

# Topic 1: Work-Sharing and Work-Products related to Biosequences

Transparency of examination in national phases

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**PCT International Cooperation Division** 

Manila May 20, 2019

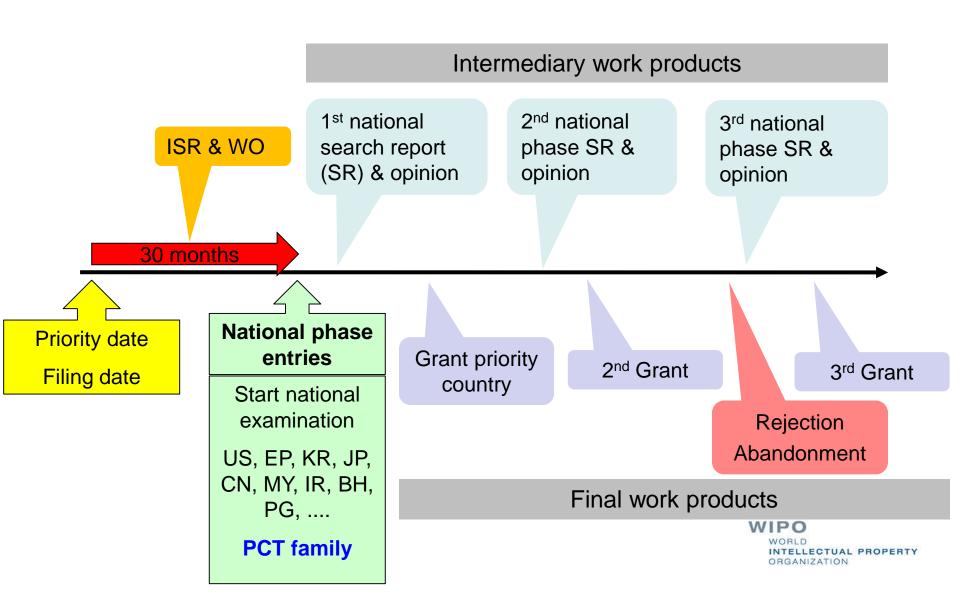
### Agenda

- Growing transparency because of work-sharing platforms
  - Diversity of examination work-products
    - Visible for other examiners
    - Visible for third parties
- Opportunities and implications for national phase examination
  - Enhancing efficiency and improving quality
  - Regional cooperation cooperative examination
  - Monitoring of quality:

Has an examiner seen what he could have seen?



# Potential life cycle of a PCT application



# Work-Sharing through patent families

- Patent family: same or similar invention was filed in several IPOs, e.g. a PCT application entered several national phases
- PCT family: all applications linked through same PCT application number
- Simple family or extended family: may include more than one PCT family (e.g. WO2014136037 has WO2014136055 in SF; WO2015058464 has 31 WO in EF)
- Examination results/work products for members of the patent family may be utilized for improving efficiency and quality of examination
  - Opportunities for small/under-resourced IPOs



### Types of examination work products

- Intermediary or pre-grant work products
  - Search reports
    - basic list of citations (cited by examiner, by applicant)
    - enriched search reports (citation category X, Y, ..; relevant claims;...)
    - Patent literature; non-patent literature; bio-sequences
  - Search strategies
  - Written opinions, examination reports
  - Communications from applicant to examiner
  - Protocols of hearings
  - Third party observations
- **Final** work products/results
  - Granted claims; claims after opposition
  - Rejections; withdrawals following substantive reports; abandoned claims
- Post-grant work products/results
  - Additional prior art from opposition/re-examination/invalidation
  - Restricted claims
  - Communications between involved parties (3+)



### WO2010098129

### Inpadoc family table in Espacenet

#### 4. A METHOD FOR RECOVERING HYDROCARBON COMPOUNDS AND A HYDROCARBON RECOVERY APPARATUS FROM A **GASEOUS BY-PRODUCT**

Inventor: **TASAKA** 

KAZUHIKO [JP]

Applicant: JAPAN OIL GAS & METALS JOGMEC

INPEX CORP [JP]

(+4)

CPC: B01D3/00

Grant

Grant

IPC: C10G2/00

Publication info: CA2752839 (A1) 2010-09-02

CA2752839 (C) 2014-02-18

**Priority date:** 2009-02-27

**Priority date:** 

2009-02-27

Priority date

Priority date:

**Priority date:** 

2009-02-27

2009-02-27

2009-00

5. Method for collecting hydrocarbon compound from gaseous by-product and apparatus for collecting hydrocarbon

Inventor: **KAZUHIKO TASAKA** 

Applicant:

JAPAN OIL GAS & METALS JOGMEC

INPEX CORP

(+4)

CPC: B01D3/00 IPC: C10G2/00

Publication info: CN102333846 (A) 2012-01-25

CN102333846 (B) 2014-01-29

Global Dossier

6. METHOD FOR COLLECTING HYDROCARBON COMPOUNDS FROM GASEOUS BY-PRODUCT AND APPARATUS FOR **COLLECTING HYDROCARBON** 

Inventor: Тасака. Казухико Applicant:

ДЖЭПЭН ОЙЛ, ГЭЗ ЭНД МЕТАЛЗ НЭШНЛ КОРПОРЕЙШН.

ИНПЕКС КОРПОРЕЙШН,

(+4)

CPC: B01D3/00

IPC: C10G2/00

Grant

Publication info: EA201170995 (A1) 2012-02-28

EA018772 (B1) 2013-10-30

publication kind code for grants B or C (sometimes A)

publication date

7. METHOD FOR COLLECTING HYDROCARBON COMPOUND FROM GASEOUS BY-PRODUCT AND APPARATUS FOR **COLLECTING HYDROCARBON** 

Inventor:

**TASAKA** KAZUHIKO [JP] Applicant:

JAPAN OIL GAS & METALS JOGMEC

[JP]

INPEX CORP [JP]

(+4)

CPC: R01D3/00

IPC: R01D53/14

No grant

Publication info: EP2402418 (A1)

2012-01-04 EP2402418 (A4) 2012-11-21

Global Dossier



8. METHOD FOR COLLECTING HYDROCARBON FROM FT GAS COMPONENT AND APPARATUS FOR COLLECTING **HYDROCARBON** 

Inventor: **TASAKA KAZUHIKO**  Applicant:

JAPAN OIL GAS & METALS JOGMEC

INPEX CORP

(+4)

CPC:

