis stock attenuated by \*\* cost to cited document 2, The antigen of other virus origin in which it is known that it is a pathogenic organ of a cow, the adjuvant, and the vaccine containing a medically permissible additive agent are described (see claim1, [0012], and [0020] especially.). Since both cited document 1-2 are document about the attenuated M. bovis stock, the antigen of other virus origin by the M. bovis stock attenuated by \*\*\*\*, and suitable age — mixing with a band or an additive agent, manufacturing a vaccine, and medicating animals, such as a cow, with an adequate amount is that the person skilled in the art easily conceived. And it cannot be said that the prominent effect which a person skilled in the art cannot predict was produced by having made it such.

The list of cited documents etc.

- 1. Res. Vet. Sci., 1980, and Vol.29 and pp.328-32
- 2. By restriction of the US,2007/0077260,A Description (notes) law or a contract, some or all of nonpatent literatures that was shown may not be sent.

#### Reasons for Refusal by JPO examiner

3. Sufficiency of Disclosure (Enablement)

#### - Reason: 3

"The attenuation M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9666" described in Claim 2, Or about "the attenuation M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9667" described in Claim 3, since the copy of the trust certificate is not submitted, it cannot check that a person skilled in the art is available. Therefore, the detailed description of the invention of this application is described neither clearly nor sufficiently as to enable a person skilled in the art to work the invention in Claims 2-3.

#### Reasons for Refusal by JPO examiner

#### 4. Sufficiency of Disclosure/ Support in Description

- Reason: 3, 4

"It described in Claim 2 Any attenuation which has the same characteristics as M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9666, The specific description of an working example etc. is not shown about acquiring such an M. BOBISU bacteria stock to the detailed description of the invention about a nonpathogenic M. BOBISU bacteria stock." Although it is not clear, as pointed out also by following "Reason 5" (1), [ what kind of characteristics are included in "the same characteristics" ] The place accepted that "new M. BOBISU strain which has the mutatic which PTA-9666 has" is contained in the M. BOBISU bacteria stock, If the technical common sense in the field concerned that it is difficult for mutation to occur at random on a genome and to induce mutation in the specific part of a genome artificially is taken into consideration. It cannot say that it is clear that such a new M. BOBISU strain is acquirable by the trial and error within the within the scope which can usually be expected from a person skilled in the art, in view of the technical common sense in the field concerned. Therefore, the detailed description of the invention of this application is described neither clearly nor sufficiently as to enable a person skilled in the art to work the invention in Claim 2.

The same reason for refusal exists also about Claims 3-6 and 11-30. The invention which relates to Claims 2-6 and 11-30 for the same Reason is not what was described in the detailed description of the invention.

#### Reasons for Refusal by JPO examiner

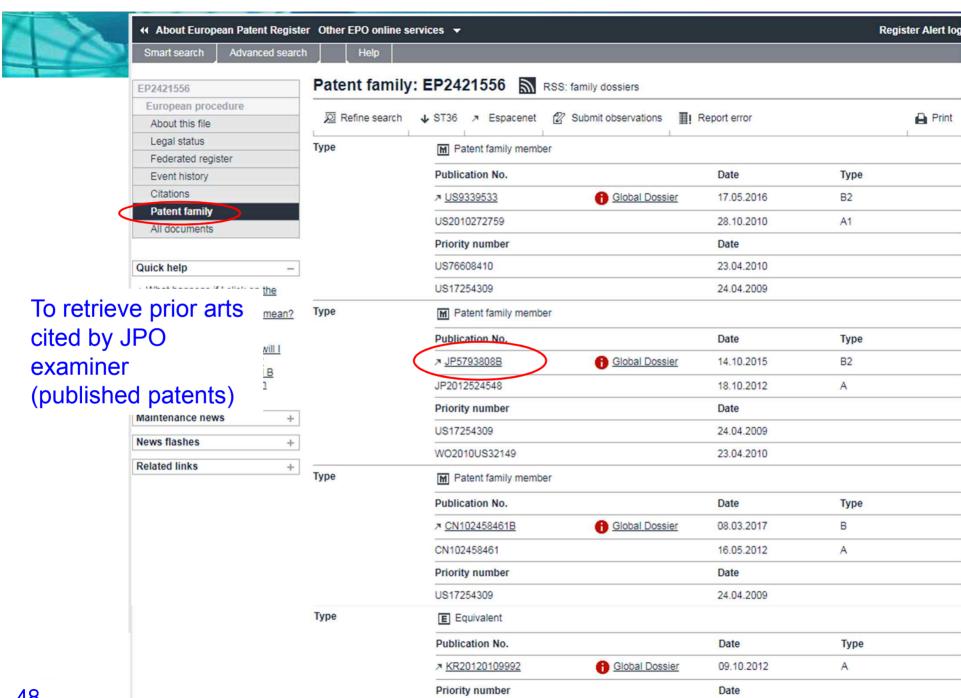
5. Clarity (Indefiniteness)

#### - Reason: 5

(1), [ which was described in 6 / the Claims 2-3 and / the "any attenuation / which has the <u>same characteristics</u> as M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9666/PTA-9667 / M. BOBISU bacteria stock" ] Since it is not clear in what kind of characteristics are included in "the same characteristics", it cannot be judged whether it has the same characteristics as "M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9666/PTA-9667" about any attenuation M. BOBISU bacteria stock. Therefore, The claimed invention in Claims 2-3 and 6 is not clear.

(2) Since "the <u>aforementioned</u> attenuation and the nonpathogenic M. BOBISU stock" of Claim 20 are not clear in where is pointed out, please correct in "attenuation of a <u>description in any 1 item of Claim 1 to 6</u>, a nonpathogenic M. BOBISU stock", etc.

(3) It is admitted that "M. BOBISU antigen of a description in any 1 item of Claim 1 to 6" of Claim 28 is an erroneous description of "attenuation of a description in any 1 item of Claim 1 to 6 and a nonpathogenic M. BOBISU stock."

