

**Access to essential medicines,
patents and the law**
Introduction to patent law

Alexandria
15th Mai 2013

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- I. The international patent system**
- II. Patentability criteria**
- III. Some post grant issues**
- IV. Flexibility in the patent system**

The protection and enforcement of intellectual property rights should contribute to the **promotion of technological innovation** and to the **transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a **balance of rights and obligations**.

(Article 7, WTO Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPs Agreement)

- Promotion of innovation
- Technology transfer

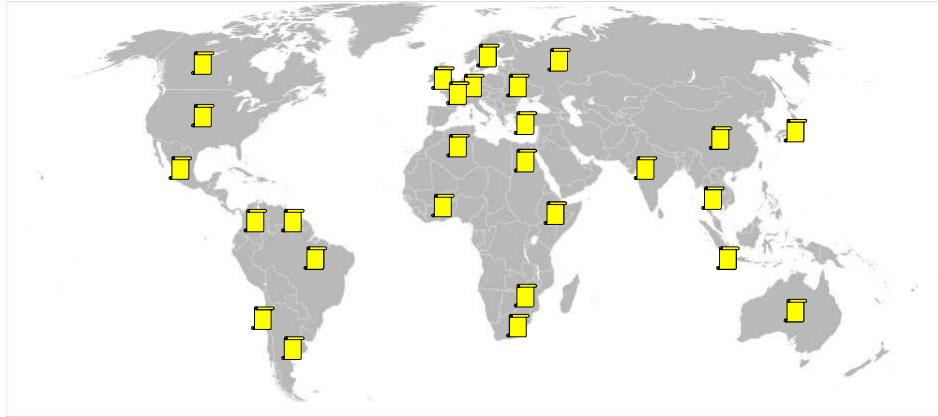
(see for example:

Article 3, WIPO Convention - Objectives of the Organization

Article 1, Agreement between the United Nations and WIPO)

I. The international patent system

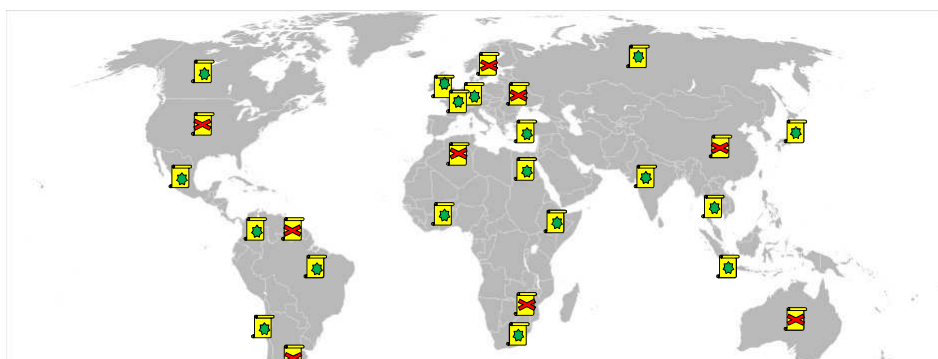
Topic: Filing Abroad



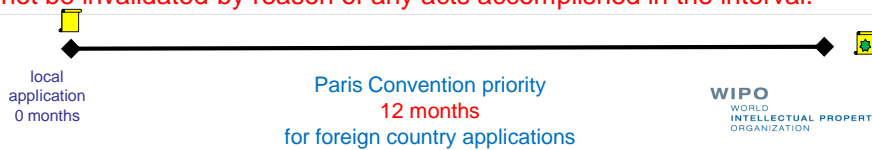
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The Paris Convention Route



