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Biotech patents and case law related to the implementation of the Directive 98/44/EC

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EPO, Directorate 1.2.12 Biotechnology

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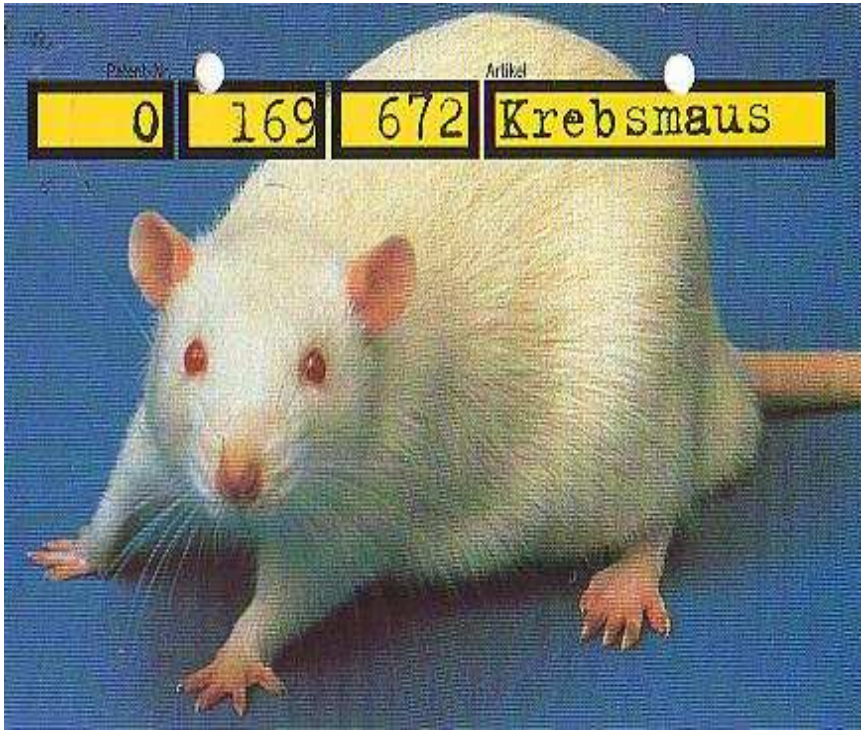
The Harvard oncomouse

first case where the EPO had to deal with the question whether animals are patentable *per se*

The Harvard oncomouse. What is it about ?

- It is a transgenic mouse which contains and expresses an active oncogene.
- The animal develops a tumour.
- The scope is to use such animal as an *in vivo* system for testing anti-cancer drugs



The oncomouse (1): from first filing 1985 to refusal 1989

1985: application was filed:

- A transgenic non-human eukaryotic animal ... .
- A method for producing a transgenic eukaryotic animal ...

Amended claims during examination

- A transgenic non-human eukaryotic animal...
- A method for producing a transgenic **non-human** eukaryotic animal ...

1989: Rejection by the Examining Division (OJ. 11/1989)

The oncomouse (2): from first filing 1985 to refusal 1989

Amended claims during examination

- A transgenic non-human eukaryotic animal...
- A method for producing a transgenic **non-human** eukaryotic animal ...

1989: Rejection by the Examining Division (OJ. 11/1989) based on:

Article 53(b) EPC: animal varieties, although not specifically mentioned, are covered by the claims. The different terms used in Art. 53(b) EPC (animal varieties, races animales, Tierarten) were taken into account. Tierarten (species) is broader than the corresponding EN and FR terms.

Article 83 EPC: one oncogene (*myc*) in mice only. The extent of protection is unrealistically broad and not justified by the experimental part of the application.

Article 53(a) EPC: (morality) mentioned in the Decision, but not used for refusal.

The oncomouse (3): refusal 1989 - appeal - grant 1992

The Decision to Refuse was appealed (T19/90).

eukaryotic → mammalian

- A transgenic non-human mammalian animal ...
- A method for producing a transgenic non-human mammalian animal ...

The Board of Appeal decided to remit the case to the Examining Division for further prosecution, with the order to grant the patent according to the claims above.

The oncomouse (4): refusal 1989 - appeal - grant 1992

- A transgenic non-human mammalian animal...
- A method for producing a transgenic non-human mammalian animal ...

Reasons from the Board of Appeal:

Article 53(b) EPC (animal varieties): the position of the E.D. leads to the conclusion that Art. 53(b) excludes all animals from patentability, which is not the meaning of the Article. The fact that the EN, FR and DE terms are not consistent in the matter covered by them does not mean *per se* that animal varieties are embraced by the scope of the claim. The E.D. should provide further reasons thereabout.

Article 83 EPC: one oncogene (myc) in mice only. Only when there are serious doubts, substantiated by verifiable facts, may an application be objected to for lack of sufficient disclosure, which is not the case here.

Article 53(a) EPC: Decision T19/90 introduces the concept of balance between animal suffering and invention's **usefulness** to mankind.

The E.D. granted the patent in 1992

The oncomouse (5): grant 1992 - opposition - maintenance in amended form 2003

The Decision to Grant (1992) was opposed. 17 Opponents.

- A transgenic non-human mammalian animal ... .
- A method for producing a transgenic non-human mammalian animal ... .

In June 1999, the EPO implemented the Dir. 98/44/EC into the EPC (Rules 23b-23e EPC).

