Bioethics and patenting of biological material

Case law and practice in the European Patent Office

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General Information

- European Patent Organisation
- Member states
- Structure of the European Patent Office
  - Technical fields of examination

The European Patent Organization

European Patent Organisation

European Patent Office

Administrative Council

The executive body

The Office's task is to grant European patents.

The legislative body

Important functions:

- to adopt the budget
- to approve the President's actions in implementing the budget
- to amend the Implementing Regulations and Rules

The Administrative Council consists of delegates from the Member States.

32 Member States

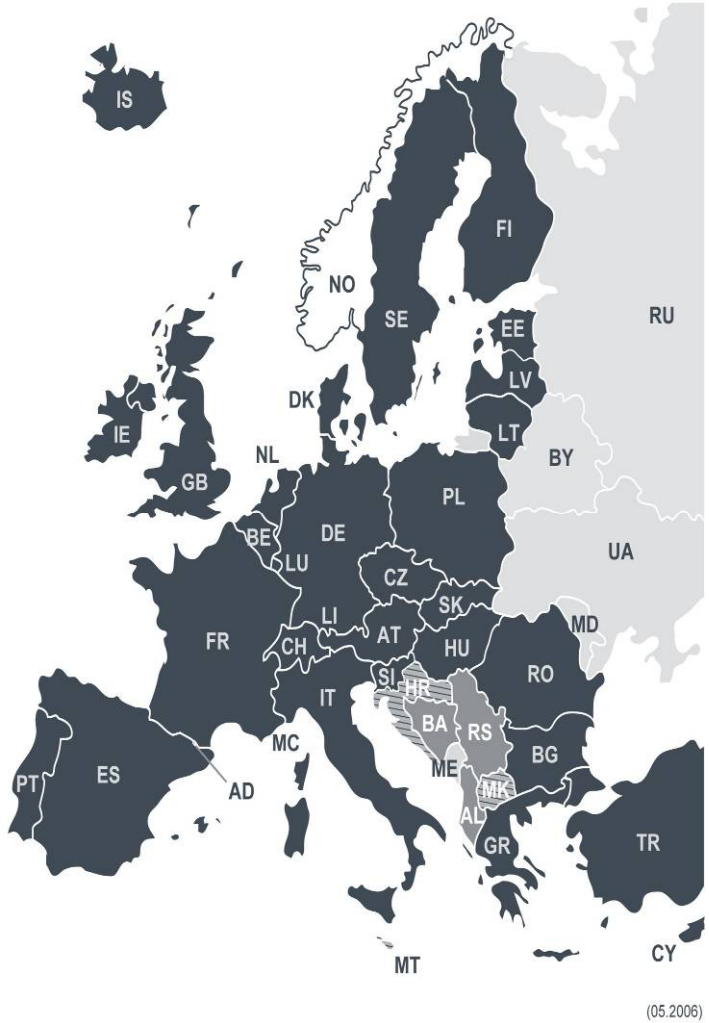
September 2007

Member states of the European Patent Organisation
AT Austria, BE Belgium, BG Bulgaria,CH Switzerland, CY Cyprus, CZ Czech Republic, DE Germany, DK Denmark, EE Estonia, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, HU Hungary, IE Ireland, IS Iceland, IT Italy, LI Liechtenstein, LT Lithuania, LU Luxembourg, LV Latvia, MC Monaco, NL Netherlands, PL Poland, PT Portugal, RO Romania, SE Sweden, SI Slovenia, SK Slovakia, TR Turkey

States entitled to join the European Patent Convention (EPC)
NO Norway

States which have been invited to join the EPC
HR Croatia, MK Former Yugoslav Republic of Macedonia, MT Malta

States recognising European patents ("EXTensionstates")
AL Albania, BA Bosnia-Herzegovina, HR Croatia, MK Former Yugoslav Republic of Macedonia, RS Serbia



The structure of the European Patent Office

EPO President Ms Brimelow	DG1 Mr Hammer	Operations: Search Examination-Opposition
	DG2 Mr Vermeij	Operational Support: Patent administration, IT, Quality management
	DG3 Mr Messerli	Appeals
	DG4 Mr Edfjäll	Administration
	DG5 Mr Desantes	Legal and International Affairs, European Patent Academy