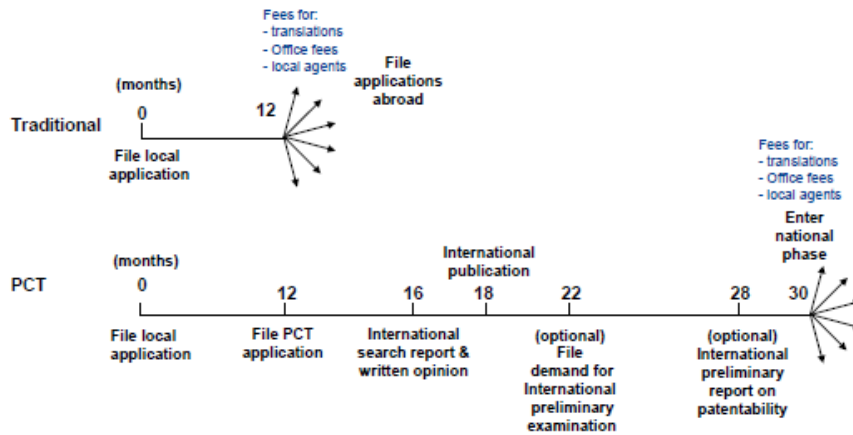
Any subsequent filing within a year after a first national application shall not be invalidated by reason of any acts accomplished in the interval.



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The Patent Cooperation Treaty (PCT)



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II. Patentability criteria

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Patentable subject matter

35 U.S.C. § 101: Inventions patentable

Whoever **invents** or **discovers** any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- Discovery?
 - Invention?
- Patentable subject matter

Diamond v Chakrabarty 447 U.S. 303 (1980)

- Bacterium capable of breaking down crude oil, proposed to use in treating oil spills
- USPTO: living things are not patentable
- US Court of Customs and Patent Appeals:
"the fact that micro-organisms are alive is without legal significance for purposes of the patent law"
- Supreme Court:
"anything under the sun that is made by man"

US Supreme Court Reasoning

- Laws of nature, physical phenomena and abstract ideas are not patentable
- The claimed invention, however, was not directed to an existing natural phenomenon but to a new bacteria with markedly different characteristics from any found in nature
- The invention was thus not nature's handiwork but resulted from the inventor's ingenuity and effort

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Production of a therapeutic against tuberculosis through continued vaccination of tubercle bacilli from turtles

DEUTSCHES REICH



AUSGEGEBEN
AM 22. APRIL 1921

REICHSPATENTAMT
PATENTSCHRIFT

— № 336051 —

KLASSE 30h GRUPPE 6

Dr. Friedrich Franz Friedmann in Berlin.

Verfahren zur Herstellung von Heil- und Schutzstoffen gegen Tuberkulose.

Patentiert im Deutschen Reiche vom 20. Juli 1911 ab.

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Reichsgericht

German Supreme Court, October 27, 1922

8.

a) Wichtigkeitsabteilung.
Vom 24. Juni 1922.

b) Reichsgericht, I. Zivilsenat,
vom 27. Oktober 1922.

hindernd. Sedenfalls wird bei vorliegendem

The process influences the outcome in the same manner as a conventional chemical process would do: through human interference.

eingestellte menschliche Tätigkeit beeinflusst.

Does the grant of a patent on a process for the production of therapeutic substances against tuberculosis contravenes **morality**?

Is such a procedure generally excluded from patentability, because the invention does not fall in a **technical** field?

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Novelty

- Publication / disclosure
(inventor's disclosure → grace period in some countries)
- To the relevant audience
→ Confidentiality agreements
- In the relevant form
→ oral/documented/internet
- Before the relevant date
→ filing date
- At the relevant place
→ domestic/regional/worldwide

Inventive Step / Non-obviousness

- Similar concepts, but differences in detail
 - Person skilled in the art
 - Non-obviousness at the relevant time
- Criteria, i. a.:
 - Surprising effect
 - Considerable technical advance
 - Overcoming important and known technical complications or a common misconception
 - Further development in neglected areas
 - Improvements of refined technology
 - Simpler and cheaper production
 - Solving a problem that could not be solved for a long time
 - Lack of established expert knowledge in a not explored field
 - etc.

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Industrial applicable - Useful

Europe: made or used in any industry, including agriculture

US: a specific, credible, and substantial utility

Example: EPO Board of Appeal T 870/04

- identified naturally occurring substance
- made available through some method
- unknown or incompletely understood function
- no related disease or condition identified
- no other practical use is suggested
- maybe a considerable scientific achievement, but not industrially applicable

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Disclosure

- an applicant for a patent shall disclose the invention
- in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art
- Some countries:
indicate the best mode for carrying out the invention known to the inventor at the relevant date
- **Disclosure** (Article 29 TRIPS)
distinct from **publication** (Article 12 Paris Convention)

