



**Patents:**

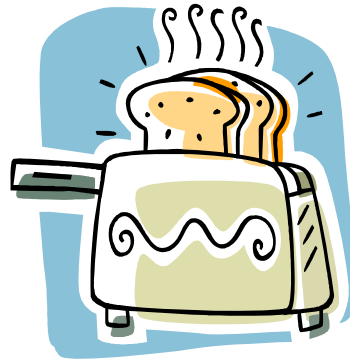
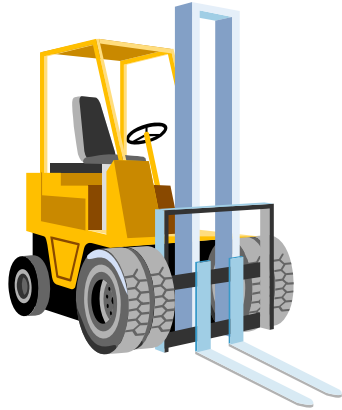
**Novelty, inventiveness, ownership  
and ethical considerations.**

**RESCUES 2008**

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# Patentable inventions?



# Invention categories

- **Products:**
  - objects (chemical compounds, materials, utility goods, machines, equipments, instruments etc.)
- **Processes/methods:**
  - e.g. processes for the manufacturing of a product, or methods of measurement, manoeuvring, signalling etc.
- A patented **use** may comprise use of objects and/or use of a process or method.

# How to get a patent?

- Application to national and/or regional patent offices.
- Example in Europe:
  - The European patent office (EPO)
    - The European Patent Convention (EPC)
  - A National patent office
    - National Patent Laws
- Patent Cooperation Treaty facilitates for international applications.
- No World patent!
- NO EU-patent!

# From application to grant

- Application
- Examination: novelty, inventive step etc.
  - Opposition
- Grant

# From application to grant

- The **timing** of the patent application depends on several factors: the research/practical results, competitors, disclosure, clinical trials etc.
- The **examination** time of the patent office for granting a patent is generally 3 years, or longer.
- Anyone may **oppose** a granted patent at the patent office within a limited time.
- A granted patent may be **revoked, amended** or **upheld** following such opposition procedures.
- Application for a **limitation** of the patent can be made during the lifetime of the patent (i.e. 20 years from the day of the patent application).
- A granted patent may always be challenged in **court proceedings**.

# Only inventions can be protected

- Discoveries etc. are not patentable.
- Biological material already existing in nature is in principle patentable, provided that the material is **isolated** from its natural environment or produced by means of a **technical process**.
- The human body in its natural state, including elements, is non-patentable.
- An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is **identical to that of a natural element**.

(See e.g. Article 3 and 5 of the Biotech Directive regulating certain principles of protection of biotechnological inventions.)

# Exclusions from patentability

- Inventions the commercial exploitation of which would be contrary to **ordre public** or **morality**(...)
  - Which in particular, concern the following:
  - Processes for cloning human beings;
  - Processes for modifying the germ line genetic identity of human beings;
  - **Uses of human embryos for industrial or commercial purposes**;(...)
- Plant or animal varieties or essentially biological processes for the production of plants or animals (...)
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body (...)

(Article 53(a) and Rule 27-28 of the EPC)



# The invention must fulfil the patentability criteria

- Novelty
- Inventive Step
- Industrial Application

# The invention must be novel

- **Absolute and Objective**
- **Beware of publication** of research results before the patent application is filed.
- Or publish if you want to **prevent** someone else from getting a patent.
- Other **novelty-destroying acts** are: exhibition of the invention, speeches, seminars, publishing of posters and description of the invention in funding applications.
- The principle of **priority** allows an applicant a one-year right to file a subsequent application in another state for the same invention.

# Ownership

- In **employment relations**, the ownership of inventions and transfers of rights from employee to employer are determined by law or agreements (individual or collective).

# Right to compensation

- In most states the employee has a mandatory right to a **reasonable remuneration** in compensation for the patent rights in an invention that is transferred to the employer.
- Employees at **universities** are also subject to laws or agreements of diverging kinds.

# Rights of the patent holder

- A right to prevent all third parties not having his/hers consent from **using the invention**:
  - e.g. making, offering, putting on the market or using the product which is the subject-matter of the patent, or importing or stocking the product for these purposes.
- **Limited exemptions** exist for private use, experimental use, magistral ordination etc.