In 2002, the Opposition Division decided to maintain the Patent in amended form:

- A transgenic rodent ... .
- A method for producing a transgenic rodent ... .

The oncomouse (6): grant 1992 - opposition - maintenance in amended form 2003

Reasons from the Opposition Division for maintenance of the Patent in amended form:

- A transgenic rodent ... .
- A method for producing a transgenic rodent ... .

The term " mammal " embraces also animals which are not suitable as test models, therefore offending against Article 53(a) EPC, in combination with Rule 23d(d).

Restriction of the subject-matter claimed to " rodent " represents an appropriate balance between the availability of test models and the justified suffering of the animals.

Restriction to mice only would be unfairly restrictive and not justified, because mice are not the only rodents available as test models.

The oncomouse (7): maintenance 2003 - appeal - end of the story

The Decision to maintain the patent in amended form was appealed (T0315/03). 6 Appellants.

- A transgenic rodent ... .
- A method for producing a transgenic rodent ... .

In 2004, the Board of Appeal decided to remit the case to Opposition Division, with the order to maintain the patent in amended form:

- A transgenic mouse ... .
- A method for producing a transgenic mouse ... .

The Opposition Division followed the instructions of the Board of Appeal (2005). The Applicant did not pay the due fees → the patent was revoked.

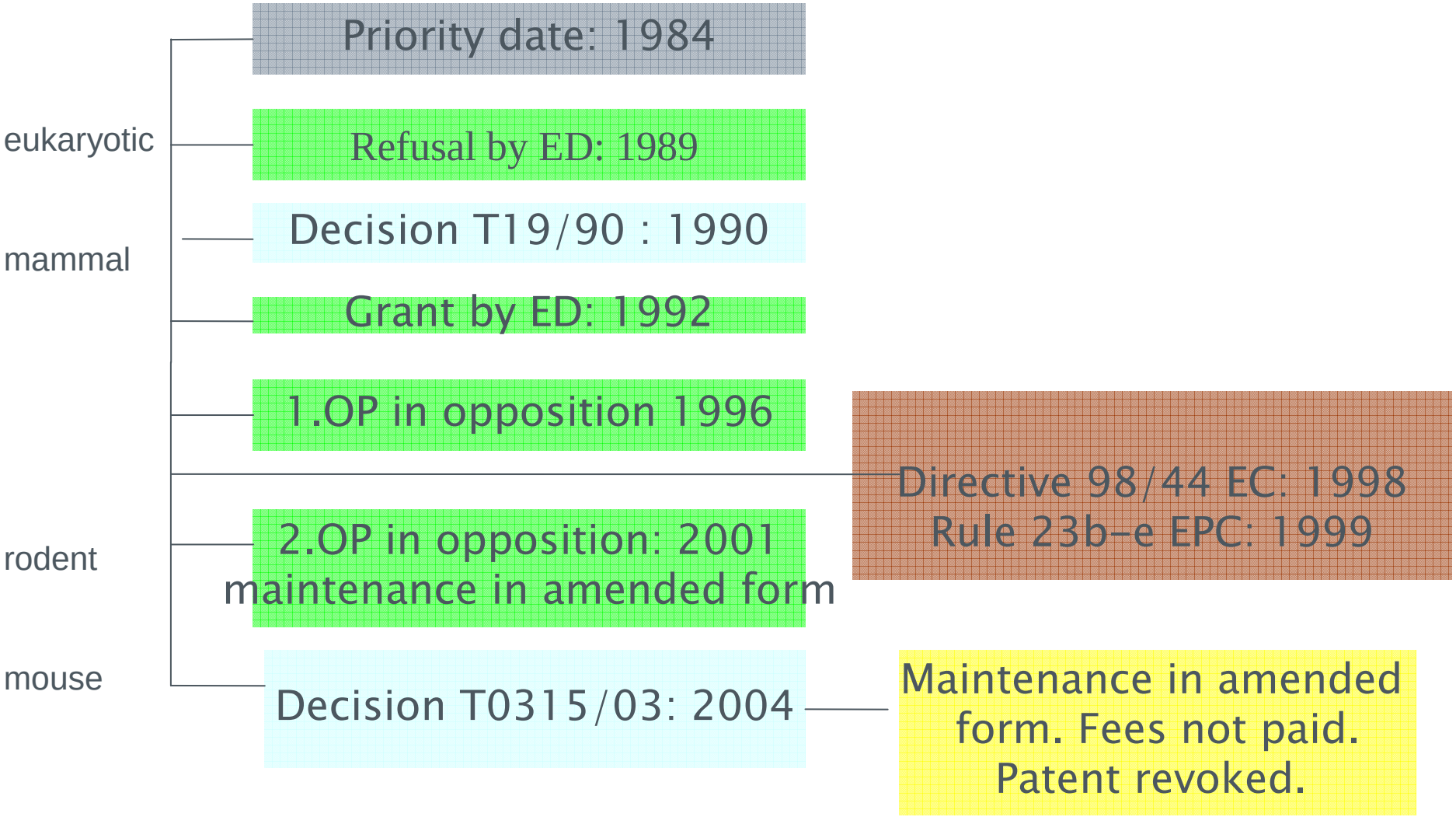
The oncomouse (8): maintenance 2003 - appeal - end of the story

Reasons from the Board of Appeal:

- A transgenic mouse ... .
- A method for producing a transgenic mouse ... .