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Sufficiency of disclosure

- To what **extent** must a patent disclose the invention?
- Legal and technical **purpose** of the patent system:
A person skilled in the art can carry out the invention
- To produce the invention to an economically profitable extent, the technical information contained in a patent document often needs to be **supplemented** with further information
- Technical information disseminated through the patent system does not **replace** other sources of information such as text books and scientific journals

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Incremental and adaptive innovation Evergreening

- **WHO CIPIH:**
“in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term”
- **Examples:**
New dosage forms, improved efficacy, improved storage characteristics, routes of delivery
- **Progress** of technology is incremental, innovation is incremental
- The mere fact that an innovation is **incremental** is not a basis for a patent refusal
- The **therapeutic** value of a product **as such** is usually not a patentability criterion
- Therapeutic advantages can help determining **inventive step**
- Judge every invention on its **merits** and ensure **good quality** of patents
- Granting a patent on an incremental improvement of a pharmaceutical is **independent** from the granted patent of the original product and does **not extend** the patent term

First and second medical indication

- **Product protection**
 - A **known** substance is found effective to treat a disease (first medical use – also: secondary or new use)
 - First use was already medical: second medical indication
- **TRIPs Agreement does not address this issue**
 - Some countries **exclude** patenting of substances for a new medical indication
 - Some countries **allow** patents on known medical substances for a new medical indication
- **Opponents:** impede access to medicines, reward uninventive activities and unnecessarily prolong **effective** patent protection for a certain medical substance
- **Proponents:** a development and clinical testing of a second use is no less in need of **incentives** than the first use and in some cases may be more therapeutically valuable than the first use
- Judge every invention on its **merits** and ensure **good quality** of patents
- Granting a patent on a product for a first or second medical indication is **independent** from the granted patent of the original product and does **not extend** the patent term

III. Some post grant issues

Public interest Scope of protection – Rights conferred

- Patent **claims** determine the scope of the protection
 - the basis of interpretation of patent protection
 - allow competitors to know what they may do and what they may not do
- A patent does not entitle to **anything**, but
 - **exclude** others from (TRIPs Article 28 – Rights conferred)
 - making, using, selling or importing the patented product
 - use of the patented process
 - making, using, selling or importing the product directly obtained through the patented process
 - assign, or transfer by succession, the patent and to conclude licensing contracts

▶ **Intangible rights: Licensing**
voluntary and compulsory licensing

Patent vs. Substantive Law

Paris Convention Article 4^{quater}

The **grant** of a patent shall **not be refused** and a patent shall not be **invalidated** on the ground that the sale of the patented product (or a product obtained by the patented process) is subject to **restrictions or limitations** resulting from the **domestic law**

WTO TRIPS Agreement Article 27(2)

Members may **exclude** from **patentability** inventions, the **prevention** within their territory of the **commercial exploitation** of which is **necessary** to protect **ordre public** or **morality**, including to protect human, animal or plant life or **health** or to avoid serious prejudice to the environment, **provided** that such **exclusion** is not made **merely** because the exploitation is **prohibited** by their **law**.

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Protection of Pharmaceutical Test Data

- Market approval
 - quality, safety, efficacy
 - clinical trials
 - observation rather than innovation
- Protection of test data
 - unfair competition (Art. 10^{bis} Paris Convention)
 - unfair commercial use and disclosure (Art. 39.3 TRIPs)
- How to protect test data?
- What is the linkage with patents?

- **WIPO Symposium on the Evolution of the Regulatory Framework of Test Data - From the Property of the Intellect to the Intellect of Property**
http://www.wipo.int/meetings/en/2010/wipo_ip_iss1_ge_10/

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IV. Flexibility in the patent system

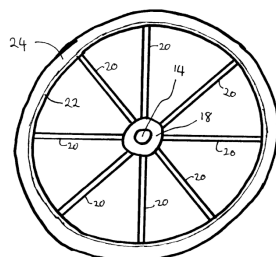
Invent the wheel

(12) INNOVATION PATENT	(11) Application No. AU 2001100012 A4
(19) AUSTRALIAN PATENT OFFICE	
(54) Title	Circular transportation facilitation device
(51) International Patent Classification(s)	B60B 001/00
(21) Application No.	2001100012 (22) Date of Filing: 2001.05.24
(45) Publication Date:	2001.08.02
(45) Publication Journal Date:	2001.08.02
(45) Granted Journal Date:	2001.08.02
(71) Applicant(s)	John Keogh
(72) Inventor(s)	Keogh, John Michael
(74) Agent / Attorney	Sandercock & Cowie 69 Robinson Street Dandenong Victoria AU

