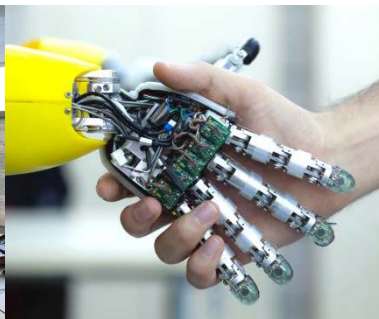
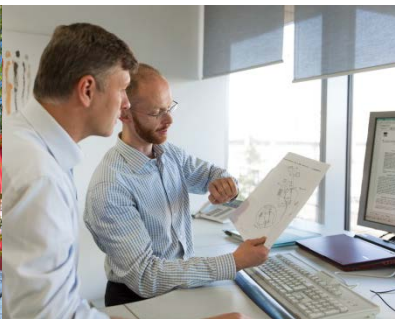




Europäisches
Patentamt
European
Patent Office
Office européen
des brevets

Patentability of plant and animal-related inventions: legal framework and case law of the EPO



Patentability of plant and animal-related inventions: legal framework and case law of the EPO

- I. EPC legal framework
- II. Patentability of plant-related inventions
- III. Patentability of animal-related inventions
- IV. Focus on EPO

Legal framework for biotechnological inventions

- **European Patent Convention (EPC)** of 5 October 1973, revised on 29 November 2000
- **Case Law** of the Enlarged Board of Appeal (EBOA) and the Boards of Appeal (BOA) of the EPO, as well as the CJEU
- **Directive 98/44/CE** of 6 July 1998 on the legal protection of biotechnological inventions
- **National laws** applicable after the grant of the patent (extent of the protection, compulsory licenses, exemptions)



I. EPC legal framework (1)

- The relevant provisions of the EU Biotech Directive 98/44/EC have been **incorporated** in the Implementing Regulations to the EPC as of 01.09.1999 (by decision of the Administrative Council of 16.06.1999).
- The Biotech Directive is used as a **supplementary means of interpretation** (Rule 26(1) EPC) for application of the EPC provisions relating to biotechnological inventions.

I. EPC legal framework (2)

- The case law of the EPO Boards of Appeal and Enlarged Boards of Appeal has provided guidance to take adequate account of technological developments involving biological material.
- CJEU judgments on the interpretation of the Directive are considered as persuasive (see decisions T 2221/10 and T 1441/13 of the EPO Boards of Appeal).

Patentability criteria

- Plant and animal-related inventions are subject to the general **patentability criteria** (Article 52(1) EPC):

“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**.”

- In addition, some inventions are subject to the **exceptions to patentability**:
 - ordre public/morality (Article 53(a) EPC);
 - plant/animal varieties and essentially biological processes (Article 53(b) EPC).

Ordre public & Morality (Article 53(a) EPC)

- Inventions which commercial exploitation would be contrary to ordre public or morality are excluded from patentability
- "Ordre public"
 - Protection of public security
 - Protection of physical integrity of individuals
 - Protection of the environment
- Morality
 - Conventionally accepted standards of conduct of European culture

Plant and animal varieties and essentially biological processes (Article 53(b) and Rule 28(2) EPC)

- Plant or animal **varieties** are not patentable.
- **Essentially biological processes** for the production of plants or animals are excluded from patentability.
- This doesn't apply to a microbiological or other technical process, or a product obtained by means of such a process (bacteria, yeast).
- **Plants or animals *exclusively* obtained** by means of essentially biological processes are excluded from patentability (**new Rule 28(2) EPC**)

Patentability of biotechnological inventions

- Biotechnological inventions shall 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 (e.g. plant genes);
 - b) *without prejudice to Rule 28(2), **plants or animals** if the technical feasibility of the invention is **not** confined to a particular plant or animal **variety**;...*

Rule 27(a), (b) EPC

Recent legislative history (1)

- The Commission Notice (C(2016)6997 of 03.11.2016) on certain articles of the Biotech Directive set out the Commission's view on the intention of the EU legislators.
- The Commission took the view 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.
- Non-binding instrument

Recent legislative history (2)

- Decision of the EPO Administrative Council on 29.06.2017 to amend Rules 27 and 28 EPC in order to align the EPO's law and practice with the EU Commission Notice.
- Application to European patent applications and European patents pending at or after 01.07.2017 (entry into force).