B01D3/00

IPC: C10G2/00

Grant

**Publication info:** JP2010202677 (A)

2010-09-16 JP5301318 (B2) 2013-09-25

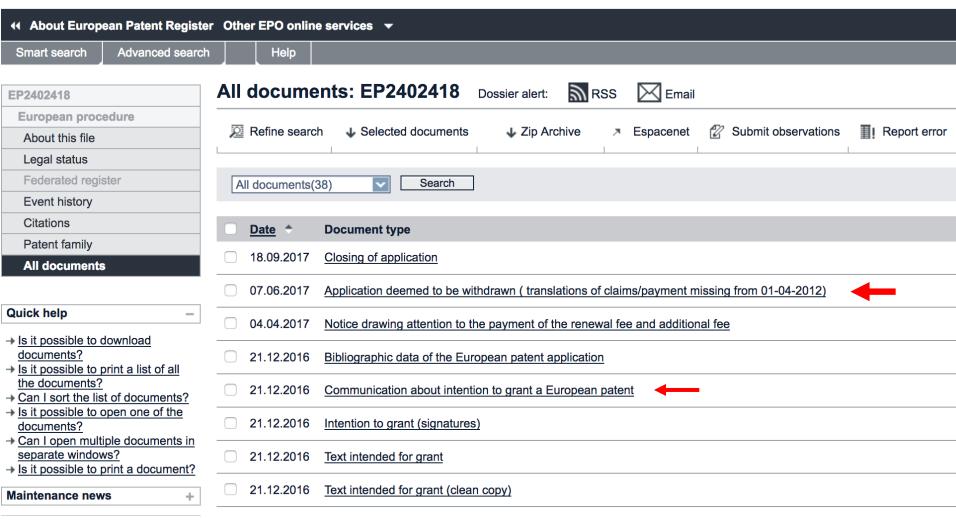
Global Dossier

WIPO WORLD INTELLECTUAL PROPERTY ORGANIZATION

### Status EP family member



### European Patent Register



### What is needed for work-sharing?

- Comprehensive patent family information, detailed as
  - Simple family (all priorities are the same; descriptions are very likely equivalent)
    - Distinguishing PCT families
  - Extended family (largest possible family)
- Examination (legal) status information
- Access to examination work products/dossiers
- Platforms which integrate this information user friendly
- Translation tools for work products
- Tools for comparing work products
  - Citations (search reports)
  - Claims
- Information on differing national practices (naming and content of work products; important case law; exclusions; ..)

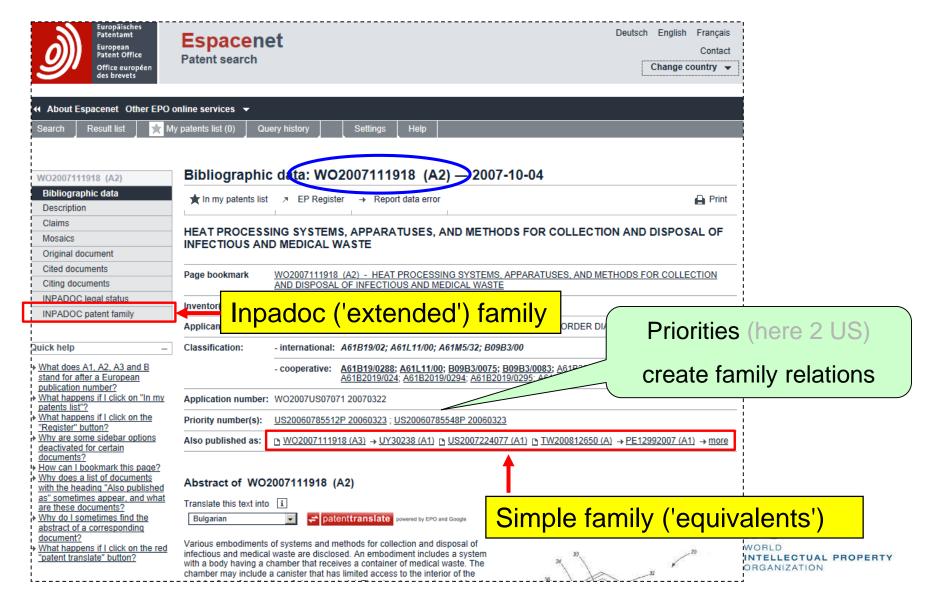
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### Sources of family information

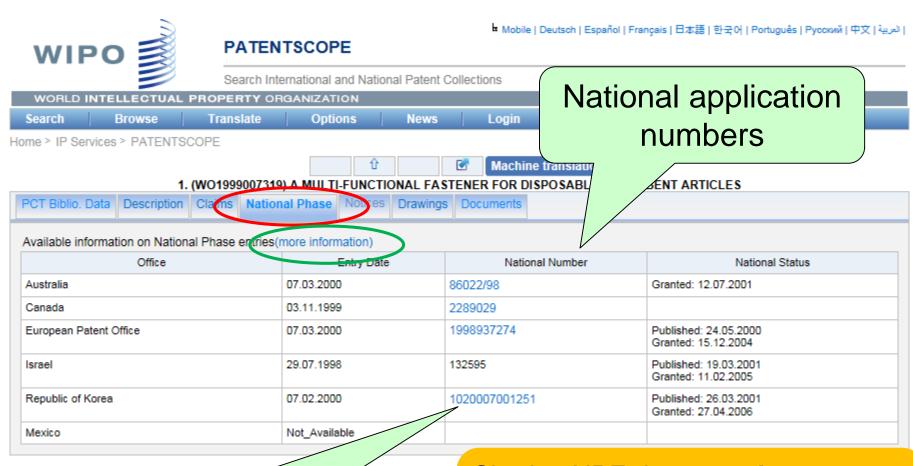
- **Family building**: family relations are derived from priority and PCT application data
- EPO processes accordingly bibliographic data of all publications included in its database (90+ jurisdictions) obtained from offices sharing publication data
- EPO's INPADOC database is major source of such family information, accessible through:
  - Espacenet, EP-Register and CCD (simple and extended families; domestic families)
  - Other free patent information databases, like Depatis, Google Patents,...
- WIPO's PATENTSCOPE aggregates national phase entry data <u>reported</u> from Designated/Elected Offices (obligation as from July 1, 2017; rule 95)
- WIPO CASE performs family building among applications shared by providing offices; families are complex families (i.e. share at least one priority)
- Commercial patent databases obtain and use widely INPADOC data, and apply proprietary family building rules and data cleaning, e.g.
  - Clarivate/Derwent: WPI family
  - Questel/Orbit: Fampat family
  - ...
- Other specialized platforms, e.g. WIPO's Pat-Informed



