

The European Perspective on Patentability and Exceptions to Patentability (Patent Eligibility)

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Patent Eligibility – The European Perspective

- Legal Basis
- EPC
 - Convention („Articles“)
 - Implementing Regulations („Rules“)
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions („Biotech-Directive“)
- TRIPs-Agreement, SECTION 5: PATENTS, Article 27: Patentable Subject Matter

Patent Eligibility – The World's Perspective

- World Trade Organization (WTO) – TRIPs
- Article 27: Patentable Subject Matter
- 1. [...] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application [...] patents shall be available and patent rights enjoyable **without discrimination** as to the **place of invention**, the **field of technology** and whether products are imported or locally produced.

Patent Eligibility – The World's Perspective

- World Trade Organization (WTO) –
- Article 27: Patentable Subject Matter
- 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.

Patent Eligibility – The World's Perspective

- World Trade Organization (WTO) –
- Article 27: Patentable Subject Matter
- 3. Members may also exclude from patentability:
 - (a) **diagnostic, therapeutic and surgical** methods for the treatment of humans or animals;
 - (b) **plants and animals** other than micro-organisms, and **essentially biological processes** for the production of plants or animals other than non-biological and microbiological processes.
- However, Members **shall provide** for the protection of plant varieties either by patents or by an effective sui generis system [..]. The provisions of this subparagraph shall be reviewed [..].

Patent Eligibility – The European Perspective

- Art. 52 (1) EPC
- (1) European patents shall be granted for any inventions, in all fields of technology, provided that they are **new**, involve **an inventive step** and are susceptible of **industrial application**.
- ... and which are not explicitly excluded from patentability

Patent Eligibility – The European Perspective

- Art. 52 (1) EPC
- Patentable inventions
- ... and which are not explicitly excluded from patentability
 - “not technical” (Art. 52 (2) and (3) EPC)
 - Exceptions to patentability (Art. 53 EPC)

Patent Eligibility – The European Perspective

- Art. 52 (1) EPC – Patentable inventions
- “Technicality”
- Requirement of technical character or technicality
- Technical effect is achieved by the invention or technical considerations are required to carry out the invention
- Assessment of the invention independent of the prior art

Patent Eligibility – The European Perspective

- Patentable inventions - Art. 52 (2) EPC
 - (2) The following **in particular** shall not be regarded as inventions:
 - (a) **discoveries**, scientific theories and mathematical methods;
 - (b) aesthetic creations;
 - (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
 - (d) presentations of information.
- Relates only to discoveries, etc. “**as such**”

Patent Eligibility – The European Perspective

- Patentable inventions - Art. 52 (2) EPC
 - “Discoveries”
 - Products isolated from nature but not yet disclosed (and present) in the (technically useable) “prior art”
- Discovery that the product exists in nature
 - Not patentable
- Provision of the discovered **and** (first time) isolated product to the art
 - In principle patentable

Patent Eligibility – The European Perspective

- Are (human) genes patentable or (non-patentable) discoveries ?
- Biotech-Directive, Article 3.2
- 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.
- EPC, Rule 27, Patentable biotechnological inventions:
- Biotechnological inventions shall also be patentable if they concern:
 - a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

Patent Eligibility – The European Perspective

- Patentable inventions - Art. 52 (2) EPC
 - “programs for computers” (“Computer-implemented inventions”, “CII”)
- EU-Directive discussed, not enacted
 - EPO Case Law
 - Enlarged Board of Appeal (EBA): G 3/08 (“Programs for computers”)
 - Technical Board of Appeal (TBA): T 1173/97 (“Computer program product/IBM”), T 258/03 (“Auction method/HITACHI”), T 424/03 (“Clipboard formats I/MICROSOFT”)

Patent Eligibility – The European Perspective

- Patentable inventions - Art. 52 (2) EPC
 - “programs for computers” (“Computer-implemented inventions”, “CII”)
- EU-Directive discussed, not enacted
 - G 3/08: T 424/03 (“Clipboard formats I/MICROSOFT”) is a **legitimate development of the case law** (e.g. of T 1173/97 (“Computer program product/IBM”))
 - T 258/03 (“Auction method/HITACHI”),

Patent Eligibility – The European Perspective

- Patentable inventions - Art. 52 (2) EPC
 - “programs for computers” (“Computer-implemented inventions”, “CII”)
- Patent eligibility level set low
- An apparatus for carrying out an activity excluded as such from patentability by Art. 52(2) and (3) EPC is not itself excluded from patentability.
- However: for considering inventive step: only “features contributing to the technical character of the claimed subject matter” are taken into account

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality
 - b. plant or animal varieties or essentially biological processes for the production of plants or animals
 - c. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality
- Biotech-Directive Article 6
 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality

- Biotech-Directive Article 6.2

On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

- (a) processes for **cloning** human beings;
- (b) processes for **modifying the germ line** genetic identity of human beings;
- (c) **uses of human embryos** for industrial or commercial purposes;
- (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.