Circular transportation facilitation device



Register of Patents
Patents Act 1990



Innovation Patent

Patent no: 2001100012

Patentee(s): Keogh, John Michael of 29 Lennox Street Hawthorn VIC 3122 Australia
Inventor(s): Keogh, John Michael
Title: Circular transportation facilitation device
Term: Eight years from 24 May 2001
Date Sealed: 13 June 2001
Date Certified: 24 May 2001
Date of Patent: 24 May 2001
Status: REVOKED
Expiry Date: 24 May 2009
Date Ceased: 30 August 2001
Date Revoked: 30 August 2001

Policy choices for the patent system

flexibility

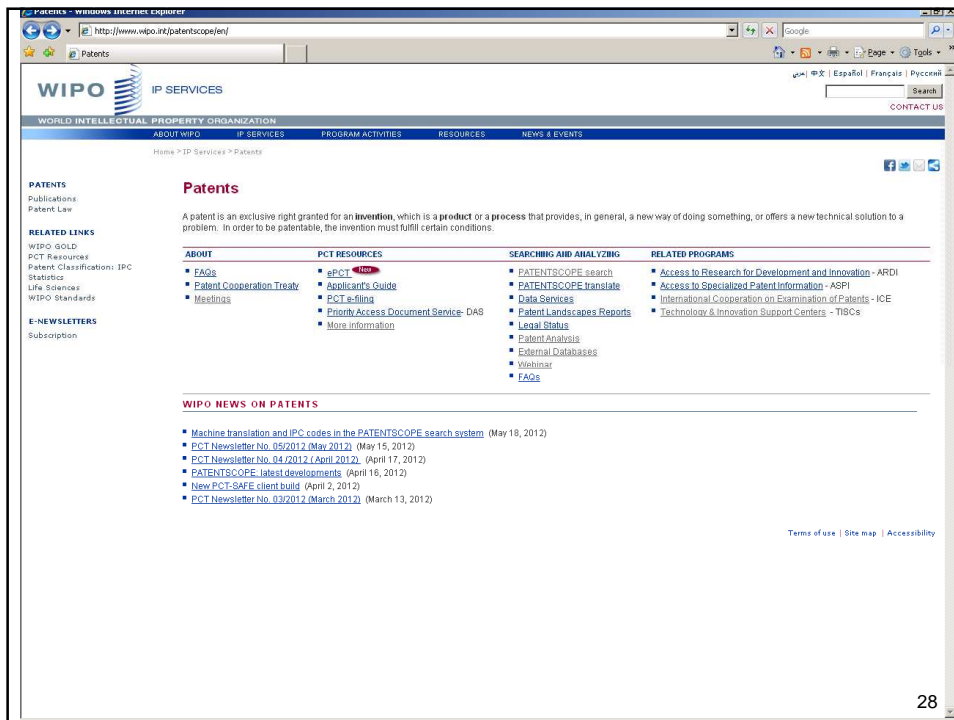
- Broader policy contexts
- International framework
- Participation in regional systems
- Legislation, patentability, procedure, rights conferred, exceptions and limitations, term, review mechanism
- Search and examination practice
- Application of law
- Infrastructure and resources
- Cooperation and worksharing

Policy

law

practice

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- Joint Technical Symposium Access to Medicines: Pricing and Procurement Practices, **July 16, 2010**
http://www.wipo.int/meetings/en/2010/wipo_wto_who_ge_10/index.html
- Workshop on Patent Searches and Freedom to Operate, **February 17, 2011**
http://wipo.int/meetings/en/details.jsp?meeting_id=22342
- Joint Technical Symposium to Address Access to Medicines, Patent Information and Freedom to Operate, **February 18, 2011**
http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/index.html
- See also
 - http://www.wipo.int/globalchallenges/en/health/trilateral_cooperation.html
 - http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
 - <http://www.who.int/phi/en/>



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