# Source of family information: Espacenet



# National phase entries in Patentscope

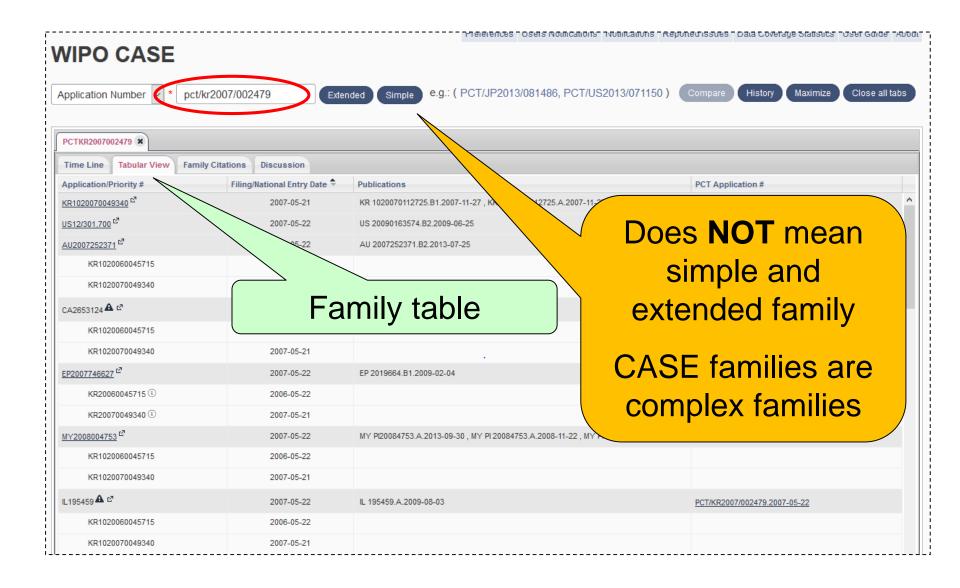


Hyperlinked to national registers

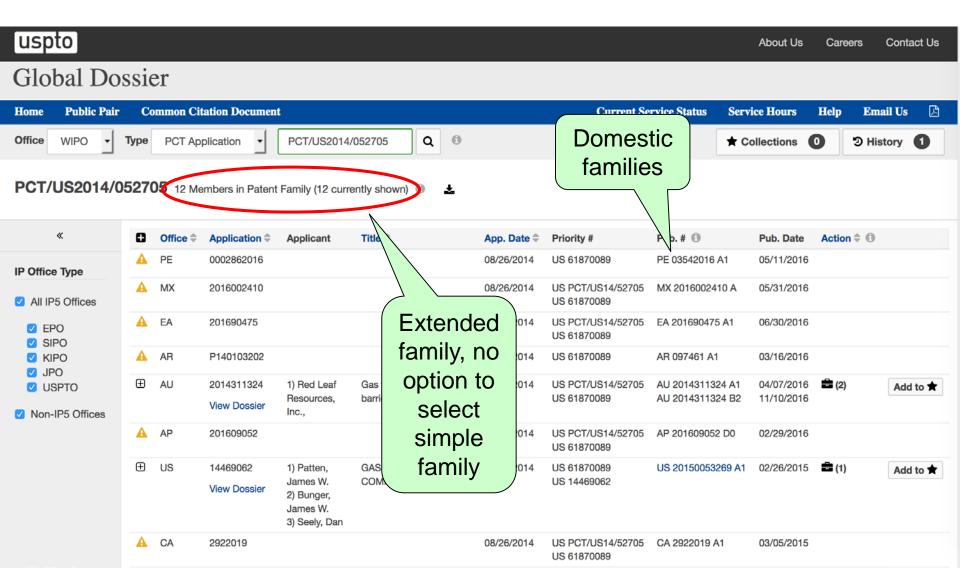
Sharing NPE data **mandatory** as from July 2017

Currently some 60 jurisdictions

### WIPO CASE family table



# Patent family in Global Dossier (USPTO)



# Comparison of family data of 4 samples

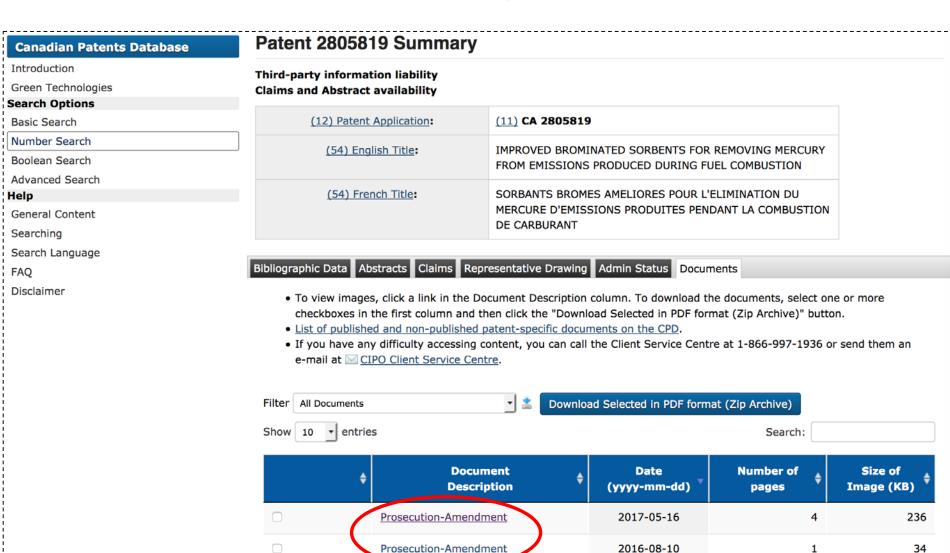
Status as of Aug 22, 2018	EPO Inpadoc	USPTO GD	Patentscope NPE	WIPO CASE
PCT/KR2007/002479	26: AU, BR, CA,	= Inpadoc	15: AU, CA, CN,	21: AU, BR, CA,
stable composition	CN, CR, EA, EC,		<b>CO</b> , EA, <b>EG</b> , EP,	CN, EC, EP, GE, <b>ID</b> ,
	EP, ES-T, GE, GT,		GE, IN, JP, MX,	IL, IN, JP, KR, MA,
	HK, IL, JP, 2xKR,		NZ, <b>PH</b> , US	MN, MY, MX, SG,
	MA, MX, MY,			SV, VN, US
	NZ, SV, <b>TN</b> , <b>UA</b> ,			
	US, ZA			
PCT/JP2010/001325	12 : AU, BR, CA,	= Inpadoc	7: AU, CA, CN, EA,	13: AU, BR, CA,
collecting hydrocarbon	CN, EA, EP, JP,		EP, US	CN, EP, <b>ID</b> , JP, MY,
compound	MY, 2xUS, ZA			TH, VN, 2xUS
PCT/US2014/052705	12 : AR, AU, CA,	= Inpadoc + IL	13: AU, CA, CN,	<b>11</b> : AR, AU, CN,
composite barrier	CN, EA, EP, MA,		EA, EP, <b>GE</b> , ID, IL,	EA, EP, ID, <b>IN</b> , MA,
	MX, PE, TN, US		MA, MX, PE, UA	MX, <b>MY</b>
PCT/IB2016/000305	<b>19</b> : AR, <b>AU</b> , CA,	= Inpadoc + IL	<b>16</b> : AU, CA, CN,	<b>15</b> : AR, AU, CN,
mercury based	CL, CN, CO, CR,		CO, EA, EP, GE, IL,	CU, DO, EA, EP,
compound	CU, DO, EA, EP,		KR, MX, <b>2xNI</b> , PE,	ID, IN, KR, MX,
	JP, KR, MX, PE,		PH, SG	MY, PE, PH
	PH, SG, TW			
	Green Bold: prese			
	Black Bold: present only in one database			
	Counts include PCT applications			