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality
- Directive Article 6.2/Art. 53a EPC
- (c) **uses of human embryos** for industrial or commercial purposes
- EBA: G 2/06 "WARF/Stem Cells" EP 0 770 125 A
- CJEU: C-34/10 (Oliver Brüstle vs. Greenpeace; "Brüstle/Stem Cells"); C-364/13 (ISCC vs. Comptroller UK IPO; "Parthenogenesis")

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality
- Directive Article 6.2/Art. 53a EPC
- (c) **uses of human embryos** for industrial or commercial purposes
- **Broad exclusion** of (embryonic) stem cells from patentability: **if prior destruction** of human embryos or their use as base material **is required, whatever the stage** at which that takes place (**even if the description of the technical teaching claimed does not refer to the use of human embryos**)

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b.** plant or animal varieties or essentially biological processes for the production of plants or animals
- Biotech-Directive
- EBA

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. **plant** or animal **varieties** or essentially biological processes for the production of plants or animals
- EBA (G 1/98)
- “A claim wherein specific plant varieties are not individually claimed is not excluded from patentability [..] even though it may embrace plant varieties.”
- “The exception to patentability [..] applies to plant varieties **irrespective of the way in which they were produced**. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.”

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. **plant** or animal **varieties** or essentially biological processes for the production of plants or animals
- Biotech-Directive, Art. 4.2
- “2. Inventions which concern plants or animals shall be patentable if the **technical feasibility** of the invention **is not confined to a particular plant or animal variety.**”

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. plant or animal varieties or **essentially biological processes for the production of plants** or animals
- EBA (G 2/07 (“Broccoli”), G 1/08 (“Tomato”))
- “A non-microbiological process for the production of plants which **contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants** is **in principle excluded** from patentability as being “essentially biological“ [..]”

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. plant or animal varieties or **essentially biological processes for the production of plants** or animals
- EBA (G 2/07 (“Broccoli”), G 1/08 (“Tomato”))
- “Such a process **does not escape the exclusion** of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, **a step of a technical nature** which **serves to enable or assist the performance** of the steps of **sexually crossing the whole genomes** of plants or of **subsequently selecting plants.**”

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. plant or animal varieties or **essentially biological processes for the production of plants** or animals
- EBA (G 2/07 (“Broccoli”), G 1/08 (“Tomato”))
- “If, however, such a process contains **within the steps of sexually crossing and selecting an additional step of a technical nature**, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is **not the result of the mixing of the genes of the plants chosen for sexual crossing**, then the process is **not excluded** from patentability [..].”

Patent Eligibility – The European Perspective

- Exceptions to patentability (Art. 53 EPC)
 - b. plant or animal varieties or **essentially biological processes for the production of plants** or animals
- Plants produced by essentially biological processes?
- EBA (G 2/13 (“Broccoli II”), G 2/12 (“Tomato II”))
- “The **exclusion of essentially biological processes** for the production of plants in Article 53(b) EPC **does not have a negative effect** on the allowability of a **product claim directed to plants or plant material such as a fruit.**”

Patent Eligibility – The European Perspective

- Opinion by the European Commission 3 November 2016
 - with the view of the EU Commission “that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes”.
- Moratorium by the EPO on 24 November 2016
 - on the examination of patent applications and patents (in opposition proceedings) in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process .
 - stayed ex officio with no date for re-entering into active proceedings. In the “notice” of the EPO, it was mentioned that the “effect of the Commission Notice for the EPO's examination practice including any necessary follow-up measures is currently under discussion with the representatives of the member states of the European Patent Organisation”.