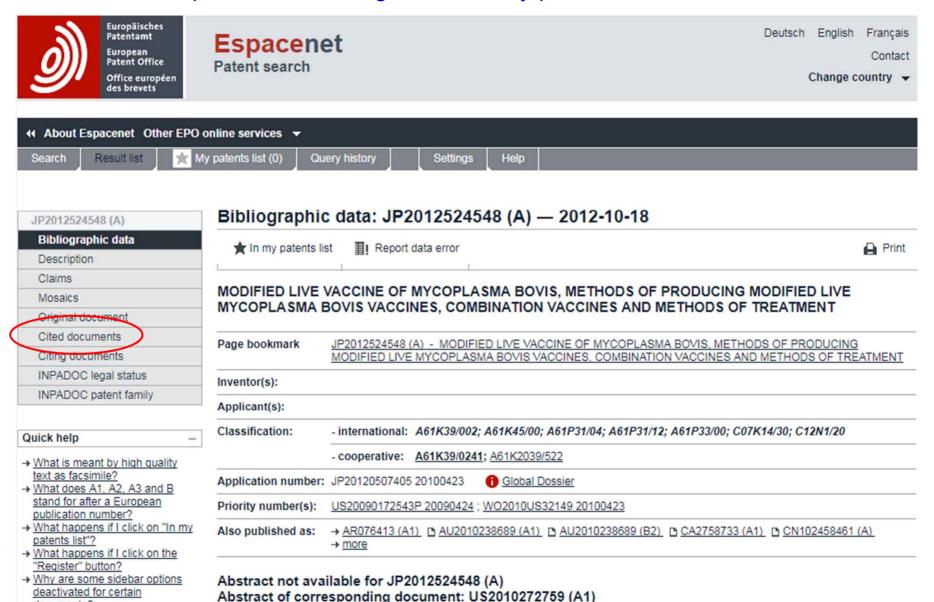


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24.04.2009

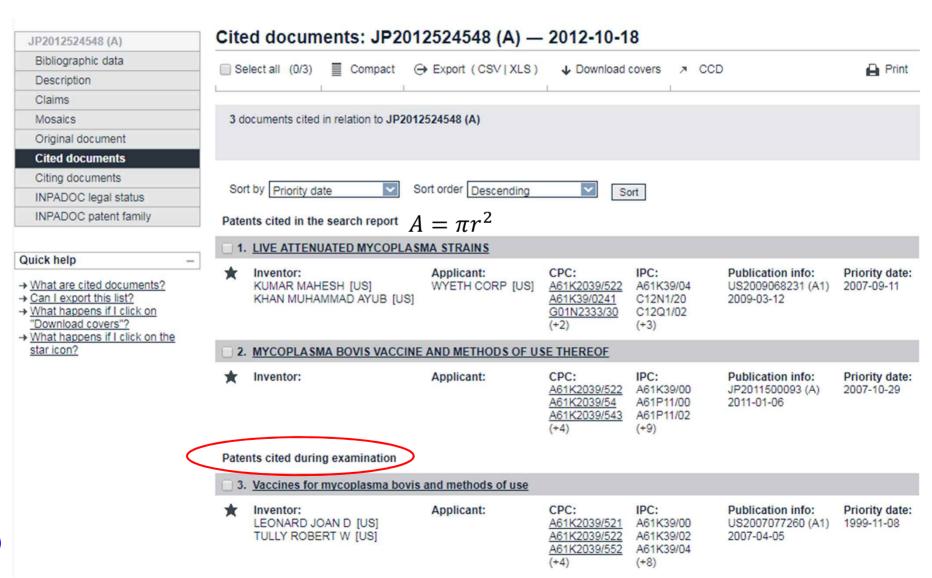
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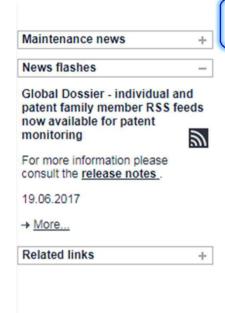
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- Final Office Action
  - ~ Notification of Reasons for Refusal (non-final)
  - Notice of Final Rejection ~ Final Rejection

Sending number: 9-5-2015-073354093

Dispatched date: 2015.10.24. Submission due 2015.12.24.

date:

#### YOUR INVENTION PARTNER

#### KIPC

#### Notification of Reason for Refusal

pplicant. Name. ANTICANCER, INC.(applicant code: 520020217473)

Address. Secure Information

jent. Name, Yong-Ho Moon Address, Secure Information

ventor. Name. AMo YaSuYuKi
AddresSecure Information

plication No. 10-2009-7006423

tle of Invention The rapid in vivo model for the vascularization.

Because of having the reason for refusal like the examination result next about this oplication and notifying of this according to the article 63 of Patent Act in case it has the pinion or the correction is needed or it wants opinion (the reply, and the Written Reply) submit the Amendment [form of attached document No.9 of Enforcement Regulation of atent Act]. 2. In the case to extend the submission due date (2015.12. 24.), the due date submission of the can be extended through the request for an extension of designated griod to 4 month. In this case, request for the extension has to decide to 1 month unit. Ind 2 month or greater is summed up in the need in the range that may not exceed 4 month and it can request the extension. The Written Substantiation describing the proprietary is additionally attached in the time for to postponing the designated period to the generation (the guideline reference of the lower part) of the inevitable proprietary in excess of 4 month and request for the extension has to be applied.

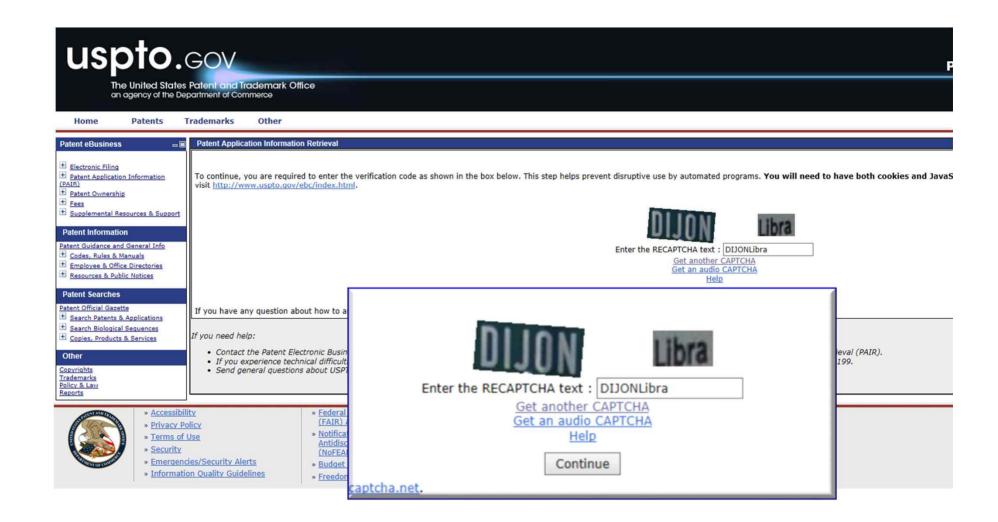
[Examination result]
□Subject of examination claim:
1st to 5th, 6, 8, 9, 10, 11, 13, 14, 15 claim.
☐ The law articles in connection with the part in which it has the reason for refusal of this application.
The part related law articles in which it has the sequence numbe reason for refusal.
1
Claim preceding clause.
Patent Act article 42(4)(1).
2
Claim preceding clause.
Article 32 of Patent Act.