Technical fields in DG Operations

Search-Examination-Opposition

- Audio-Video Media
- Electricity & Semiconductor Technology
- Electronics
- Handling and Processing
- Human Necessities
- Industrial Chemistry
- Polymers
- **Biotechnology**
- Civil Engineering & Thermodynamics
- Computers
- Measuring and Optics
- Pure and Applied Organic Chemistry
- Telecommunications
- Vehicles and General Technology

Requirements for patentability

- **Basic requirements**
  - Novelty, Inventive step, Industrial application, Sufficiency of disclosure (Art. 54, 56, 57, 83 EPC)
  - Exceptions to patentability Article 53(a) EPC

- **Specific for biotechnological inventions**
  - Directive 98/44/EC
  - Rules 23b-23e EPC
  - Case law exploring the morality issue
    - Edinburgh case EP-B-695351
    - WARF case EP 96903521

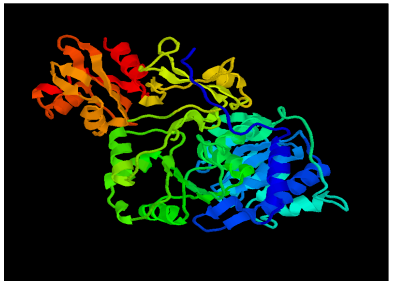
Legal basis for patenting biotechnological inventions

- The EU **Directive 98/44/EC** of 6 July 1998 was published in OJ EPO p.101, 1999.
  - It considers in detail the patentability of bio-molecules, partial sequences, living organisms, plants, animals, elements isolated from the human body, etc
    - e.g. Recital 23: A mere nucleic acid sequence without indication of a **function** does not contain technical information
  - It deepens the ethical dimension of patenting biological material
    - e.g. Recital 16: the human body at any stage of its formation or development, **including germ cells**, cannot be patented;
    - Recital 38: excluded from patentability are **chimeras** from germ cells or totipotent cells of humans and animals

The Directive is used as a supplementary means of interpretation of
Rules 23b - 23e EPC
(entered into force 01.09.99) .

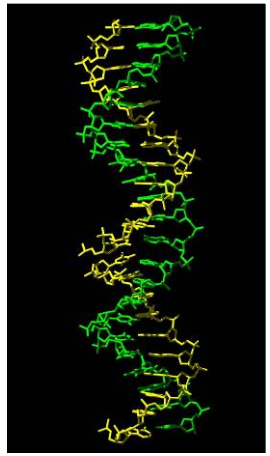
...what is patentable

- **Biotechnological inventions shall be patentable if they concern**
  - biological material which is **isolated** from its natural environment or **technically produced**



even if it previously occurred in nature

- e.g. nucleic acid molecules, proteins, cells



  - plants or animals if **not confined** to a particular plant or animal variety
    - e.g. transgenic plants or animals
  - microbiological processes and products

(Rule 23c EPC)

...what is NOT patentable

- **Article 53 EPC : Exceptions to patentability**

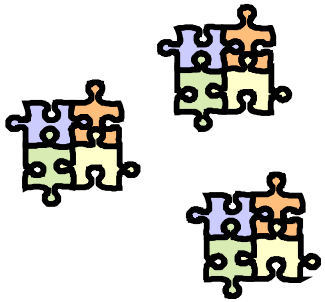
European patents shall not be granted in respect of :

  - (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States

EPC Working Party recognized that

"**there was no European definition of morality**"

"interpretation of the concept of morality should be a matter for European institutions"



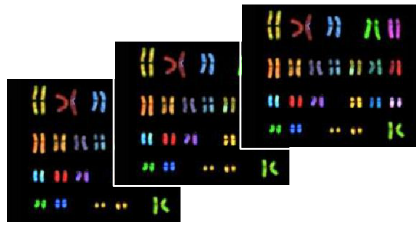
T356/93: Prior to any assessment of the patentability of the claimed subject-matter under Article 53(a) EPC, the meaning of morality and "ordre public" must be defined by way of interpretation. (Reasons 4)

"**ordre public**" covers the protection of public security and physical integrity of individuals as part of society (Reasons 5)

morality pertains to conventionally-accepted standards of conduct in the European culture (Reasons 6)