Patent Eligibility – The European Perspective

- Opinion by the European Commission 3 November 2016
- Moratorium by the EPO on 24 November 2016
- Legislative change in the Implementing Regulations to the EPC
 - Rules 27 and 28 EPC were changed (with effect of 1 July 2017) to exclude from patentability plants and animals exclusively obtained by an essentially biological breeding process.
 - Rule changes apply to European patent applications filed on or after this date, as well as to European patent applications and European patents pending at that time
 - The President of the EPO has decided that the moratorium is released as of 1 July 2017 and affected proceedings will be gradually resumed

Patent Eligibility – The European Perspective

➤ Exceptions to patentability (Art. 53 EPC)

- C.** methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

➤ EBA, TBA

Patent Eligibility – The European Perspective

- Exclusion of medical methods
- Art. 53c EPC

- Art. 27 (3) TRIPs
- “3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;”

Patent Eligibility – The European Perspective

- Art. 53c EPC
- “European patents shall not be granted in respect of: .. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision **shall not apply to products, in particular substances or compositions, for use in any of these methods.**”
- treatment of the human or animal body by therapy
- treatment of the human or animal body by surgery
- diagnostic methods practised on the human or animal body

Patent Eligibility – The European Perspective

- Art. 53c EPC
- “European patents shall not be granted in respect of: .. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision **shall not apply to products, in particular substances or compositions, for use in any of these methods.**”
- treatment of the human or animal body by therapy
- treatment of the human or animal body by surgery
- diagnostic methods practised on the human or animal body

Patent Eligibility – The European Perspective

- Art. 53c EPC
- treatment of the human or animal body therapy
 - no “method of treatment” claims (“Method for the treatment of disease X by administering Substance Y”)
 - no simple “use” claim: (“Use of Substance Y for the treatment of disease X”)
 - one step in a multi-step method
 - treatment includes prevention
 - G 5/83 "Second medical indication/EISAI"

Patent Eligibility – The European Perspective

- Art. 53c EPC
 - no “method of treatment” claims (“Method for the treatment of disease X by administering Substance Y”)
 - no simple “use” claim: (“Use of Substance Y for the treatment of disease X”)
 - G 5/83 "Second medical indication/EISAI" (“Use of Substance Y for the manufacture of a medicament for the treatment of disease X”)

Patent Eligibility – The European Perspective

- Art. 52 (4) EPC
 - G 5/83 "Second medical indication/EISAI" ("Use of Substance Y for the manufacture of a medicament for the treatment of disease X")
- EPC 2000: Art. 52 (4) → Art. 53c
 - G 2/08 "Dosage Regime/Abbott Respiratories"
 - Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.
 - Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.



No use-claims available anymore

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Patent Eligibility – The European Perspective

- Art. 53c EPC
 - no “method of treatment” claims (“Method for the treatment of disease X by administering Substance Y”)
 - no simple “use” claim (“Use of Substance Y for the treatment of disease X”)
 - no “Swiss-type” use claims (“Use of Substance Y for the manufacture of a medicament for the treatment of disease X”)
 - G 2/08: “Substance Y for use in the treatment of disease X [characterised in by oral administration once per day prior to sleep]” (with priority from 29 January 2011 onwards)

Patent Eligibility – The European Perspective

➤ Art. 53c EPC

- no “method of treatment” claims (“Method for the treatment of disease X by administering Substance Y”)
- no simple “use” claim (“Use of Substance Y for the treatment of disease X”)
- no “Swiss-type” use claims (“Use of Substance Y for the manufacture of a medicament for the treatment of disease X”)
- **G 2/08: “Substance Y for use in the treatment of disease X [characterised in by oral administration once per day prior to sleep]”**
(applies to patent applications with a priority from 29 January 2011 onwards)

Patent Eligibility – The European Perspective

- Art. 53c EPC: G 1/04 "Diagnostic methods"
 - a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:
 - (i) the diagnosis for curative purposes stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
 - (ii) the preceding steps which are constitutive for making that diagnosis, and
 - (iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

Patent Eligibility – The European Perspective

- Art. 53c EPC: G 1/04 "Diagnostic methods"
 - In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion "practised on the human or animal body".
 - type, intensity of interaction: not of importance
 - medical practitioner needed: not of importance

Patent Eligibility – The European Perspective

- Art. 53c EPC
- diagnostic methods practised on the human or animal body
 - G 1/04 "Diagnostic methods"
 - only excluded, if all steps (i) to (iii) are "practised on the human or animal body"

Patent Eligibility – The European Perspective

- Art. 53c EPC - diagnostic methods practised on the human or animal body
 - G 1/04 "Diagnostic methods"
 - only excluded, if all steps (i) to (iii) are "practised on the human or animal body"
 - "practised on the human or animal body" is to be considered only in respect of method steps which are of a **technical nature**