### Using Publicly available websites

### Search the Examination Results from Other National Phase

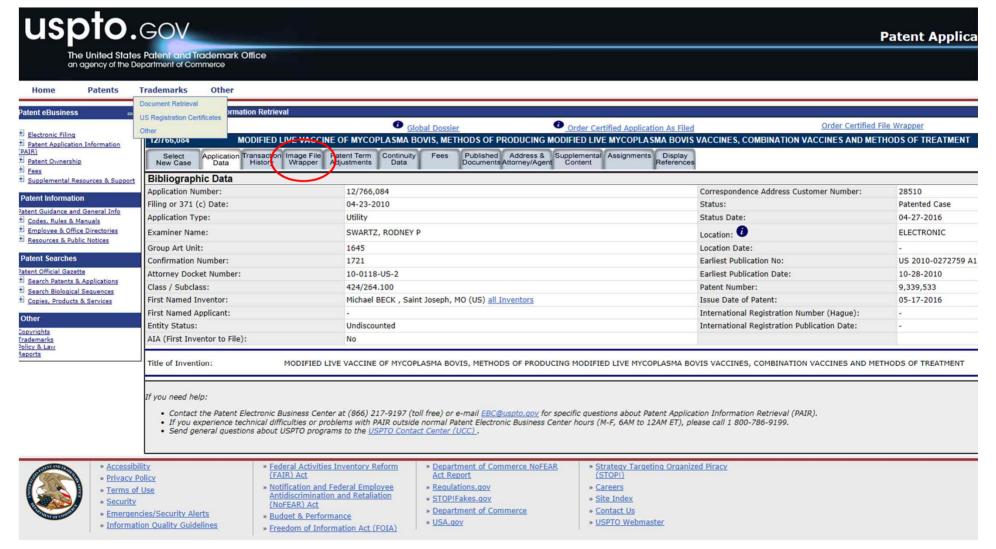
2. USPTO

https://portal.uspto.gov/pair/PublicPair



Publication No.: US 2010-0272759 A1

Search for Application:	
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	O Control Number
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	Publication Number
	O International Design Registration Number (EXAMPLE: DM/999999)
* Enter number:	US 2010-0272759 A1 SEARCH



#### Image File Wrapper: to retrieve all documents during USPTO prosecution

12/766,084 MODIF	FIED LIVE VACCINE OF MYCOPLASMA	A BOVIS, METHODS OF PRODUCING MODIFIED LIVE MYCOPLASMA BOVIS VACCINES, COMBINATION VACCIN	ES AND METHODS OF TREATMENT 10-0118-US-2	
Select Application Transa New Case Data Hist	action Image File Patent Term Continu	uity Fees Published Address & Supplemental Assignments Display Documents Attorney/Agent Content References		
s application is officially mair	ntained in electronic form. To View: Clic	k the desired Document Description. To Download and Print: Check the desired document(s) and click Start Download	d.	
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Mail Room Date ↓↑	<b>1</b> Document Code ↓↑	Document Description 🕩	<b>∂</b> Document Category ↓↑	Page Count ↓↑ □
1-27-2016	ISSUE.NTF	Issue Notification	PROSECUTION	1
4-05-2016	IFEE	Issue Fee Payment (PTO-85B)	PROSECUTION	1
1-05-2016	WFEE	Fee Worksheet (SB06)	PROSECUTION	2
4-05-2016	N417	EFS Acknowledgment Receipt	PROSECUTION	2
I-08-2016	NOA	Notice of Allowance and Fees Due (PTOL-85)	PROSECUTION	7
1-08-2016	SRFW	Search information including classification, databases and other search related notes	PROSECUTION	2
1-08-2016	BIB	Bibliographic Data Sheet	PROSECUTION	1
1-08-2016	FWCLM	Index of Claims	PROSECUTION	1
1-08-2016	IIFW	Issue Information including classification, examiner, name, claim, renumbering, etc.	PROSECUTION	3
2-14-2015	RCEX	Request for Continued Examination (RCE)	PROSECUTION	3
2-14-2015	WFEE	Fee Worksheet (SB06)	PROSECUTION	2
2-14-2015	N417	EFS Acknowledgment Receipt	PROSECUTION	2
2-14-2015	136A	Authorization for Extension of Time all replies	PROSECUTION	2
-20-2015	A.NE	Response After Final Action	PROSECUTION	1
1-20-2015	XT/	Extension of Time	PROSECUTION	1
1-20-2015	CLM	Claims	PROSECUTION	5
1-20-2015	REM	Applicant Arguments/Remarks Made in an Amendment	PROSECUTION	2
1-20-2015	WFEE	Fee Worksheet (SB06)	PROSECUTION	2
1-20-2015	N417		PROSECUTION	2
1-20-2015	WFEE	Mon Final Poinction	PROSECUTION	1
1-16-2015	CTAV	Non-Final Rejection	PROSECUTION	7
1-16-2015	ANE.I		PROSECUTION	1
1-16-2015	SRFW	Search information including classification, databases and other search related notes	PROSECUTION	2
1-16-2015	BIB	Bibliographic Data Sheet	PROSECUTION	1
1-16-2015	FWCLM	Index of Claims	PROSECUTION	1
0-30-2015	A.NE	Response After Final Action	PROSECUTION	1
0-30-2015	XT/	Extension of Time	PROSECUTION	1
0-30-2015	CLM	Claims	PROSECUTION	6
0-30-2015	REM	Applicant Arguments/Remarks Made in an Amendment	PROSECUTION	1
0-30-2015	WFEE	Fee Worksheet (SB06)	PROSECUTION	2
0-30-2015	N417	EFS Acknowledgment Receipt	PROSECUTION	2
0-30-2015	WFEE	Fee Worksheet (SB06)	PROSECUTION	1
-15-2015	CTAV	Advisory Action (PTOL-303)	PROSECUTION	7
-15-2015	ANE.I	Amendment After Final or under 37CFR 1.312, initialed by the examiner.	PROSECUTION	1
-15-2015	SRFW	Search information including classification, databases and other search related notes	PROSECUTION	2
)-15-2015	BIB	Bibliographic Data Sheet	PROSECUTION	1
)-15-2015	FWCLM	Index of Claims	PROSECUTION	1
9-14-2015	ANE	Response After Final Action	PROSECUTION	1
9-14-2015	CLM	Claims	PROSECUTION	5