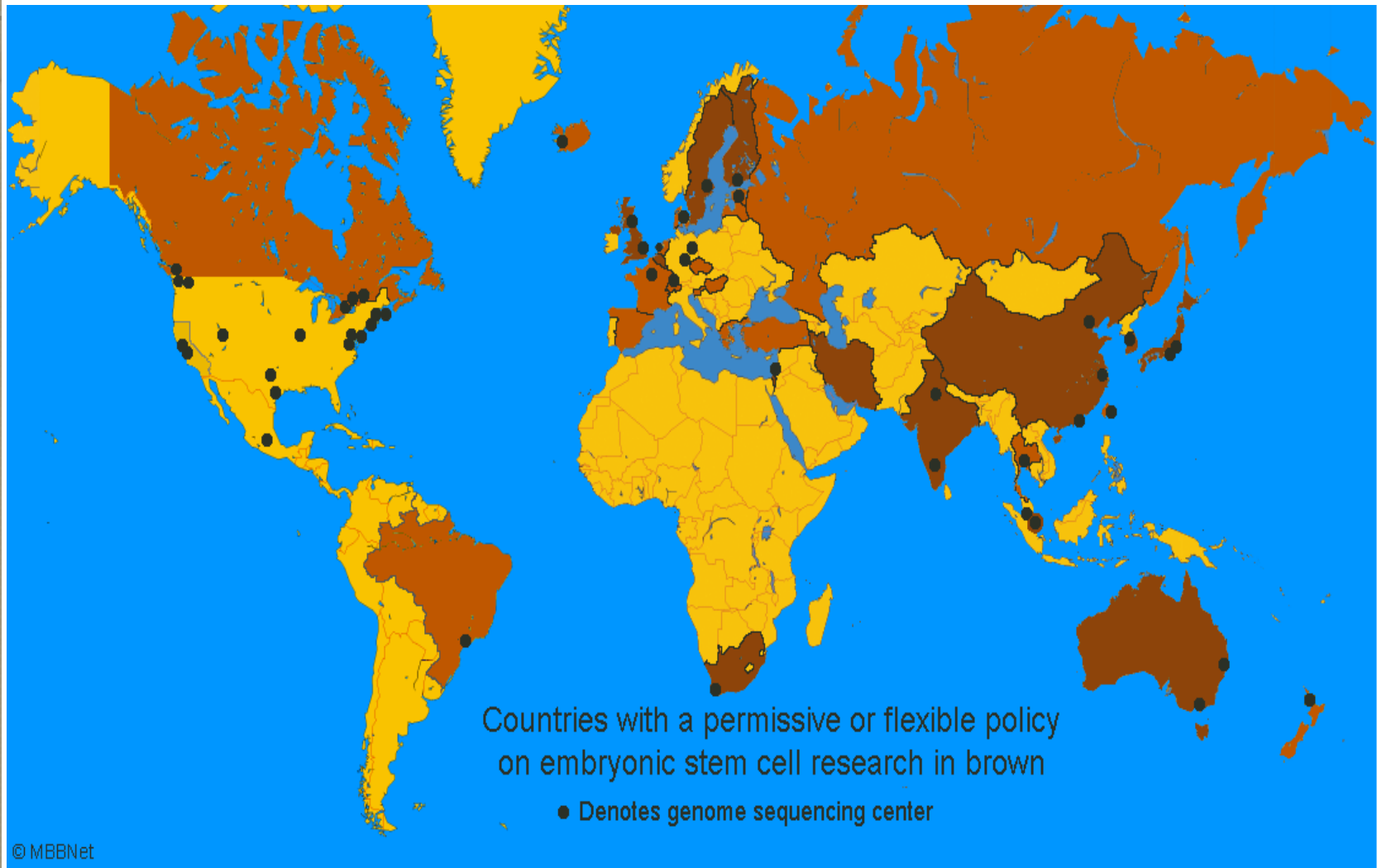
# Experimental use exemption

- **No exemption** for the use of an invention in **research** (except for in Belgium).
- Experimental use exemptions exist in most states, and enables third parties to experiment **on the invention** without the consent of the patent holder:
  - to establish or demonstrate its functions, or
  - to develop the invention further, e.g. to find new indications or improve its features.
- Experiments are allowed **on** a patented invention, but never **with** (the help of) a patented invention.
- An invention may never be used for its patented purpose.



# Patents for Stem Cell Inventions

# The Regulatory Framework: Permissive or Flexible States





# Stem Cell Patents

- Foetal and adult stem cells and related processes (e.g. generation of cells from donated tissues) have consistently been patented in the U.S. and Europe.
- hESC patents in U.S. (e.g. WARF)
- In Europe, patents have been filed for processes of cultivation of hESC, differentiated cells and hESC as such, but these applications have raised ethical considerations (i.e. the legal exclusion for use of human embryos).
- 23 ESC patents already granted by the EPO, but disclaimed as “non-human”.
- 31 hESC applications pending at the EPO (2006).

# hESC inventions and the effects of patent exclusions in Europe

- The human body in its natural state, including elements, is non-patentable.
  - Precludes patents on human embryos and totipotent cells as such.
- The uses of human embryos for industrial or commercial purposes is not patentable.
  - Pluripotent cells and processes of extraction?
  - Under interpretation by the EPO: G 2/06 (WARF), decision anticipated during autumn 2008.

# Uses of human embryos for industrial or commercial purposes?

- The process of generation of hESC (by the destruction of human embryos.)
  - Would it constitute an exclusion under the “use of human embryos for industrial or commercial purposes”?
- hESC or lines per se in their natural state or modified e.g. genetically.
  - Will the generation process preclude the patenting of resulting inventions?
- Uses of hESC or –derived products.
  - Will the generation process preclude the patenting of “downstream” inventions?

# Conclusions

- Early publication of research may preclude patenting.
- A patent right gives the holder choices and responsibilities: free use, licensing etc.
- In the patenting of biological material, especially stem cell inventions, a number of hurdles must be passed: ethical considerations (Europe), novelty, inventiveness.
- The situation on hESC patenting is depending on national policies, as well as the EPO.
- The opposition procedure establishes possibilities for third parties to react towards improper patents.
- There is no exemption for use of inventions in research.

# Discussion

- How do you feel about the patent situation in your field of research?
- Effects of patent rights – impediments to research or bringing knowledge further?
- Is there a need for patents to recoup investments or should patent be banned from certain types of research?



**Thank you for your attention!**

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