- " The Applicant has referred to the advantageous provision of several model systems for studying cancer without being restricted to the limited physiology, metabolism, etc. of mice. However, there is quite simply no evidence to show that all the various animals in the category of rodents are so different that each of them would provide a contribution to cancer studies, such as being specifically suited as a model for studying a specific type of cancer " (from §12.2.3 of the reasons).

History of the oncomouse patent



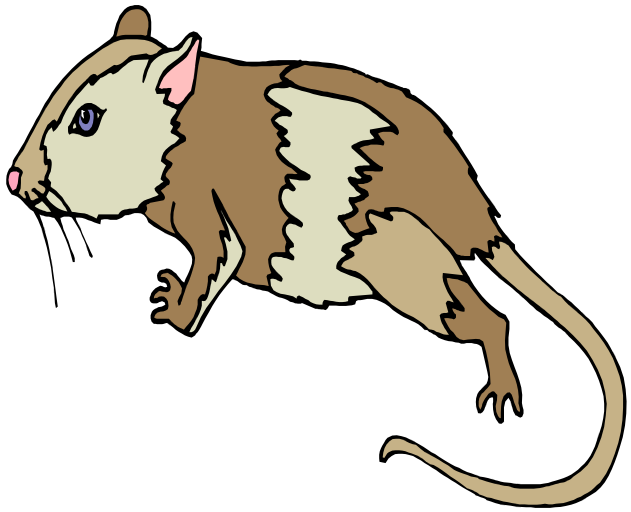
Conclusion:
transgenic animals are patentable provided that (1):

- Rule 23d(d) EPC; Rule 28d EPC^{2000}:

- Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern:

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes

- Dir. 98/44/EC Art. 6 2.(d)



Usefulness to mankind (T19/90) narrowed to substantial medical benefit (Rule 28d EPC^{2000})

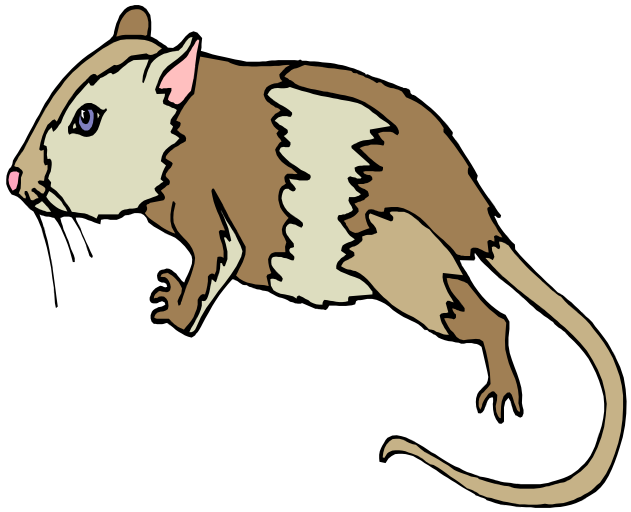
and that (2):

- Article 53(b) EPC^{2000}:

- European patents shall not be granted in respect of animal varieties ... .

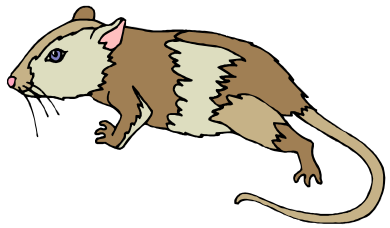
Rule 27(b) EPC^{2000} Biotechnological inventions shall also be patentable if they concern: animals, if the technical feasibility of the invention is not confined to a particular animal variety.

- Dir. 98/44/EC Art. 4 1.(a)



Examples of suffering of animals Vs medical benefits to man or animal

- NO ⌖
- A transgenic "naked" mouse used to test hair cosmetic products



- YES √
- The Harvard oncomouse used as a model for studying cancer

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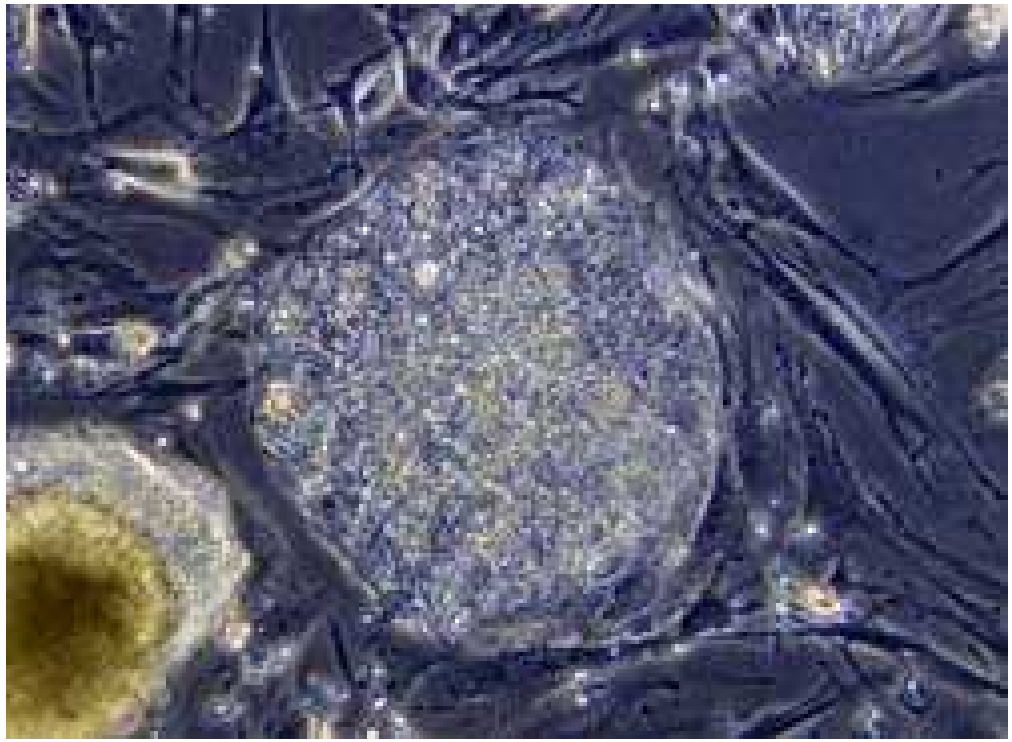
Patentability of embryonic stem cells