Application/Control Number: 12/766,084

Page 2

Art Unit: 1645

#### DETAILED ACTION

This Office is responsive to Applicant's amendment and response filed on 10-8-2012. Claims 1-35 are pending. Claims 6-8, 17-26, 30-35 are withdrawn from consideration. Claims 1-5, 9-16, and 27-29 under examination.

#### Election/Restrictions

Applicant's election without traverse of claims 1-5, 9-16, and 27-29 in the reply filed on 10/8/2012 is acknowledged.

Claims 6-8, 17-26, 30-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claims 6-8 (Group II), claim 17 (Group III), claims 18-26 and 30-34 (Group IV), claim 35 (Group V), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 10/8/2012.

#### Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

#### Sequence Requirements

- a) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 for the reason(s) set forth below. Full compliance with the sequence rules is required in response to this office action.
- The drawings (see Figure 8) are without the requisite sequence identifiers. The drawings must be amended to recite SEQ ID NOs to be in sequence compliance.

### Non-Final Rejection

### Using Publicly available websites

# Search the Examination Results from Other National Phase

3. JPO

https://aipn.j-platpat.inpit.go.jp/AI2/cgi-bin/AIPNSEARCH

(Input 2012-524548)

### AIPN of JPO

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#### Search from JAPANESE Application/Priority/Publication/Patent Number

Type A: Publication of unexamined patent application				
Document Number 2012-524548				
Display Type    File Wrapper Information    Patent Family				
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#### Search from OTHER Application/Priority Number

Application Priority N	on Number e.g. US-2015-0001 lumber	2X
	3 technical dictionaries in order	of priority.
Dictionary1	Select Dictionary	~
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Dictionary3	Select Dictionary	

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### AIPN of JPO









#### Patent application number 2012-507405

File Wrapper Document List - Click document title to display contents. The dates in the list are shown in the format of "dd.mm.yvvv"

- Application data and Transaction history
- 1. 21.10.2011: National Entry Form
- 2. 21.12.2011: Written Submission of Translation of International Application
- -- . -- . --- : -- Description
- -- , -- , ---- : -- Sequence listing
- -- . -- . : -- Claims
- -- . -- . --- : -- Abstract
- -- . -- . --- : -- Drawings
- 3. 15.03.2012: Written Notice of Determination of Application Number
- 4. 16.04 2013: Request for Examin.
- 5. 16.04.2013: Written Amendment
- 6. 25.08.2014: Notification of Reasons for Refusal
- 7. 19:11.2014: Request for Term Extension
- 8. 19.11.2014: Request for Term Extension
- 9. 19.11.2014: Request for Term Extension
- 10. 25.02.2015: Written Argument
- 11. 25.02.2015: Written Amendment
- 12. 15.07.2015: Decision to Grant a Patent
- 13. 04.01.2012: International Publication
- 14. 04.01.2012: International Search Report
- 04.01,2012: Drawings in International Publication in a language other than Japanese (Ex Officio)
  - -- . -- . --- : -- Drawings
- 16. 04.01.2012: Sequence listings of International Publication in a language other than Japanese (Fx Officio)
  - -- . -- . --- : -- Sequence listing
- 17. 04.01.2012: International Preliminary Report on Patentability(I)
- 18. 04.01.2012: Priority Documents
- 04.01.2012: Representative drawing of International Publication in a language other than Japanese (Ex Officio)

-- . -- : -- Drawings

#### Notification of Reasons for Refusal

Application number Patent Application No. 2012-507405

Date of Drafting: Heisei 26(2014) August 19 Patent examiner: KODA, Toshiki 4671 4N00

Representative/Applicant: TSUJII, Koichi (and 6 others)
Applied Provisions: Article 29(1), Article 29(2), Article 36

This application should be refused for the reason that the following Reason. If the applicant has any argument against the reason, please submit a Written Argument within three months after the day of dispatch of this notification.

Reason

Reason 1 The claimed invention(s) in the each claim listed below of this patent application should not be granted a patent under the provision of Patent Law Article 29 (1)(iii) for the reason that the claimed invention(s) has/have been deemed to be identical with the invention(s) described in the distributed publication(s) listed below or made available to the public through electric telecommunication lines in Japan or other foreign countries prior to the filling of the patent application.

Reason 2 The claimed invention(s) in the each claim listed below of this patent application should not be granted a patent under the provision of Patent Law Article 29 (2) for the reason that the claimed invention(s) could have easily been made by persons who have common knowledge in the technical field to which the claimed invention(s) pertains, on the basis of the invention(s) described in the distributed publication(s) listed below or made available to the public through electric telecommunication lines in Japan or other foreign countries prior to the filing of the patent application.

Reason 3 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(4)(i) in terms of the item(s) listed below regarding the statement of the detailed explanation of the invention.

Reason 4 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(6)(i) in terms of the item(s) listed below regarding the statement of the scope of claims.

Reason 5 This patent application does not fulfill the requirement of the provision of Patent Law Article 36(6)(ii) in terms of the item(s) listed below regarding the statement of the scope of claims.

Note (See the list of cited documents etc., below.)