### What is available for work-sharing?

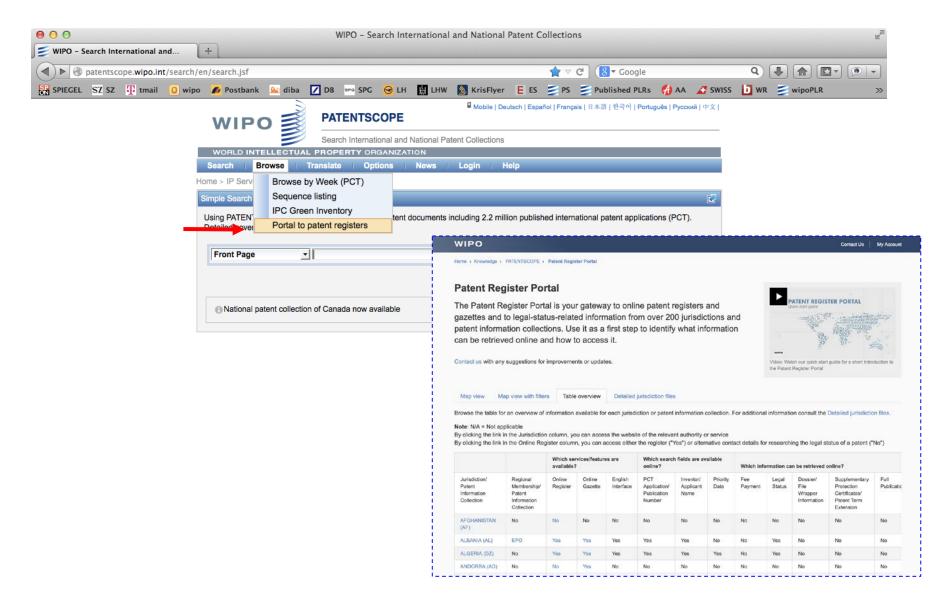
- Primary sources: National Patent Registers are authoritative sources for
  - national legal status (!),
  - national family relations (divisions, continuations)
  - national publications,
  - access to national dossiers (public file inspection).
- For some countries, national registers are accessible online and therefore useful for work-sharing:
  - legal status only: AP, AR, CL, GC, ID, MY, PH, SA, ZA, ...
  - dossier as well: AU, BR, CA, CN, DE, EP, FI, GB, IL, IN, JP, KR, MX, SE, TW, US, ...
- RSS feeds enable examiners of other offices and other experts to be alerted of changes to status/dossiers
- Many registers enable deeplinking



# Example: Canadian Register



### WIPO patent register portal



### What is available for work-sharing?

**Secondary work-sharing platforms** ("one-stop-shop") aggregate information or enable access to work products from several authoritative sources (Registers)

#### **Espacenet**

- Includes INPADOC data:
  - Very (most?) comprehensive extended and simple family data
  - National and regional legal status of jurisdictions sharing such data with EPO
- Includes Global Dossier (IP5 initiative)
  - Access to IP5 Offices' file wrappers/dossiers (One Portal Dossier)
    - always up-to-date because it is retrieved on-the-fly from IP5 national registers
    - Machine translation for non-English documents
    - Status may often be derived from recent dossier documents
    - Inpadoc legal status sometimes include complementary status that cannot be derived from most recent communication
  - Access to non-IP5 dossiers of 'providing' Offices of WIPO-CASE
    - partly operational (AU, CA, ..)



### What is available for work-sharing?

#### Secondary platforms ...

#### **Espacenet** ...

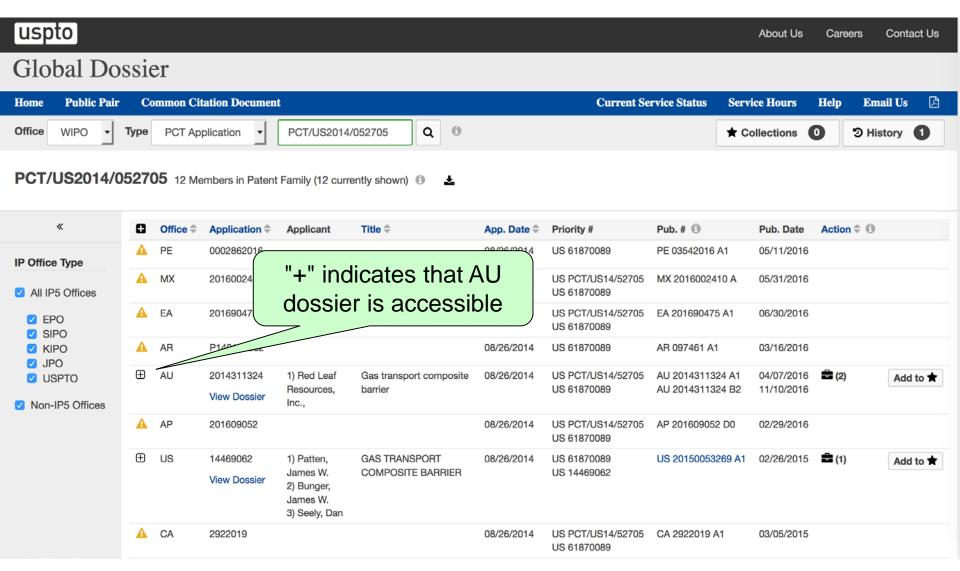
- Includes Global Dossier
- integrated access to Common Citation Document (CCD):
  - viewing <u>and</u> comparing of citations from members of extended and simple families from AP, AU, CA, CN, DE, EA, EP, JP, KR, RU, TW, US, WO, ....
  - 'comparing': which examiners have seen a particular citation or an equivalent thereof

#### **USPTO Global Dossier**

- Website dedicated to Global Dossier (appears to be still under development)
- Access to same dossiers like Espacenet GD (IP5 and CASE 'providing offices')
- presents only extended family information (without WO member); i.e. doesn't permit to view/select only simple family/PCT family
- Integrated application 'Citation List' (under development) to view comprehensive lists of citations from family members (backward and forward); not suitable for 'comparing'

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### Global Dossier at USPTO



### What is available for work-sharing?

#### Secondary platforms ...

#### WIPO-CASE (non public)

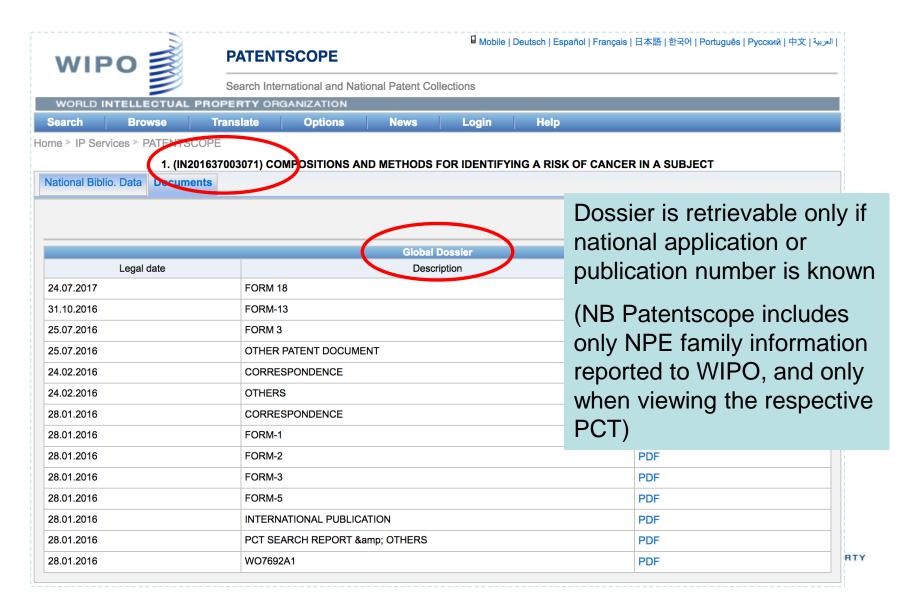
- Accessible only for 'accessing' and 'providing' Offices
- 'providing' offices share their dossiers with other participating offices
- Includes IP5 dossiers obtained from GD/OPD & AU, CA, GB, IL, IN, NZ, ...
- Family information includes only so-called 'complex' families
  - Proprietary family building based on applications of 'providing' Offices recorded in CASE, and NPEs recorded in Patentscope
- Majority of dossiers are also publicly accessible through Patentscope 'document' tab (labelled as 'Global Dossier') and Global Dossier