Acknowledgment: Pierre Treichel, EPO - Directorate Patent Law

"Edinburgh" patent

- The contested patent describes a method of using genetic engineering (selectable marker) to isolate stem cells - including embryonic stem cells - from more differentiated cells in a cell culture in order to obtain pure stem cell cultures. The public debate centred on whether the patent extended to humans.

Edinburgh patent EP 0 695 351- granted claims

1 A method of isolating and/or enriching and/or selectively propagating desired animal stem cells ... .

2 A method according to Claim 1 wherein the desired stem cells are selected from ... , embryonic stem cells, ...

20 A method according to any preceding claim wherein the source of cells is obtained by ... cells derived from an embryo ... .

21 A method according to Claim 20 wherein the source of cells is obtained by cells obtained from a transgenic animal.

47 A method for preparing a transgenic animal comprising obtaining a desired stem cell according to the method of any of claims 1-36, excising the selectable marker from the desired stem cell and generating the transgenic animal therefrom.

48 A method of preparing a transgenic animal ... .

Edinburgh patent EP 0 695 351

In the claims as granted, human embryo/cells/organisms are not explicitly mentioned.

HOWEVER

Article 69(1) EPC: The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Page 2 of the Patent specification as granted: ... in the context of this invention, the term " animal cell " is intended to embrace all animal cells, especially of mammalian species, including human cells.

Example of stem cells include ... embryonic stem cells, ...

Experimental part carried out in mice.

Edinburgh patent EP 0 695 351 - Opposition

- Opposition filed (14 initial Opponents)
- Main grounds for objections were Articles 83 EPC (scope of protection broader than justified by the description) and 53(a)/Rule 23d(c) EPC (uses of human embryos for industrial or commercial purposes.
- 2002: the patent was maintained in amended form:
  Embryonic stem cells were excluded from claims (" other than embryonic stem cells " introduced in claim 1) and description.

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

  Specification " non human " introduced in the claims related to transgenic animals.
- It was made clear by the OD that cloning methods were not and could not be embraced by the Application.
- The present Patent no longer includes human or embryonic stem cells, but it still covers modified human and animal stem cells other than embryonic stem cells.
- Appealed by the applicant: T1079/03. Pending

Opinion No. 16 EGE and Edinburgh Decision (EP B 695 351)

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 = **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“

EGE European Group on Ethics in Science and New Technologies

Opposition Division

- No legal obstacle to patenting (see genes: they are at least as close to the human body as the stem cells)
- Conflict with Biotech-Dir. / EPC, since adult stem cells, irrespective of their degree of modification = isolated element of the human body → in principle patentable
- Ethical distintion between process and product patents unjustified; Example letter bomb

Embryonic stem cells - Case 2 - EP 0 658 194

The application relates to a population of mammalian neural crest cells separated from other embryo cells, and uses thereof.

- Refusal of the ED dated 17.10.2003 based on Article 53(a) / Rule 23d(c) EPC.

- Invention concerning uses of human embryos for industrial or commercial purposes are not patentable. The Applicant argued that the invention would be **useful to mankind**, but no arguments were provided that the invention would be useful to the embryo itself.

- Appeal filed: T 0522/04 - pending
- disclaimer introduced: " not derived from an embryo "
- sufficient ?

Embryonic stem cells - WARF case EP 0 770 125

- Claim 1: “A cell culture comprising primate embryonic stem cells ...”

- **Rejection by Examining Division:**

  – **Use of human embryos** as starting material is **described** in the application as being **indispensable**

  – 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

  – 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 all aspects that made the claimed subject-matter available to the public.

Embryonic stem cells - WARF case EP 0 770 125

- **Rejection by Examining Division:**

  – The **description provided only one source of starting cells, namely a pre-implantation embryo**. It is therefore irrelevant that the claimed subject-matter related to cell cultures and not to a method of production of said cultures.

  – Recital 42 does not apply because the **generated cell cultures do not serve any therapeutic or diagnostic purpose useful to the embryo that gave rise to the said cultures,** even if the availability of the said cell cultures would potentially benefit the development of substances for treating conditions relating to human infertility

Recital 42 of Dir. 98/44/EC: such exclusion (industrial or commercial use of human embryos) does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it.