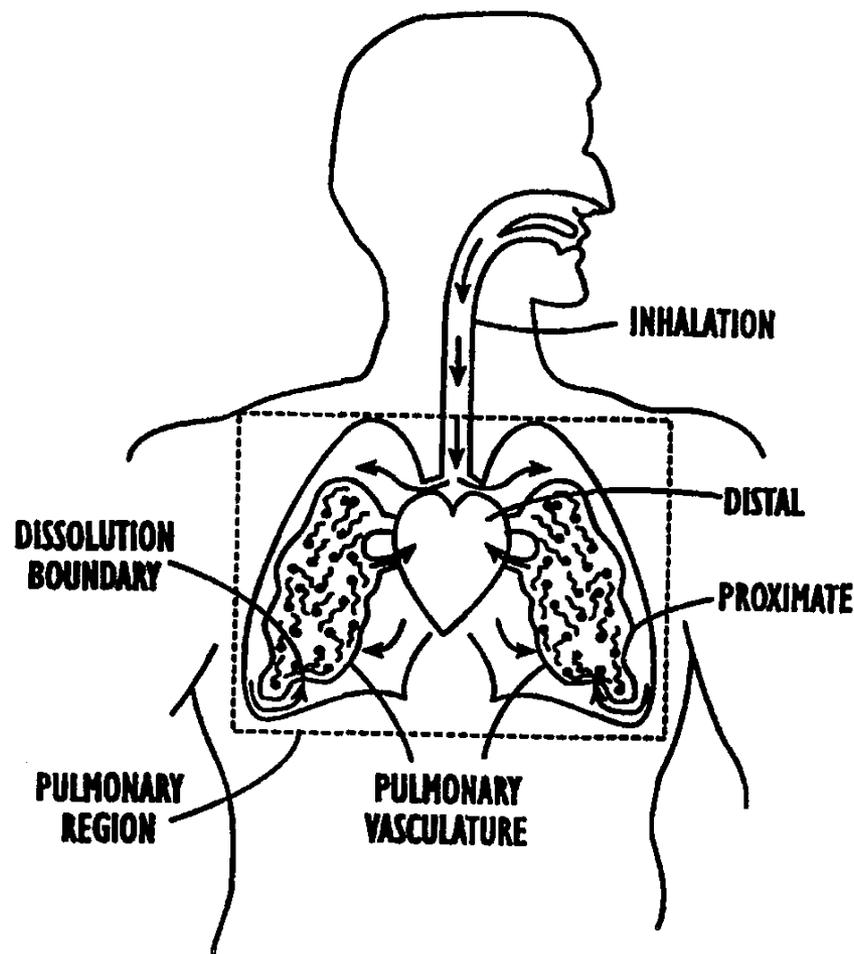
Patent Eligibility – The European Perspective

- Art. 53c EPC
- treatment of the human or animal body by surgery
 - G 1/07 “Methods for treatment by surgery”
 - Surgical step in diagnostic method?

(54) Title: MR METHODS FOR IMAGING PULMONARY AND CARDIAC VASCULATURE AND EVALUATING BLOOD FLOW USING DISSOLVED POLARIZED ^{129}Xe

(57) Abstract

MR spectroscopy and imaging methods for imaging pulmonary and cardiac vasculature and the cardiac region and evaluating blood flow or circulatory deficits use dissolved phase polarized ^{129}Xe gas and large flip angle excitation pulses. Pulmonary and cardiac vasculature MRI images are obtained by delivering gas to a patient via inhalation such as with a breath-hold delivery-procedure, exciting the dissolved phase gas with a large flip angle pulse, and generating a corresponding image. Preferably, the image is obtained using multi-echo imaging techniques. Blood flow is quantified using low field MR spectroscopy and an RF excitation pulse with a frequency which corresponds to the resonance of the dissolved phase ^{129}Xe .



Patent Eligibility – The European Perspective

- Art. 53c EPC
- treatment of the human or animal body by surgery
 - G 1/07 “Methods for treatment by surgery”
 - “A claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses a step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails substantial health risk even when carried out with professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC”

Patent Eligibility – The European Perspective

- G 1/07 “Methods for treatment by surgery”
- A claimed imaging method, in which,
 - when carried out, maintaining the life and health of the subject is important and
 - which comprises or encompasses a step representing a substantial physical intervention on the body
 - which requires professional medical expertise to be carried out and
 - which entails substantial health risk even when carried out with professional care and expertise
- is excluded from patentability!

Questions?

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