#### **PATENTSCOPE**

- Access to WIPO CASE dossiers in 'document' tab (labelled as 'Global Dossier')
- Includes PCT family (limited; only NPEs reported to WIPO from Designated and Elected Offices); only visible for WO publications; no separate family building
- No extended or simple families (EPO data are not integrated)
- No citation data



# 'GD' in Patentscope (WIPO CASE data)



### Secondary platforms for work-sharing

- Espacenet, US-Global Dossier, WIPO-CASE and Patentscope are (at the present) complementary to each other
- Shall, in future, cover access to same set of dossiers
- Which one to use then?
  - Better user interface?
    - Searching, viewing, exporting, ...
  - Additional tools (comparing, translations, alerts, ..)
  - Additional information (citations, enriched citations, different types of families, ...)
- Many national registers already enable deep linking
- Do we still need secondary platforms then? Or just a 'federated register' linking to national registers



### How different are examination results?

#### Sample WO2008035580

- 2 JP priorities
- Extended family: 39 members
- Simple family: 35 members

Derived from kind codes of publications recorded in Espacenet

Simple family: grants in AP, AU, CA, 2xCN, NZ, EA, EP, KR,

MA, MX, MY, NZ, TW, UA, US, PH, VN, ....?

- **Extended** family: further grants in: 2xJP (priority country)
- Pendency: 2-10 years
  - 2006-09-20 earliest priority date
  - 2008-09-03 JP grant
  - 2016-10-26 EP
- Still pending in BH, LA,..



# Examples of grants: WO2008035580

#### **WO-A1 = AU-B2 = JP-B1**

- 1. A plant cultivation system comprising:
- a nonporous hydrophilic film for cultivating a plant thereon, and
- a feeding means for supplying water or a nutrient fluid to the lower surface of said nonporous hydrophilic film in the absence of a hydroponic tank for accommodating water or a nutrient fluid and cultivating a plant therein.

#### CA-C

- 1. A plant cultivation system comprising:
- a nonporous hydrophilic film for cultivating a plant thereon;
- a feeding means for feeding water or a nutrient fluid to the lower surface of said nonporous hydrophilic film,
- said feeding means comprising at least one layer which is a water impermeable material layer or a water absorbing material layer,
- said at least one layer is laid and extends under said nonporous hydrophilic film,
- wherein, when said feeding means comprises both the water impermeable material layer and the water absorbing material layer, the water absorbing material layer is disposed between said nonporous hydrophilic film and said water impermeable material layer and in contact with the lower surface of said nonporous hydrophilic film;
- and a drip tube as an irrigation means for supplying water or a nutrient fluid to the feeding means,
- said drip tube being disposed below said nonporous hydrophilic film in a man- ner such that water or a nutrient fluid supplied from the drip tube is fed to the lower surface of the nonporous hydrophilic film.

AU, JP granted initial claims without any modification

CA granted heavily modified claim

### Examples of grants: WO2008035580

#### CA-C

- 1. A plant cultivation system comprising:
- a nonporous hydrophilic film for cultivating a plant thereon;
- a feeding means for feeding water or a nutrient fluid to the lower surface of said nonporous hydrophilic film,
- said feeding means comprising at least one layer which is a water impermeable material layer or a water absorbing material layer,
- said at least one layer is laid and extends under said nonporous hydrophilic film,
- wherein, when said feeding means comprises both the water impermeable material layer and the water absorbing material layer, the water absorbing material layer is disposed between said nonporous hydrophilic film and said water impermeable material layer and in contact with the lower surface of said nonporous hydrophilic film;
- and a drip tube as an irrigation means for supplying water or a nutrient fluid to the feeding means,
- said drip tube being disposed below said nonporous hydrophilic film in a man- ner such that water or a nutrient fluid supplied from the drip tube is fed to the lower surface of the nonporous hydrophilic film.

US granted even more restricted claim

#### US-B2

- 1. A plant cultivation system comprising:
- a nonporous hydrophilic film for cultivating a plant thereon,
- a feeding means for feeding water or a nutrient fluid to the lower surface of said nonporous hydrophilic film in the absence of a hydroponic tank for accommodating water or a nutrient fluid and cultivating a plant therein,
- said feeding means comprising at least one layer selected from the group consisting of a water impermeable material layer and a water absorbing material layer,
- which is laid and extends under said nonporous hydrophilic film,
- wherein, when said feeding means comprises both of said water impermeable material layer and said water absorbing material layer, said water absorbing material layer is disposed between said nonporous hydrophilic film and said water impermeable material layer and is in contact with the lower surface of said nonporous hydrophilic film,
- and a drip tube as an irrigation means for supplying water or a nutrient fluid to said feeding means,
- said drip tube disposed below said nonporous hydrophilic film in a manner such that water or nutrient fluid supplied from said drip tube is fed to the lower surface of said nonporous hydrophilic film;
- wherein said nonporous hydrophilic film is a film which exhibits an electrical conductivity (EC) difference of 4.5 dS/m or less,
- said EC difference being determined by a method comprising contacting water with a saline solution having a salt concentration of 0.5% by weight through said nonporous hydrophilic film, measuring the electrical conductivity of each of the water and the saline solution 4 days (96 hours) after the start of the contact, and calculating the difference in electrical conductivity between the water and the saline solution.



# ISR: 2 category A documents only

#### INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2007/067578

A. CLASSIFICATION OF SUBJECT MATTER

A01G27/00(2006.01)i, A01G1/00(2006.01)i, A01G7/00(2006.01)i, A01G13/00 (2006.01)i, A01G25/00(2006.01)i

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

#### B. FIELDS SEARCHED

ategory

Minimum documentation searched (classification system followed by classification symbols) A01G27/00, A01G1/00, A01G7/00, A01G13/00, A01G25/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Jitsuyo Shinan Koho 1922-1996 Jitsuyo Shinan Toroku Koho 1996-2007 Kokai Jitsuyo Shinan Koho 1971-2007 Toroku Jitsuyo Shinan Koho 1994-2007

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

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

Citation of document, with indication, where appropriate, of the relevan

JP 2001-292643 A (Taiyo Kogyo Kabushi) Kaisha),

23 October, 2001 (23.10.01) Full text; all drawin

(Family: none)

JP 2003-506051 A (E.I. Du Pont De Nemours &
Co.),

18 February, 2003 (18.02.03), Full text; all drawings

& EP 1530896 A2

Only A documents

1 - 13

Only JP publications

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# EP-A4: Supplementary EP search report



### SUPPLEMENTARY PARTIAL EUROPEAN SEARCH REPORT

Application Number

under Rule 62a and/or 63 of the European Patent Convention. This report shall be considered, for the purposes of subsequent proceedings, as the European search report EP 07 82 8221

	DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)	
X	EP 1 695 615 A1 (UNIV LAVAL [CA]) 30 August 2006 (2006-08-30) * paragraph [0011] - paragraph [0013]; figures * 	1	INV. A01G27/00 A01G1/00 A01G7/00 A01G13/00 A01G25/00 A01G31/02	

Also seen by CA and US examiners

comparing citations in CCD

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### Explanations for substantial differences

- Examiners may have applied different prior art
  - Different prior art searches, i.e. prior art documents
  - Different priority dates applied
- Differences in national legislation (exclusions) or case law
- Individual examiner's views/experience
- Patents do not belong to same simple family, i.e. applicants have sought protection for different subject matter (e.g. continuations/divisions); descriptions most likely differ