The WARF case: G 2/06 Referral

- The Decision to Refuse was appealed (T1374/04).

- The following points of law were referred to the Enlarged Board of Appeal by decision **T 1374/04** (pending under **G 2/06**):

1. Applicability of 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 ?

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).

Embryonic (stem) cells - outstanding issues

The specific exclusion under Rule 23d(c) EPC (Art. 6(2)(c) Dir. 98/44/EC)

- European patents shall not be granted in respect of **biotechnological inventions which**, in particular, **concern**:

  uses of human embryos for industrial or commercial purposes".

- The isolation of human ES cells involves the destruction of human embryos.

- Question: Are human ES cells prepared **without** destroying a human embryo patentable ?

  i.e. in this case is this **use** acceptable ?

  - even when the purpose of the invention is **not** for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it ? (rec. 42 Dir. 98/44/EC)

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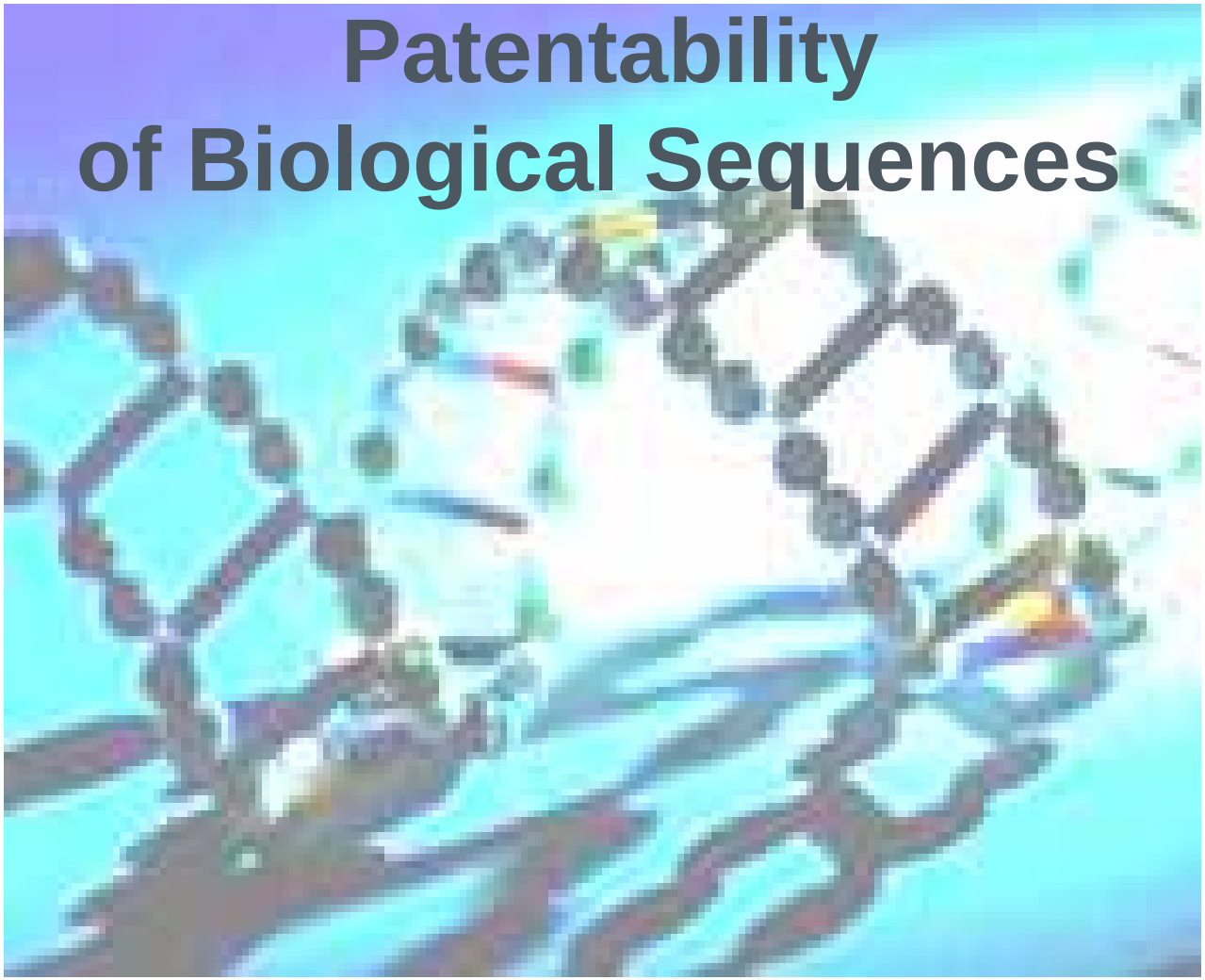
Patentability of Biological Sequences



Acknowledgment: Sigrid Weiland, EPO Munich

Basic Requirements for Patentability

- The claimed subject-matter must represent an **invention** in the sense of **Art. 52 EPC**, *i.e.* it must not be a discovery.
- The invention must be **novel**, involve an **inventive step** and be **industrially applicable (Arts. 54, 56, 57 EPC).**
- The invention must be **sufficiently disclosed**, so that it can be repeated by the skilled person **(Art. 83 EPC).**
- The claims defining the subject-matter for which protection is sought must be **clear** and **concise** and be **supported** by the description **(Art. 84 EPC).**