...what is NOT patentable

- **Exceptions to patentability under Article 53(a) EPC**

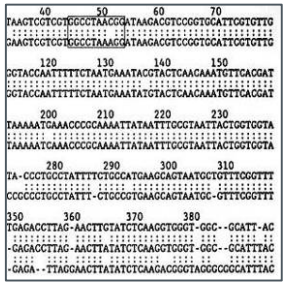


  - cloning of human beings
  - modifying the human germ line
  - industrial or commercial use of human embryos
  - the generation of genetically modified animals
    if their production causes suffering without substantial medical benefit

(Rule 23d EPC)

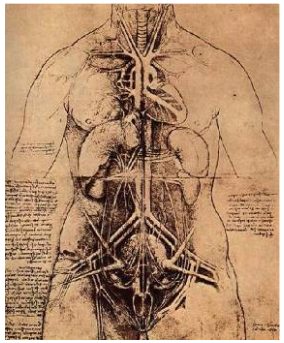
....the human body is special

- Patentable may be:



an **element isolated** from the human body or **produced by technical means** including the sequence or partial sequence of a gene even if its structure is identical to that of a natural element may constitute a patentable invention

- However, NOT patentable:



the human body, at the **various stages of its formation** and development,

and the **simple discovery** of one of its elements, including the sequence of a gene,

cannot constitute patentable inventions.

- The **industrial application** of a sequence or partial sequence of a gene must be disclosed in the application.

(Rule 23e EPC)

Human embryonic stem cells pose a dilemma

- Neither EPC nor Directive 98/44/EC specifically deal with human embryonic stem cells
  - reference to
    - uses of embryos in Rule 23d(c) EPC, recital 42 of Directive

commercial industrial use of embryo
vs
therapeutic diagnostic inventions useful to the embryo

    - the human body as such EPC 23e(1) EPC, recital 21 of Directive

embryo is a stage of the human body
vs
cell lines are technically produced

    - elements of the human body EPC 23e(2) EPC, recital 16 of Directive

isolated cells
vs
germ cells are not patentable

EGE European Group on Ethics in Science and New Technologies

- Article 7 of the Directive and Recital 44:

  "The European Group on Ethics in Science and New Technologies of the Commission (EGE) evaluates all ethical aspects of biotechnology".

- OPINION No. 16 of 16 May 2002 of the EGE:

  ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS

  http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf

EGE European Group on Ethics in Science and New Technologies

EGE Opinion 16

- **Unmodified stem cells** are **too close to the human body**; their patenting may be considered as a form of commercialisation of the human body; would also lead to „too broad patents“
- Only **stem cell lines** which have been **modified** by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application may be patentable
- „As to the patentability of **processes** involving human stem cells, whatever their source, there is **no specific ethical obstacle**, in so far as they fulfil the requirements of patentability“

Edinburgh case EP -B1-695351

University of Edinburgh

- Claim: *A method of isolating and/or enriching and/or selectively propagating desired animal stem cells*
  - Mention of grant of a patent 08.12.99

- Oppositions filed by 14 parties; among other grounds, the morality of claiming human embryonic stem cells was contested
  - The OD followed **a broad interpretation of Rule 23d(c) EPC**

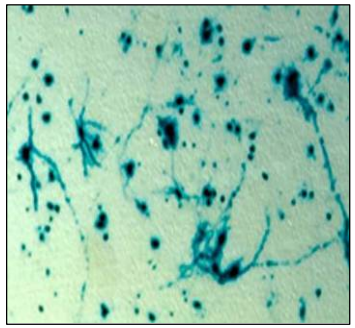
  - The patent was maintained for

    A method of isolating and/or enriching and/or selectively propagating desired animal stem cells other than embryonic stem cells (21.07.03)

- The Patentee filed an appeal which will be examined by the Board as **T1079/03**

Neural crest cells EP 93921175

Application 93921175 by (Caltech)



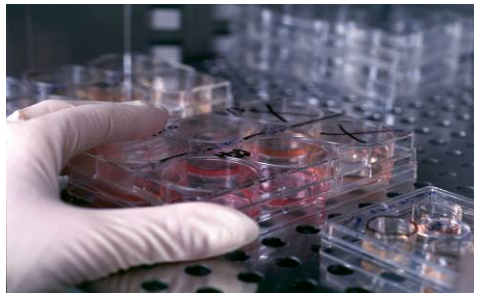
- Refused in examination under Article 53(a) and Rule 23d(c) EPC (17.10.2003);
- Appeal lodged **T522/04**