### Reasons for additional citations/searches

- Lack of trust in other work product, e.g. if
  - ISR with only category A documents
  - ISR including citations of only one single jurisdiction
- Claims amended before or with national phase entry (e.g., if ISRs with X citations)
- Claims amended during national phase examination
- Language skills of examiners
- Familiarity/expertise of examiner with relevant documentation
- Strict prior art disclosure requirement, for example in the US



### Reasons for additional citations/searches

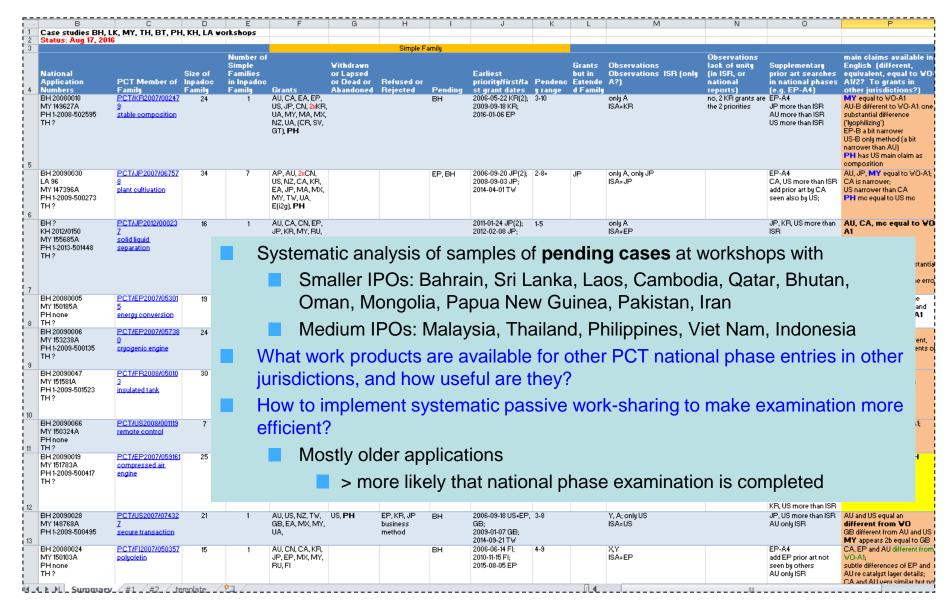
- ISRs by USPTO are outsourced
  - US examiner in national phase is different from ISR expert
  - For example <u>PCT/US2014/030776</u>
    - ISR expert: Lee W. Yung (only A documents in ISR)
    - National phase examiner: Albert M Navarro
- Prior art disclosure requirement of USPTO
  - A lot of prior art known to applicant may be added at national phase
- EPO establishes Supplementary European Search Report (published as EP-A4) whenever EPO was not ISA

#### CONCLUSIONS

- ISR and WO may be very **useful for applicants** to assess potential success of application before investing in national phase entries
- ISR and WO may be of **limited utility for examiners**, in particular, when claims are amended for national phase entry, and additional prior art searches often appear to be needed in national phases.

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# Family table for PCT NPEs sample cases



### Evidence & conclusions derived from sample set

- Large patent families: 10++ members
  - Many work products from many other national phases can be utilized
- Large fraction of families with grants: >95%
  - Most likely a patent can be granted; but which claims from which country are best?
  - The first foreign grant (PPH; e.g. for the sake of speediness)?
- Wide range of pendencies: 3-10 years after priority filing
  - What is backlog? How long to wait?
- Granted claims substantially different from claims granted in other jurisdictions: >60%
  - Careful selection of suitable claim sets
- Granted claims different from WO-A1/2 claims: >90%
- Additional prior art searches in national phases: >90%
  - Take into account for claim selection or decision to await further results
  - Do not solely rely on ISR
- Grants in some, rejections and withdrawals on other jurisdiction: **20%** 
  - Carefully analyze reasons for rejections/substantial withdrawals



### What are the implications of transparency?

- Examination work products are **easily visible**, after application is published, for
  - Examiners
  - Third parties
- Foreign examination work products are **usable** for
  - Examiners in national phase
  - Managers to monitor examination quality
  - Third parties to monitor prosecution, examination quality, prepare oppositions,
- Available foreign examination work products cannot be ignored for national phase examination
  - Even examination of PPH requests need to include a check if other work products from further national phases have become available, in particular relevant prior art.



### Observations/Conclusions

- Duplication/repetition of work is not a bad thing as such
  - Improves the overall quality of patents
  - For PCT NPEs, examiners should never exclusively rely only on ISR/WO
  - However, work products become only gradually available and visible
  - Awaiting results from other national phases may be an option to enhance quality and efficiency, particularly in under-resourced Offices
  - Most recent or last grant is potentially of best quality
    - What does this mean for PPH?
- Currently examination of PCT NPEs starts in many jurisdictions at almost the same time; no coordination
- Cooperative examination would be the ideal way for improving
  - Quality of all patents of a family, and not just those ones granted last, and
  - Efficiency of procedures overall



### Observations/Conclusions

- Sharing of application and legal status data (including NPE) still needs to improve,
   e.g. for regional cooperation
- Family building needs to be expanded, in particular with a view to IPOs in emerging and developing economies
- Patent families are global: Only platforms for work-sharing with global coverage make work-sharing efficient
  - regional solutions are not really useful
- Which work-products from other nation phases to use?
  - 'Trusted' Offices?



### Thank you

lutz.mailander@wipo.int



- SYNTHETIC IMMUNOGENS FOR PROPHYLAXIS OR TREATMENT OF TUBERCULOSIS
- 1. A **composition** comprising selected from the group consisting of:
  - a) a combination of a **nucleic acid molecule comprising esxV, esxS and esxW coding sequences**, a nucleic acid molecule comprising esxD, esxQ and esxE coding sequences, a nucleic acid molecule comprising esxH, esxA and esxT coding sequences, a nucleic acid molecule comprising esxB, esxC and esxU coding sequences, and a nucleic acid molecule comprising esxO, esxR and esxF coding sequences;
  - b) a combination of a **nucleic acid molecule comprising SEQ ID NO: 19 or SEQ ID NO: I**, a nucleic acid molecule comprising SEQ ID NO:21 or SEQ ID NO:3, a nucleic acid molecule comprising SEQ ID NO:23 or SEQ ID NO:5, a nucleic acid molecule comprising SEQ ID NO:25 or SEQ ID NO:7, and a nucleic acid molecule comprising SEQ ID NO:27 or SEQ ID NO:9;
  - c) a combination of a nucleic acid molecule comprising SEQ ID NO: 19, a nucleic acid molecule comprising SEQ ID NO:21, a nucleic acid molecule comprising SEQ ID NO:23, a nucleic acid molecule comprising SEQ ID NO:25, and a nucleic acid molecule comprising SEQ ID NO:27;
  - d) a combination of a nucleic acid molecule that encodes SEQ ID NO:20, a nucleic acid molecule that encodes SEQ ID NO:22, a nucleic acid molecule that encodes SEQ ID NO:24, a nucleic acid molecule that encodes SEQ ID NO:26, and a nucleic acid molecule that encodes SEQ ID NO:28;
  - e) one or more nucleic molecules selected for the group consisting of: a nucleic acid molecule that comprises SEQ ID NO: I, a nucleic acid molecule that comprises SEQ ID NO:5, a nucleic acid molecule that comprises SEQ ID NO:7, a nucleic acid molecule that comprises SEQ ID NO:9, a nucleic acid molecule that comprises SEQ ID NO: I 1, a nucleic acid molecule that comprises SEQ ID NO: 13, a nucleic acid molecule that comprises SEQ ID NO: 15, a nucleic acid molecule that comprises SEQ ID NO: 17, a nucleic acid molecule that comprises SEQ ID NO: 19, a nucleic acid molecule that comprises SEQ ID NO:21, a nucleic acid molecule that comprises SEQ ID NO:23, a nucleic acid molecule that comprises SEQ ID NO:25, a nucleic acid molecule that comprises SEQ ID NO:27 fragments thereof having at least 90% of full length, homologous sequences having at least 95% homology, and fragments of homologous sequences having at least 95% homology having at least 90% of full length; and f) one or more nucleic molecules that encodes an amino acid sequences selected for the group consisting of: SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:26, SEQ ID NO:26, SEQ ID NO:28 fragments