Patentability of Biotechnological Inventions

EU-Directive 98/44/EC on the legal protection of biotechnological inventions (30.07.98)

→ Implemented into **Rule 23(b)-(e)** of the EPC (01.09.99) - Rule 26-29 EPC 2000

→ Recitals as further means of interpretation

Rule 23(e) EPC – Rule 29 EPC^{2000} relevance for the patentability of sequences

Rule 23(e)(1) EPC - Rule 29(1) EPC^{2000}
The simple **discovery** of a sequence or partial sequence of a gene is **not patentable.**

Rule 23(e)(2) EPC - Rule 29(2) EPC^{2000}
Sequences or partial sequences of a gene may be patentable if they have been **isolated** from the human body or have been produced by a **technical process**.

Rule 23(e)(3) EPC - Rule 29(3) EPC^{2000}
The **industrial application** of a sequence must be **disclosed** in the patent application.

Article 57 EPC with special regard to sequences

- Rule 23e(3)EPC - Rule 29 EPC^{2000} - Rec. 22 Dir. 98/44/EC
  The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application

- Rule 27(1)(f) EPC - Rule 42(1)f EPC^{2000}
  The description shall indicate **explicitly**, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry.

- EU-Directive 98/44/EC, recital 24
  When the gene is used to produce a protein, in order to comply with the IA criterion, it is necessary to specify which protein is produced and what function it performs.

- Rule 23b(1) EPC - Rule 26(1) EPC^{2000}: ... Dir. 98/44/EC shall be used as a supplementary means of interpretation.

Article 56 EPC with special regard to sequences

- Rule 27(1)(c) EPC - Rule 42(1)c EPC^{2000}
  The description shall disclose the invention in such terms that the technical **problem and its solution** can be understood, and state any advantageous effects of the invention with reference to the background art.

Article 52(2)a EPC with special regard to sequences
discoveries are not to be regarded as patentable inventions

- Rule 23(e)(1) EPC - Rule 29(1) EPC^{2000}
  The simple **discovery** of a sequence or partial sequence of a gene is **not patentable.**

- EU-Directive 98/44/EC, recital 23:
  A mere nucleic acid sequence **without** indication of a **function** does not contain any **technical information** and is therefore not a patentable invention.

- Rule 23b(1) EPC - Rule 26(1) EPC^{2000}:
  ... Dir. 98/44/EC shall be used as a supplementary means of interpretation.

Different types of applications relating to Sequences and their evaluation by the EPO

Sequences the **function** of which is **sufficiently characterised by experimental data**

Patentable, provided all other requirements of the EPC are fulfilled.

Sequences with **no function** indicated in the application:

ESTs or full-length cDNAs where no more than the source is indicated (tissue or organism - Human Genome project), GPCRs, orphan receptors.

Article 56 EPC

No technical effect ⇒ no **meaningful** technical problem solved (T0939/92)

Technical Problem: provision of a further DNA from a certain tissue or organism, regardless of its likely useful properties (if any)

Solution: **arbitrary selection** from a great number of possible nucleic acid molecules

Sequences with **no function** indicated in the application:

ESTs or full-length cDNAs where no more than the source is indicated (tissue or organism), GPCRs, orphan receptors.

Article 56 EPC

Rule 27(1)(c) EPC - Rule 42(1)c EPC^{2000}
The description shall disclose the invention in such terms that the technical **problem and its solution** can be understood, and state any advantageous effects of the invention with reference to the background art.

T 22/82, OJ EPO 1982, 341, reasons No. 6: a chemical compound is not patentable merely because it potentially enriches chemistry; the structural originality has no intrinsic value or significance for the assessment of inventive step as long as it does not manifest itself in a valuable property in the widest sense, an effect or an increase in the potency of an effect. (see also T0111/00).

Sequences with **no function** indicated in the application:

ESTs or full-length cDNAs where no more than the source is indicated (tissue or organism), GPCRs, orphan receptors.

Article 57 EPC

No technical information, no function ⇒ no industrial applicability (T0870/04)

Rule 23e(3)EPC - Rule 29 EPC^{2000}: the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application

Rule 27(1)(f) EPC - Rule 42(1)f EPC^{2000}: the description shall indicate **explicitly**, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry.

EU-Directive 98/44/EC, recital 24: when the gene is used to produce a protein, in order to comply with the IA criterion, it is necessary to specify which protein is produced and what function it performs.

Sequences with **no function** indicated in the application:

ESTs or full-length cDNAs where no more than the source is indicated (tissue or organism), GPCRs, orphan receptors.

Article 52(2)a EPC

no invention but rather discovery

Rule 23(e)(1) EPC - Rule 29(1) EPC2000
The simple **discovery** of a sequence or partial sequence of a gene is **not patentable.**

EU-Directive 98/44/EC, recital 23:
A mere nucleic acid sequence **without** indication of a **function** does not contain any **technical information** and is therefore not a patentable invention.

Article 56 EPC: no function → no problem to be solved
Article 57 EPC: no function → if the claimed molecule is not disclosed to have any function (e.g. biological, which would implicate a therapeutic use or as a marker which would implicate a diagnostic use), it cannot be seen why it would be useful to produce said protein on a large scale in industry.
Article 52(2)a EPC: a sequence without a function is to be regarded as a discovery, rather than an invention.