- Reason: 1, 2
- Claim: 1-3, 7-8, 11, 14-16, 19-21, 26 Cited Documents: 1

Examination Results are the same as those retrieved from the **Global Dossier** of the EPO Register

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4. KIPO

http://eng.kipris.or.kr/enghome/main.jsp

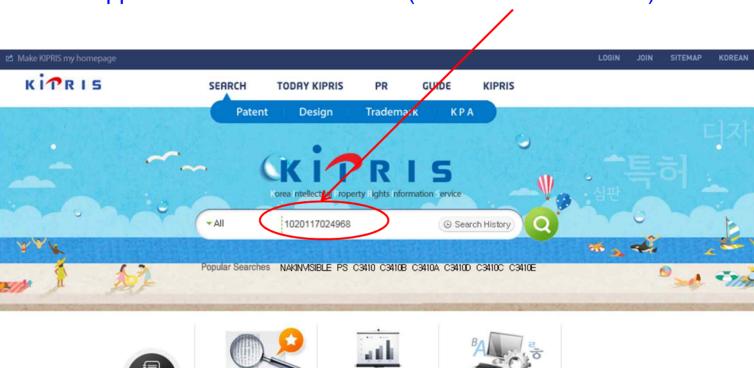
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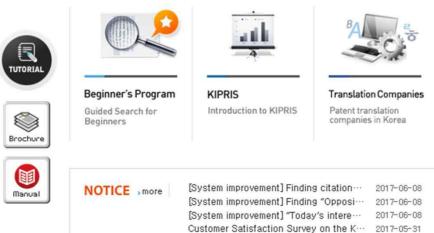
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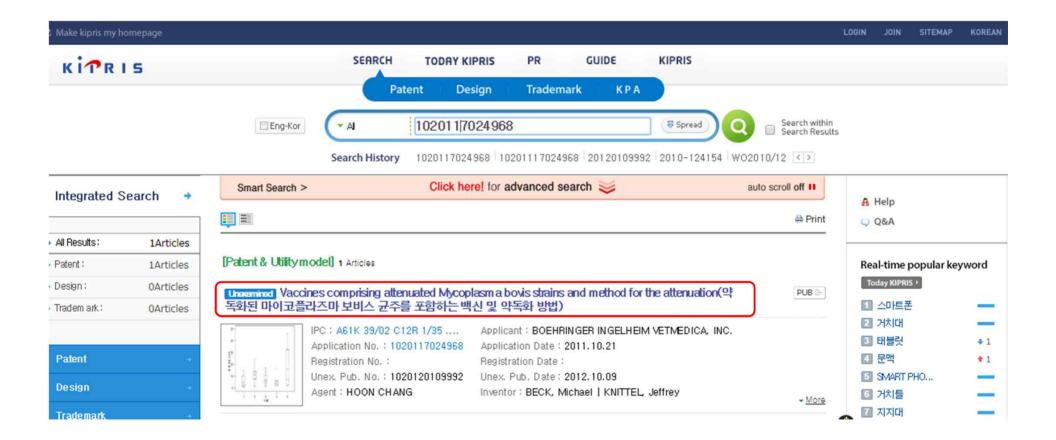
#### Bibliographic data: KR20120109992 (A) — 2012-10-09 In my patents list Report data error Print VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE **ATTENUATION** Page bookmark KR20120109992 (A) - VACCINES COMPRISING ATTENUATED MYCOPLASMA BOVIS STRAINS AND METHOD FOR THE ATTENUATION Inventor(s): BECK MICHAEL [US]: KNITTEL JEFFREY [US] + Applicant(s): BOEHRINGER INGELHEIM VETMED [US] + Classification: - international: A61K39/02 - cooperative: A61K39/02; A61K39/0241; A61K39/12; A61K39/39; C12N1/20; C12R1/35; A61K2039/522; A61K2121/00 → more Application number: KR20117024968 20100423 Global Dossier Priority number(s): US20090172543P 20090424 Also published as: → AR076413 (A1) □ AU2010238689 (A1) □ AU2010238689 (B2) □ CA2758733 (A1) □ CN102458461 (A)

- Application Number: KR20117024968
- Add "10" for Patent and "20" for Utility model in place of KR
   → 1020117024968





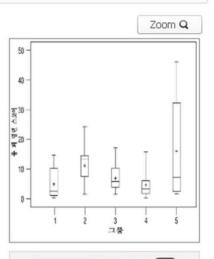




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### Vaccines comprising attenuated Mycoplasma bovis strains and method for the attenuation 약독화된 마이코플라즈마 보비스 균주를 포함하는 백신 및 약독화 방법

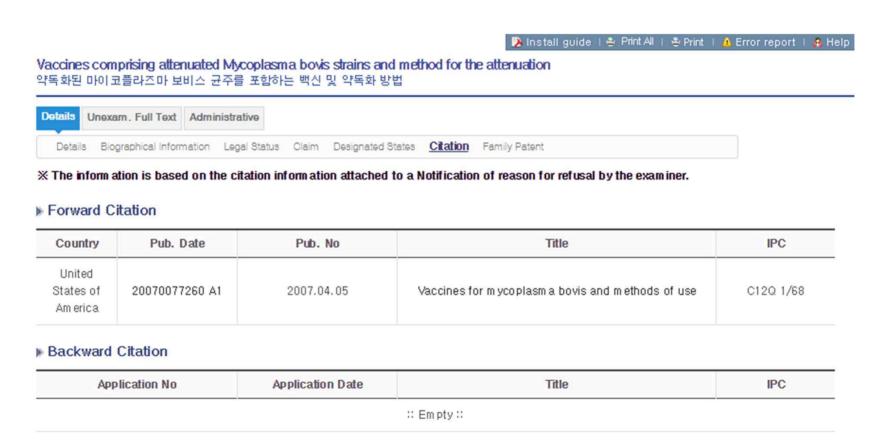
Details Unexam. Full Text Adminis	trative	
<u>Details</u> Biographical Information	Legal Status Claim Designated States Citation Family	y Pa
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(52) CPC <b>@</b>	A61K 39/0241(2013.01) C12R 1/35(2013.01) C12N 1/20(2013.01) A61K 2039/522(2013.01) A61K 2121/00(2013.01) A61K 39/02(2013.01) A61K 39/12(2013.01) A61K 39/39(2013.01)	40 20 20 20 20 20 20 20 20 20 20 20 20 20
(21) Application No. (Date)	1020117024968 (2011.10.21)	nfo.
(71) Applicant	BOEHRINGER INGELHEIM VETMEDICA, INC.	10
Translation submission Date	(2011.10.21)	0
(11) Registration No. (Date)		
(65) Unex. Pub. No.(Date)	1020120109992 (2012.10.09) Full-doc Down 🔊	
(11) Publication No. (Date)		
(86) Int'l Application No. (Date)	PCT/US2010/032149(2010.04.23)	
(87) Int'l Unex. Pub. No. (Date)	WO2010124154(2010.10.28)	
(30) Priority info. (Country / No. / Date)	US(미국)   61/172,543   2009.04.24	
Legal Status	Unexamined	
Examination Status		
Trial Info		
Kind/Right of Org. Application	international Application /	
Right of Org. Application No.(Date)		
Related Application No.		
Request for an exam ination(Date)	N	
Number of examination claims	30	