thereof having at least 90%) of full length, **homologous sequences having at least 95% homology**, and fragments of homologous sequences having at least 95% homology, said fragment of homologous sequences having at least 95% homology having at least 90% of full length.

INTELLECTUAL PROPERTY ORGANIZATION

- Sequence listings as separate <u>annex</u> in <u>Patentscope</u> (nucleotides and amino acids)
- Sequence listings as part of <u>drawings</u>, for example <u>WO2012161564</u>
- Sequence listings as part of description
  - To comply with the standard provided for in Annex C of the Administrative Instructions



### PCT family

- Espacenet: AU, CA, CN, EP, HK, JP, KR, 2xUS (NPE & divisional)
- US Global Dossier: same as Espacenet
- Patentscope: AU, CA, CN, EP, US (NPE only)
- WIPO CASE: AU, CN, EP, IN, JP, KR, US (NPE only)

### Status

- AU grant published on 2016-05-19
- CA <u>pending</u> (examination requested on 2019-03-08)
- CN grant published on 2019-02-19
- EP <u>pending</u> (amended claims on 1.04.2019)
- JP pending
- KR pending (examination requested on 28.01.2019)
- US grant (NPE) published on 2017-10-17; pending (division) po

## Indian "Form 3" (patent family disclosure)

#### FORM 3 THE PATENTS ACT, 1970 (39 of 1970)

85

The Patents Rules, 2003 STATEMENT AND UNDERTAKING UNDER SECTION 8 (See section 8, rule 12)

We, THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, 3160 Chestnut Street, Suite 200 Philadelphia, PA 19104, USA, US hereby declare:

that we, who have made this application No. 8136/DELNP/2015 filed on September 9, 2015 alone made for the same/substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

Name of	Date of	Application No.	Status of the	Date of	Date of
the	application		application	Publication	Grant
Country					
AU	17.03.2014	2014232335	Granted		01.09.2016
CA	17.03.2014	2,898,131	Pending		
CN	17.03.2014	2014800124958	Published		
EP	17.03.2014	14763920.7	Published		
HK	17.03.2014	16104666.7	Published		
JP	17.03.2014	2016-503460	Published		
KR	17.03.2014	10-2015-7022241	Pending		
US	10.09.2015	14/774,339	Granted		17.10.2017
US	26.09.2017	15/715,300	Pending		
WO	17.03.2014	PCT/US2014/030776	NAT PHASE		



### Lack of unity

- No objection in ISR or WO (USPTO as ISR)
- AU: no objection (essentially granted WO-A1 claims)
- US: <u>objection</u> led to division
  - Public on: 11.08.2016
- EP: partial supplementary European search report includes objection
  - Public on: 23.06.2016
- JP: no objection
- KR: examination started only recently
- CN: <u>objection</u>
  - Public on: 03.03.2017



### **Prior art (citations)**

- Overview/summary in <u>CCD</u>
- ISR: USPTO as ISR; only A documents (search strategy <u>available</u>)
- AU: no additional citations
- US: additional citations by examiner in national phase (NPE and divisional)
  - Public on: 11.08.2016, 28.10.2016, 30.03.2017 (search strategies available)
- EP: supplementary search report (<u>EP-A4</u>) with additional citations also seen by US examiner
  - Public on: 23.06.2016
- JP: additional citations (seen only by US examiner)
  - Public on: 09.01.2018
- KR: examination started only recently
- CN: additional citations (category A
  - Public on:



## ISR by USPTO

#### INTERNATIONAL SEARCH REPORT

International application No. PCT/US 14/30776

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 39/00, 39/02; C12N 1/20, 15/00 (2014.01)

USPC - 424/184.1, 190.1; 435/253.1, 320.1

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

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) USPC: 424/184.1, 190.1; 435/253.1, 320.1

Databases searched:

Gencore for sequences

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 424/184.1, 190.1; 435/253.1, 320.1; 514/44R; 536/23.7 (text search)

Electronic data base consulted during the international search (name of data base and, where practicable, scarch terms used)
Electronic data bases: PatBase, Google Scholar, Google Patents, GenCore sequence search (NT, AA)
Search terms: Esx gene family of TB antigens, Esx-1 secretion system, ESAT-6 secretion system, ESAT-6 like protein, Mycobacterium tuberculosis H37Rv, vaccine, nucleic acid vaccine, esxV, esxW, esxW, esxQ, esxE, esxH, esxA, esxT, esxB, esxC, esxU,

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevan	t to claim No.
A	US 2012/0039925 A1 (DIETRICH et al.) 16 February 2012 (16.02.2012). Especially para [0016], [0018]	1-13	
Α	BRODIN et al.ESAT-6 proteins: protective antigens and virulence factors? Trends Microbiol November 2004 Vol 12 No 11 Pages 500-508. Especially pg 503 table 1.	1-13	Sequ
Α	ZVI et al. Whole genome identification of Mycobacterium tuberculosis vaccine candidates by comprehensive data mining and bioinformatic analyses. BMC Medical Genomics 28 May 2008 Vol 1 No 18 Pages 1-25. Especially pg 13 table 3.	1-13	pater
Α	US 2010/0129391A1 (REED et al.) 27 May 2010 (27.05.2010). SEQ ID NOs: 217, 226.	1	
Α	US 2003/0147897 A1 (ANDERSEN et al.) 7 August 2003 (07.08.2003). SEQ ID NO: 176, 177.	1-13	

Sequences found in patent documents

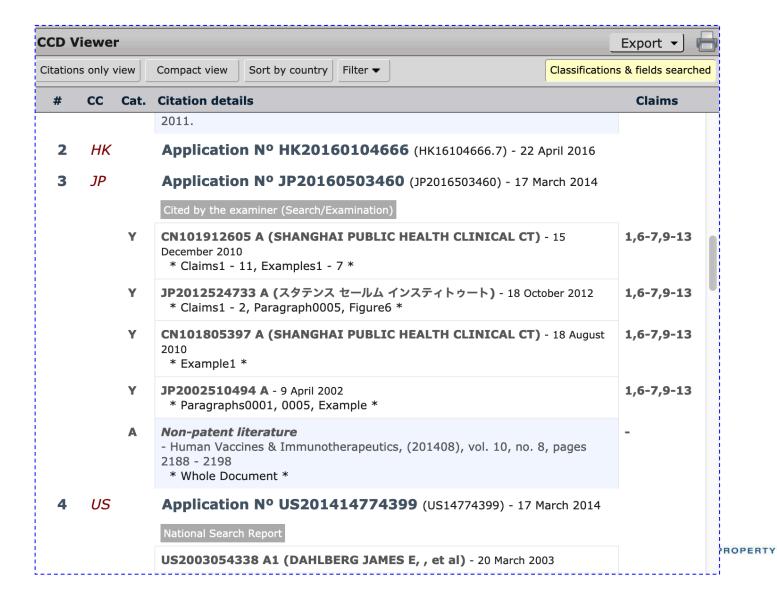
VIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