What do we mean with ***Function*** ?

- an enzymatic activity ? Pathway known ?
- interaction with another polypeptide/subunit ?
- being a receptor ? Is the ligand known, then ?
- involvement in a certain signal transduction pathway ?
  - is this signal transduction pathway related to a specific effect ?
- involvement in a disease ?
- tissue-specific expression (pattern) ?
- cell marker ?
- probe ?
- general or „throw away“ function enough ?
  - e.g., secreted protein, polypeptide as food / feed

But biotech patents are not all Black & White !

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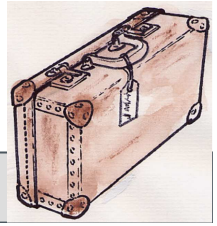
What if a function is identified, but its role is not clear ?

T0870/04

- (1) Merely because a substance (here: a polypeptide) **could be produced** in some ways does not necessarily mean that the requirements of Article 57 EPC are fulfilled, unless there is also some profitable use for which the substance can be employed (cf. point 4 of the reasons).

- Article 57 EPC:

  an invention shall be considered as susceptible of industrial application if it can be made **or** used in any kind of industry, including agriculture.

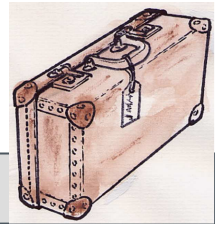


T0870/04

- (2) For the purposes of Article 57 EPC, the whole burden cannot be left to the reader to **guess or find a way to exploit an invention in industry by carrying out work in search for some practical application** geared to financial gain without any confidence that any practical application exists (cf. point 19 of the reasons).

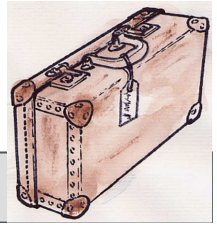
  A vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfilment of the requirement of industrial applicability.

  The purpose of granting a patent is **not to reserve an unexplored field of research for an applicant** (cf. point 21 of the reasons).



T0870/04

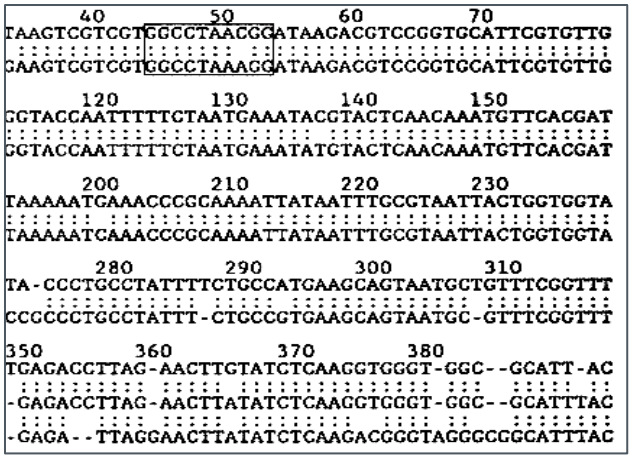
- (3) In cases where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged. Even though **research results may be a scientific achievement of considerable merit**, they are not necessarily an invention which can be applied industrially. (cf. point 6 of the reasons).



Sequences with function assignments based on **sequence comparisons** *(in silico)*

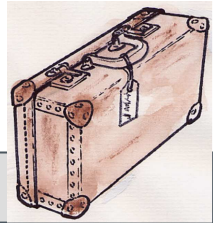
e.g. on consensus sequences or sequence identities indicating the belonging to a certain family

Is it acceptable ?



T0898/05

The fact that a function is based on computer-assisted analyses, rather than on wet-based (laboratory) results, does not diminish the relevance of the conclusions that can be drawn from the data obtained therefrom.



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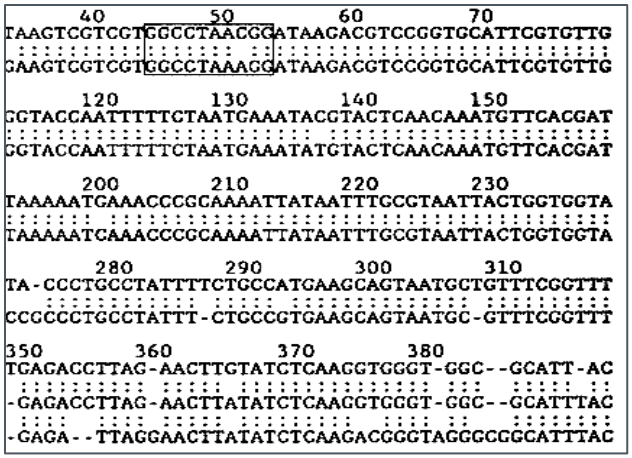


It is patentable only if:

a the indicated function is **specific** and **credible** (level of overall sequence identity, level of characterization of molecules with structural similarity)

b the claimed sequences have a **technical effect** and solve a technically **meaningful** problem

c all other requirements of the EPC are fulfilled

Function assignments based on **sequence comparisons**
ICOS decision - Patent EP 0 630 405 (OJ 6/2002 p.293)

- provision of an additional 7TM receptor (involved in immunological processes, deduced only by expression studies)
- **Disclosed**: precise sequence; predicted function based on structural elements; methods for the verification of said function; wish-list of possible applications
- **no results of said methods**
- **Granted ... Opposed**

Function assignments based on **sequence comparisons**
ICOS decision - Patent EP 0 630 405 (OJ 6/2002 p.293)

- **Decision by Opposition Division**: the disclosure of a predicted function of a protein in combination with a method of verification of this function is not necessarily adequate to sufficiently disclose the function of the protein (a seven transmembrane receptor).
- In the absence of a disclosed compound (ligand), methods utilising this compound/ligand are considered not sufficiently disclosed. A **wish-list**, in the description, of speculative functions of a protein is not in itself a reliable basis for acknowledging industrial application of this protein. A DNA sequence encoding a protein without a credible function is not a patentable invention.