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🧧 [미국] Vaccines for mycoplasma bovis and methods of use (사용의 보비스 마이코플라즈마와 방법을 위한 백신)

D2

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(13) 구분	A1 국기별 특허문전코드			
(11) 등록번호 <b>/</b> 일자				
(65) 공개번호/일자	20070077260 (2007.04.05)			
(21) 출원번호/일자 11489147 (2006.07.18)				
(71) 출원인	No Image			
(30) 우선권번호(Priority No.)				
(51) IPC(Int. Ct.)				
(52) UPC(U.S. CL)	424/264100 435/006000			
(*) CPC	A61K39/0241 A61K2039/521 A61K2039/522			
	A61K2039/552 A61K2039/555 A61K2039/55505 A61K2039/55566	크게보기 Q		
(58) Field of Search		(uno)		
(86) 국제출원번호(PCT No.)		C UPLEAN F E		

#### (57) 요약(Abstract)

(87) 국제공개번호(PCT Pub No.)

The invention of novel, effective vaccines against Mycoplasma bovis for use in cattle is described. These vaccines demonstrate no undesirable side effects and protect against M bovis related disease, such as contagious mastitis, respiratory pneumonia, joint infections, keratoconjunctivitis and middle ear infections. The novel vaccines also lessen the effect of M. bovis infections on milk production, weight gain and animal health. Methods of diagnosing, characterizing and treating M. bovis infections as specific biotypes are also disclosed. Vaccine compositions made in accordance with the invention may be either of the attenuated or inactivated variety. Vaccines may also include antigens from other pathogens so as to provide a protective immunogenic response to diseases

#### ※ 묘약 자동번역

Mycoplasm a에 대한 신규의, 유효 백신의 본 발명 보비스 축우에 사용하기 위해 기술된다. 이러한 백신은 전염성인 유선염, 호흡의 폐렴, 관절 감염, 각막 결막염과 중이 감염과 같은, 어떤 바람직하지 않은 사이드 효과도 증명하지 않고, M. 보비스 관련 질병에 대하여 보호한다. 신규 백신은 또한 우유 생산, 무게 증가 및 동물 건강 위의 M. 보비스 전염의 영향을 소감된다. 특정한 유전인자형으로서 M. 보비스 전염을 진단하고 특징짓고 처리하는 방법은 또한 기술된다. 본 발명에 따른 만든 백신 조성물은 감쇠된 또는 불활성화된 버라이어티의 어느 쪽일 수 있다. 백신이 보호하는 면역원성 반응을 M.로 인한 것인 그것들을 제외한 질병으로 제공하기 위해 또한 다른 병원균으로부터의 항원 포함할 수 있다 보비스.{자동번역}

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Vaccines comprising attenuated Mycoplasma bovis strains and method for the attenuation 약독화된 마이코플라즈마 보비스 균주를 포함하는 백신 및 약독화 방법

Details Unexam. Full Text Administrative

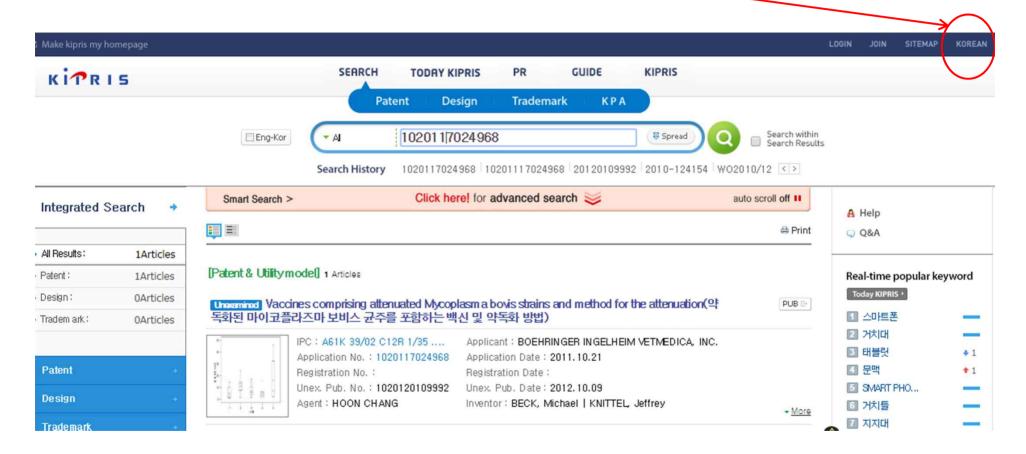
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No.	Docum ent Title	Receipt/Delivery Date	Status	Receipt/Delivery No.
1	[Patent Application] Document according to the Article 203 of Patent Act ([특허쯀원]특허법 제203조에 따른 서면)	2011.10.21	Accepted (수리)	112011082616728
2	Notice of Acceptance (수리안내서)	2011.12.13	Completion of Transmission (발송처리완료)	152011011687519
3	[Am endment to Description, etc.] Am endment ([명세서등 보정]보정서)	2015.04.23	Regarded as an acceptance of am endm ent (보정승인간주)	112015039742702
4	[Request for Examination] Request for Examination (Request for Preferential Examination) ([심사청구]심사청구(우선심사신청)서)	2015.04.23	Accepted (수리)	112015039745424
5	Notification of reason for refusal (의견제출통지서)	2017.01.18	Completion of Transmission (발송처리완료)	952017004270816
6	[Designated Period Extension] Application of Period Extension(Reduction, Progress relief) ([지정기간연장]기간연장(단축, 경과구제)신청서)	2017.03.13	Accepted (수리)	112017024446743
7	Notification for Extension of Designated Period (지정기간연장 관련 안내서)	2017.03.14	Completion of Transmission (발송처리완료)	152017003545407