- **The Board decided to delay the proceedings in view of pending G2/06**

Neural precursor cells, EP-B-1040185

- "Brüstle" patent application

  Claim 1:. Non-tumorigenic cell composition obtained from **mammalian embryonic stem cells**, obtainable by the steps of
  - (a) proliferation of ES cells,
  - .
  - .
  - **with the proviso that the method does not include the destruction of human embryos**



- The application has been granted in limited form (January 2006)

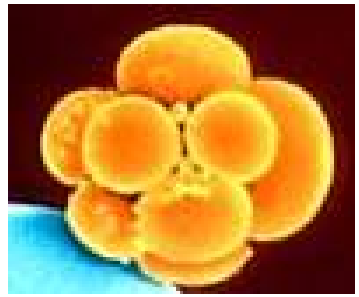
- Opposition has been filed based among other reasons on Article 53a and Rule 23d(c) EPC.

In view of pending G2/06, proceedings are delayed

WARF Case EP 96903521

Wisconsin Alumni Research Foundation

- Claim : A cell culture comprising primate embryonic stem cells....
- Refused by the Examining Division (June 2004)
  - The description provides **only one source of starting cells**, namely a pre-implantation embryo i.e. the invention relies on using human embryos
  - This use means a use for **industrial purposes** within the meaning of Rule 23d(c) EPC and is thus prohibited under Article 53(a) EPC



WARF Case EP 96903521

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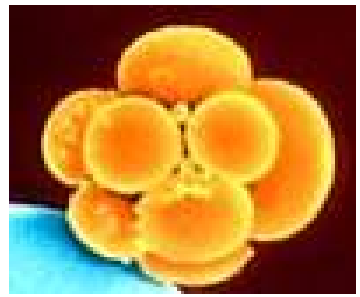
- Reasoning of the refusal
  - The provisions of Rule 23d(c) in conjunction with Article 53(a) EPC are not directed exclusively **to the claimed subject-matter** but rather concerned **inventions**, thus including the methods that made the claimed subject-matter available to the public.
  - The invention relies **exclusively on use** of human embryos
  - The generated cell cultures do not serve any therapeutic or diagnostic purpose useful to the embryo itself, thus, Recital 42 does not apply



WARF Case T1374/04

Wisconsin Alumni Research Foundation

- The Applicant filed an appeal against the refusal by the Examining Division
  - In decision T1374/04 (November 2005) the Technical Board decided to refer questions of law to the Enlarged Board of Appeal

WARF Case G02/06

Wisconsin Alumni Research Foundation

The Enlarged Board of Appeal received the following questions (16.04.06)

1. Does Rule 23d(c) EPC to an application filed before its entry into force?

2. If yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

WARF Case G02/06

Wisconsin Alumni Research Foundation

3. If the answer to question 1 and 2 is no, does Article 53(a) EPC forbid patenting such claims?

4. Is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)

TABLE 1

Regulations in EU Member States regarding hES[1] cell research

	AT	BE	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	SE	SI	SK	UK
Allowing procurement of hES cells from supernumary embryos by law		X				X		X	X	X	X								X			X			X
Specific legislation for human embryo research incl. supernumerary embryos but without specific reference to hES cells							X					X					X						X		
Prohibiting procurement of hES cells from human embryos but allowing importation of hES cell lines					X									X											
Prohibiting procurement of hES cells from human embryo	X												X		X					X				X	
No specific legislation regarding human embryo research			X	X												X		X			X				
Allowing creation of human embryos for procurement of hES cells by law		X																							X
Prohibiting creation of human embryo for research purpose and for procurement of hES cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997	X		X	X	X	X	X	X	X	X	X	X	X	X	X				X		X		X	X	

1) hES cells = human embryonic stem cells

COUNTRY CODE KEY:

AT : Austria	DK : Denmark	FR : France	LU : Luxembourg	PT : Portugal
BE : Belgium	EE : Estonia	HU : Hungary	LV : Latvia	SE : Sweden
CY : Cyprus	EL : Greece	IE : Ireland	MT : Malta	SI : Slovenia
CZ : Czech Republic	ES : Spain	IT : Italy	NL : Netherlands	SK : Slovakia
DE : Germany	FI : Finland	LT : Lithuania	PL : Poland	UK : United Kingdom

Thank you for your attention !

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