Recent legislative history (3)

- Instructions and explanations on the practice of examining and opposition divisions under the amended provisions have been included in the November 2017 edition of the EPO's Guidelines for Examination (sections F-IV, 4.12 and G-II, 5., to be published in October 2017).
- Stayed files are gradually resumed and examined according to the new legal framework (OJ EPO 2016, A104).

II. Patentability of plant-related inventions (1)

Case law on plants

Patentability of **plant varieties** (no)

G 1/98 (1999)



Patentability of **essentially biological processes for the production of plants** (no)

G 2/07 & G 1/08 – "Tomatoes I & Broccoli I" (2010)



Patentability of **products** of essentially biological breeding processes (yes)

G 2/12 & G 2/13 – "Tomatoes II & Broccoli II" (2015)

II. Patentability of plant-related inventions (2)

Excluded subject-matter

- 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, even if it contains a step of a technical nature.
- Plants, including their parts, and plant propagation material (e.g. seeds, leaves), exclusively obtained by crossing and selection.
- Plant varieties

II. Patentability of plant-related inventions (3)

Patentable subject-matter

- Do not fall under the exclusions and are subject to the general patentability requirements:
 - Genetic engineering methods for purposefully introducing new traits into a plant;
 - Plants (incl. offspring) and plant parts produced by technical processes (e.g. GMO, mutation), provided the technical feasibility of the invention is not confined to a particular plant variety;
 - Plant parts which are not propagation material (e.g. oils, sugars, flour), derived products, seeds carrying a non-heritable physical feature as well as plant genes/traits.

III. Patentability of animal-related inventions

- European patents shall not be granted in respect of biotechnological inventions which, in particular, concern:
 - ...
 - **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.
 - Processes to produce chimeras from germ cells or totipotent cells (humans/animals)

Article 53(a) and Rules 28 and 29 EPC

Case law regarding animals (1)

The teachings of G1/98, G2/07 and G1/08, although relating to plant inventions, are applied *mutatis mutandis* to animal-related inventions.

- **T19/90:** The exception to patentability under Art. 53(b) EPC applies to certain categories of animals but not to animals as such.
Suffering of the animal and possible risks to the environment vs usefulness to mankind need to be weighed under Article 53(a) and Rule 28(d) EPC.

Case law regarding animals (2)

- **T315/03:** The principle of G1/98 concerning plants and „plant varieties" should also be followed in the case of animals.
- Under Article 53(a) EPC the **suffering** of the animal versus the **(medical) benefit** to man or animal needs to be **balanced** in view of the necessary correspondence between the two **in terms of the animals in question**.

Balancing test: suffering v. medical benefit

- The substantial medical benefit referred to in Rule 28(d) EPC includes any benefit in terms of research, prevention, diagnosis or therapy (EU Dir. 98/44/EC, rec. 45).
- The level of proof required for establishing both animal suffering and substantial medical benefit is the same, namely likelihood (T1262/04).

Two Balancing tests under Article 53(a) EPC

I.

Art. 53(a) **AND** Rule 28(d) EPC Test:
Suffering vs Benefit to man or animal

II.

Article 53(a) EPC **proper** (T 19/90) Test:
Suffering and possible risks to the environment
vs usefulness to mankind

T19/90:

“The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a **careful weighing** up of the **suffering** of animals and **possible risks to the environment** on the one hand, and the invention's **usefulness to mankind** on the other.”

IV. Focus on EPO actions

- EPO/CPVO Administrative Arrangement signed in Munich on 11.02.2016
 - Bilateral workshops, 21-22.09.2016, Angers and 30.03.2017, Munich
 - Overall better understanding of each others system
 - Evaluation of enhanced use of available databases
 - Joint public conference in Brussels 29.11.2017
- Special quality systems for sensitive cases handling in examination and opposition (SECA)
- National initiatives to screen patents granted by the EPO
- NGO and media interest

Grazie per la vostra attenzione

Anna Bacchin

Lawyer - Directorate 5.2.1, Patent Law
European Patent Office, Munich
abacchin@epo.org