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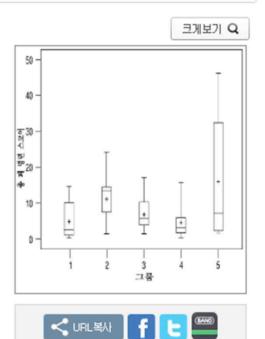


#### Administrative

#### 약독화된 마이코플라즈마 보비스 균주를 포함하는 / AUI

Vaccines comprising attenuated Mycoplasm a boy's strains and method for the attenuation

상체정보 공개전문 🕻	통합행정정보
<u>서지정보</u> 인명정보 형	정처러 <u>청구항</u> 시정국 인용/피인용 패밀리정보 국가R&D연구정5
(51) Int. CL	A61K 39/02(2012.09.03) C12R 1/35(2006.01.01) C12N 1/20(2006.01.01) A61K 39/00(2006.01.01)
(52) CPC @	A61K 39/0241(2013.01) C12R 1/35(2013.01) C12N 1/20(2013.01) A61K 2039/522(2013.01) A61K 2121/00(2013.01) A61K 39/02(2013.01) A61K 39/12(2013.01) A61K 39/39(2013.01)
(21) 출원번호/일자	1020117024968 (2011.10.21)
(71) 출원인	베링거잉겔하임베트메디카인코퍼레이티드
번역문제출일자	(2011.10.21)
(11) 등록번호/일자	
(65) 공개번호/일자	1020120109992 (2012.10.09) 전문다운 🔀
(11) 공고번호/일자	
(86) 국제출원번호/일자	PCT/US2010/032149(2010.04.23)
(87) 국제공개번호/일자	WO2010124154(2010.10.28)
(30) 우선권정보	미국(US)   61/172,543   2009.04.24
법적상태	공개

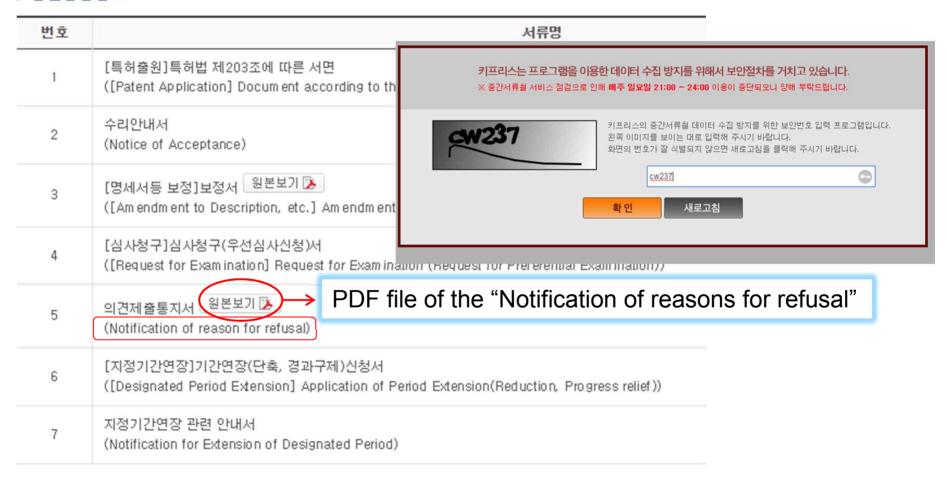


#### 약독화된 마이코플라즈마 보비스 균주를 포함하는 백신 및 약독화 방법

Vaccines comprising attenuated Mycoplasm a bovis strains and method for the attenuation



#### ▶ 통합행정정보





#### Notification of Reasons For Refusal

### KIPRIS - KIPO

발송번호: 9-5-2017-004270816

발송일자: 2017.01.18. 제출기일: 2017.03.18.

YOUR INVENTION I

특 허 청 의견제출통

출원인 성명 베링거잉겔하임년 519986003585)

주소 개인정보보호를

대리인 성명 장훈

주소 개인정보보호를

발명자 성명 벡 마이클

주소 개인정보보호를 위해 비공

성명 니텔 제프리

주소 개인정보보호를 위해 비공

출원번호 10-2011-7024968

약독화된 마이코플라즈마

번

1. 이 출원에 대한 심사결과 다음과 같은 거절이유가 있 의견이 있거나 보정이 필요할 경우에는 상기 제출기일( 법시행규칙 별지 제24호서식] 또는/및 보정서[특허법시 기 바랍니다.2. 상기 제출기일(2017.03.18.)을 연장하려 제출기일을 4개월까지 연장할 수 있습니다. 이 경우 연결 4개월을 초과하지 않는 범위에서 2개월 이상을 일괄하( 의 발생(하단의 안내참조)으로 4개월을 초과하여 지정기 기재한 소명서를 추가로 정부해서 연장신청을 해야 합니

#### [심사결과]

□ 심사 대상 청구항 :

제1-30항

□ 이 출원의 거절이유가 있는 부분과 관련 법조항

순번거절이유가 있는 부분관련 법조항

1

청구항 제1항 내지 제3항, 제7항, 제8항, 제11항, 제14항 내지 제16

항, 제19항 내지 제21항, 제26항

특허법 제29조제1항제2호

2

청구항 제1항 내지 제30항

특허법 제29조제2항

1. Novelty

2. Inventive step

인용발명 1: Thorns CJ, et al., Res Vet Sci. Vol.29(3), pp.328-332. (1980, 11.)