# Additional prior art for EP NPE (EP-A4)

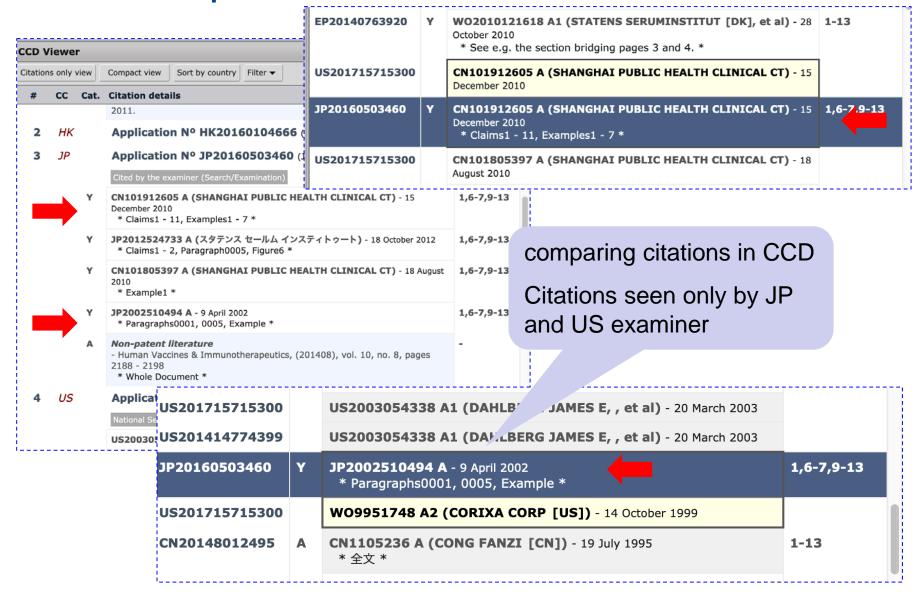
10	EP	Application Nº EP20140763920 (EP14763920.7) - 17 March 2014		
		National Search Report		
	Υ	<b>WO2010121618 A1 (STATENS SERUMINSTITUT [DK], et al)</b> - 28 October 2010 * See e.g. the section bridging pages 3 and 4. *	1-13	
	I	Differential protective efficacy of DNA vaccines expressing secreted proteins of Mycobacterium tuberculosis  Authors: KAMATH ARUN T, ET AL  Publication data: INFECTION AND IMMUNITY, 19990401 American Society for Microbiology, US  Source info: Vol: 67, Nr: 4, Page(s): 1702 - 1707  * See e.g. the abstract *	1-13 1-13	
	Υ	TB subunit vaccines-putting the pieces together Authors: Andersen P, Doherty T M Publication data: MICROBES AND INFECTION, 20050501 ELSEVIER, PARIS, FR Source info: Vol: 7, Nr: 5-6, Page(s): 911 - 921  * See e.g. the abstract or section bridging pages 914 and 915 *	1-13	
	Т	Multivalent TB vaccines targeting the esx gene family generate potent and broad cell-mediated immune responses superior to BCG  Authors: Daniel O Villarreal, Jewell Walters, Dominick J Laddy, Jian Yan, David B Weiner  Publication data: HUMAN VACCINES AND IMMUNOTHERAPEUTICS, 20140801 Taylor & Francis, US  Source info: Vol: 10, Nr: 8, Page(s): 2188 - 2198  * the whole document *	1-13	



## Additional prior art for JP NPE

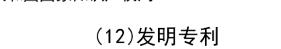


### Additional prior art for JP NPE



### **CN** citations

#### (19)中华人民共和国国家知识产权局





(10)授权公告号 CN 105025921 B (45)授权公告日 2019.02.19

(21)申请号 201480012495.8

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(65)同一申请的已公布的文献号 申请公布号 CN 105025921 A

(43)申请公布日 2015.11.04

(30)优先权数据 61/800,375 2013.03.15 US

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(86)PCT国际申请的申请数据 PCT/US2014/030776 2014.03.17

(87)PCT国际申请的公布数据 W02014/145923 EN 2014.09.18

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代理人 张英 宫传芝

(51) Int.Cl.

A61K 39/00(2006.01) A61K 39/02(2006.01)

C12N 1/20(2006.01) C12N 15/00(2006.01)

(56)对比文件

CN 1104108 A,1995.06.28, CN 1105236 A,1995.07.19,

KAMATH et al.Differential Protective Efficacy of DNA Vaccines Expressing Secreted Proteins of Mycobacterium tuberculosis.《INFECTION AND IMMUNITY》.1999,第67卷(第4期),

审查员 张全红

权利要求书2页 说明书33页 序列表25页 附图18页

(54)发明名称

用于结核病的预防或治疗的合成免疫原



## Sequence search records in ISR

### PCT/MY2015/050081

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	-& DATABASE EMBL [Online]	13,15
	1 July 2014 (2014-07-01), "Elaeis guineensis virescens R2R3-MYB gene, complete cds.", XP002750380, retrieved from EBI accession no. EM_STD:KJ789862 Database accession no. KJ789862 sequence	



	nternational application No.	
C (Continua	C (Continuation).  DOCUMENTS CONSIDERED TO BE RELEVANT  PC	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2005/0037344 A1 (STUHLMULLER et al.) 17 February 2005	
X	[0039]-[0072]; claim 1; SEQ ID NOs: 2 & 517, 100% identical to SEQ ID NO: 13; SEO ID NOs: 63 & 577, 96.92% identical to SEQ ID NO: 32; SEQ ID NOs: 71 & 585, 96.69% identical to SEQ ID NO: 32; SEQ ID NOs: 290 & 804, 73.66% identical to SEQ ID NO: 10	Q 1-20
X	US 7939282 B2 (FAST et al.) 10 May 2011 column 12, lines 35-62; claims 1-18; SEQ ID NO: 1, encoded by SEQ ID NO: 2, 96.83% identical to SEQ ID NO: 37	1-20
US 2009/0075831 A1 (RUSSWURM et al.) 19 March 2009  X table 3; claims 28, 40; SEQ ID NOs: 762 & 1091, 96.92% & 74.75% identical to SEQ ID NOs: 32 & 10, respectively		1-20
A	US 2009/0208933 A1 (PACHOT et al. ) 20 August 2009 example 1; table 3; claims 3, 10, 13; SEQ ID NO: 5, identical to SEQ ID NO: 13	



## Other examples with additional citations

- PCT/IB2014/059944
  - ISR by AU with X documents
  - EP-A4 additional X documents
- PCT/SG2014/000312
  - JP with additional X documents (seen only by JP)
  - US with additional X documents (seen only by US)
  - EP with additional NPL X documents (seen only by EP)
  - CN with additional X document (seen only by CN)