  With respect to recital 23 of EU Directive 98/44/EC: the requirement of an "indication of function" is to be interpreted to be a requirement for indications which are **more than speculative**.

The requirements of Arts. 56 (no meaningful problem), 57 and 83 EPC are not fulfilled. Appeal inadmissible for missing statement of grounds, Rule 65(1) EPC in conjunction with Article 108 EPC (T1191/01).

Relevance of post-published experimental evidence for patentability of sequences

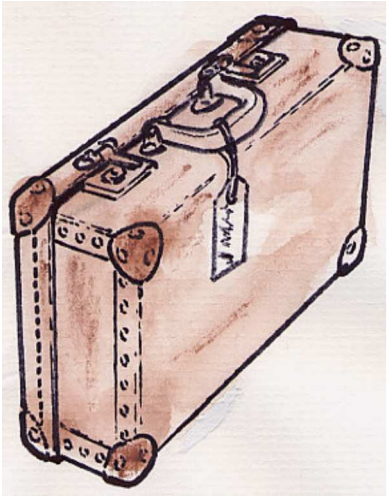
- EPC Guidelines C-IV 9.11
- The relevant arguments and evidence to be considered by the Examiner for assessing Inventive Step may either be taken from the originally-filed patent application or submitted by the Applicant during the subsequent proceedings.

- Care must be taken, however, whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application (T386/89, T184/82).

- Example: pharmaceutical composition having a certain specific activity. At first sight, not inventive in the light of the relevant prior art.
- Evidence provided later that this composition is less toxic (unexpected advantage). Even the technical problem can in this case be reformulated, taken into account the aspect of toxicity.

Function assignments based on **sequence comparisons**
T1329/04 GDF-9 (c)

- In this particular case, the function of the polypeptide concerned was not plausible form the application, due to the lack of one consensus motif.



- the definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is **at least made plausible** by the disclosure in the application that its teaching solves indeed the problem it purports to solve.

- Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.

Function assignments based on **sequence comparisons T0898/05 (a)**

- This decision introduces the concept of " **educated guess** " (identification of a function based on structural homology)
- The comparison study makes the " guess " reasonably credible.
- The fact that the comparison is based on computer-assisted analyses, rather than on wet-based (laboratory) results, does not diminish the relevance of the conclusions that can be drawn from the data obtained therefrom.
- The function of a protein can be seen at different levels, each with the same relevance for assessing IA.
- The function was proven by post-published evidence.
- Requirements of Article 57 EPC fulfilled.

Educated guess Vs Luck

- Decision **T0641/05** uses the same reasoning, leading to the conclusion that industrial applicability cannot be acknowledged in the lack of a credible function based on structural comparison.

Credibility of assigned functions

T0870/04: speculative function -> no industrial applicability

T0939/92: speculative function -> no inventive step

ICOS decision - EP 0 630 405 (OJ 6/2002 p.293) (Arts. 56, 57, 83 EPC)

(T870/04) speculative function -> no invention but rather discovery

T1329/04 Vs T0604/04: the function, based only on structural relationship with known substances must be credible (sound structural relationship and clear role of the known group of substances)

post-published evidence may contribute at assessing inventive step. However, when it is the first disclosure **going beyond speculation**, it may not serve as the **sole** basis to establish that the problem had actually been solved

So-called **“wish”** or **“laundry lists”** of functions are not credible and are not considered to disclose a function or technical effect (**ICOS decision - Patent EP 0 630 405**)

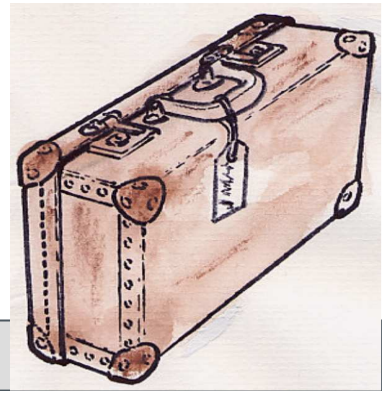
Near future of patents on human sequences

- Nr. Human sequences is limited.
- Coverage of prior art of natural (human) sequences approaching completeness.
- Less room for NOVEL / INVENTIVE sequences *per se* against developing prior art.
- Only room for further uses.
- Medical type claims (first and further medical use of known products) use-limited anyway.

Conclusion (1)

- Biotech is a highly competitive field. There's a lot of overlapping applications, in terms of time and disclosure.

- Patents are granted on subject-matter already invented, not on subject-matter which is still to be invented.



Conclusion (2)

Patents on life or *for* life ?

Developing Case-Law

Relevance of exceptional Cases

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Thanks for your attention

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