인용발명 2: 미국특허출원공개공보 제2007/0077260호 (2007, 4, 5,)



#### [심사결과]

발명의 명칭

□ 심사 대상 청구항:

제1-30항

□ 이 출원의 거절이유가 있는 부분과 관련 법조항

순번거절이유가 있는 부분관련 법조항

•

청구항 제1항 내지 제3항, 제7항, 제8항, 제11항, 제149 항, 제19항 내지 제21항, 제26항

특허법 제29조제1항제2호

2

청구항 제1항 내지 제30항

특허법 제29조제2항

3

Korea

Korean Intellectual Property Office

발명의 상세한 설명

특허법 제42조제3항

3. Enablement

4

청구항 제2항 내지 제6항, 제11항 내지 제30항

특허법 제42조제4항제2호

4. Clarity

Copy the text from the PDF file of the "Notification of Reasons For Refusal"

→ Translate it into English in "Google Translate"

영어 한국어 독일어 언어감지 [심사결과] □심사 대상 청구항 : 제1-30항 □ 이 출원의 거절이유가 있는 부분과 관련 법조항 순번거절이유가 있는 부분관련 법조항 청구항 제1항 내지 제3항, 제7항, 제8항, 제11항, 제14항 내지 제16 항, 제19항 내지 제21항, 제26항 특허법 제29조제1항제2호 청구항 제1항 내지 제30항 특허법 제29조제2항 발명의 상세한 설명 특허법 제42조제3항 청구항 제2항 내지 제6항, 제11항 내지 제30항 특허법 제42조제4항제2호 [구체적인 거절이유] 1. 이 출원의 특허청구범위의 청구항 제1항 내지 제3항, 제7항, 제8항, 제 11항, 제14항 내지 제16 항, 제19항 내지 제21항, 제26항에 기재된 발명은 아래와 같이 그 출원 전 에 국내 또는 국외에서 반포된 간행물에 게재된 발명이거나 전기통신회선을 통하여 공중이 이용 가능하게 된 발명이므로 특허법 제29조제1항제2호에 해당되어 특허를 받을 수 없습니다. - 아래 -? 인용발명 1: Thorns CJ, et al., Res Vet Sci. Vol.29(3), pp.328-332. (1980. 11.)1-1. 이 출원 청구항 제1항 발명은 110회 이상 계대된, 약독화된 비독성

한국어 영어 일본어 번역하기 [Judaina result] □ Subject to examination: Item 1-30 □ The reason for rejection of this application and the relevant legal provisions Partial Relevant Laws with Reasons for Rejection Claims (1) to (3), (7), (8), (11), (14) to . 19 to 21, 26 Article 29 (1) 2 of the Patent Act Claims (1) to Article 29 (2) of the Patent Act DETAILED DESCRIPTION OF THE INVENTION Article 42 (3) of the Patent Act Claims 2 to 6, 11 to 30 Article 42 (4) 2 of the Patent Act [Reason for refusal] Claims 1 to 3, 7, 8, 11, 14 to 16 of the claims The invention according to any one of claims 19 to 21. It is either an invention posted in a published publication or an invention made available to the public via telecommunication lines No patent is granted under Article 29 (1) 2 of the Patent Law. - Down -? Reference 1: Thorns CJ, et al., Res Vet Sci. Vol. 29 (3), pp. 328-332. (November 1980) 1-1. Claim 1 of the Invention The invention relates to the use of a nontoxic M. Three bobis (M. bovis) Mycobacterium strains.

In contrast, Reference 1 refers to a strain of Mycobacterium bovis 5M

192 & It; / RTI & gt; Vorbis strains are listed (green, Table 1,

328, left column 4 paragraph, 329 left column 2 paragraph, etc.).

### **Comparison With Prior Art**

- Step 1. Determine the relevant features of the claims
- ❖ Step 2. Determine the relevant features of the prior art
- Step 3. Compare the features: analyze for any differences
- Step 4. (If yes) Is the difference obvious to a person skilled in the art?

### EP 2421556 B1

#### Claims (patent granted)

- 1. An attenuated, avirulent *Mycoplasma bovis* bacterium strain, wherein the bacterium is passaged more than 110 times, wherein the attenuated, avirulent *Mycoplasma bovis* strain is selected from the group consisting of: the attenuated *Mycoplasma bovis* bacteria strain deposited with the ATCC under accession number PTA-9666 or PTA-9667, or any attenuated descendant *Mycoplasma bovis* bacteria strains thereof capable to reduce the mortality in a group of animals of at least 83% as compared to a non-vaccinated control group of animals.
- 3. An immunogenic composition comprising live bacteria of any of the attenuated, avirulent *Mycoplasma bovis* bacteria strains according to claims 1 or 2.
- 12. A method of producing an immunogenic composition according to any one of claims 3 to 11, comprising admixing said bacteria of an attenuated, avirulent Mycoplasma bovis strain with a pharmaceutical acceptable carrier.

### JP 5793808 B2

#### Claims (patent granted)

[Claim 1]Are attenuation and a nonpathogenic M. BOBISU bacteria stock, and the \*\* cost of the aforementioned bacteria is carried out exceeding 110 times, The aforementioned M. BOBISU bacteria stock chosen from a group which comprises an attenuation M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9666, an attenuation M. BOBISU bacteria stock deposited with ATCC by accession number PTA-9667, and any posterity attenuation M. BOBISU bacteria stock of its.

[Claim 4]How to attenuate M. BOBISU including the following processes: More \*\* cost of the a. M. BOBISU bacteria than 110 times is carried out. Process;b. which manufactures cultivation M. BOBISU bacteria Process;c. which obtains cultivation M. BOBISU bacteria The process; and d. which examine M. BOBISU bacteria obtained at the process b about those pathogenicity and immunogenicity Although it is nonpathogenicity, A process of proliferating M. BOBISU bacteria which are immunogenicity and obtaining attenuation M. BOBISU bacteria.

→ Machine translation

### US 9,339,533 B1

 (Previously Amended) An attenuated, avirulent Mycoplasma bovis (M. bovis) bacterium strain, wherein the bacterium is passaged more than 110 times and wherein the attenuated, avirulent M. bovis strain is selected from the group consisting of:

### Claims (patent granted)

- a. the attenuated *M. bovis* bacteria strain deposited with the American Type Culture Collection (ATCC) under accession number PTA-9666, and
- the attenuated *M. bovis* bacteria strain deposited with the ATCC under accession number PTA-9667.
- 6. (Rejoined Previously Amended) A method of attenuating *M. bovis*, comprising,
  - a. passaging *M. bovis* bacteria according to claim 1more than 110 times to produce a cultured *M. bovis* bacteria;
  - b. obtaining the cultured M. bovis bacteria;
  - c. testing the cultured *M. bovis* bacteria obtained under step b) for their pathogenicity and immunogenicity; and
  - d. propagating the non-pathogenic, but immunogenic *M. bovis* bacteria to obtain the attenuated *M. bovis* bacteria.

# Thank You

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