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Intellectual Property Law and the implementation of the Biotech Directive: current issues and future developments

EPO Perspective



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.**
- **Directive 98/44/CE** of 6 July 1998 on the legal protection of biotechnological inventions.
- **National laws** applicable after the grant of the patent (extension of the protection, compulsory licenses, exemptions).



Directive 98/44/EC at the EPO

- Based on the **importance of patent protection for innovation** in the field of biotechnology and genetic engineering.
- **Incorporated in the EPC Implementing Regulations in 1999.**
- The Directive and its recitals constitute a **supplementary means of interpretation** of the relevant provisions of the EPC.
- **CJEU judgments on the interpretation of the Directive** are followed by the EPO Boards of Appeal (see decisions T 2221/10 and T 1441/13 of the EPO Boards of Appeal).

Plants – Case law of the EPO Boards of Appeal

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)

Patentability of plant varieties – (G 1/98 Transgenic plant/NOVARTIS II)

- **Plant varieties are not patentable**, irrespective of the method of production.
- **A claim** wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it **may embrace plant varieties**.
- Plants and parts thereof, both GMO and non-GMO, are patentable as long as the **invention is not confined to a particular variety**.

Patentability of essentially biological processes – (G2/07, G 1/08 Tomato/Broccoli I)

- Processes for the production of plants are regarded as being essentially biological, thus not patentable, if they are based on the **sexual crossing of whole genomes and on the subsequent selection** of plants.
- Patentability is not excluded if **within the steps of sexually crossing and selection** an additional **step of a technical nature is included**, 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.
- **Genetic engineering techniques** applied to plants are in principle **patentable**.

Patentability of products of essentially biological processes – Practice after G 2/12 and G 2/13

- **The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not extend directly to a product claim or a product-by-process claim directed to plants or plant material such as a fruit, or to plant parts other than a plant variety.**
- Such inventions may be patentable if they fulfil the general patentability criteria.
- **Patentability** of a product claim or a product-by-process claim is to be examined irrespective of the **extent of protection** that is conferred after grant.
- The practice of the EPO is laid down in the Guidelines for Examination (F-IV, 4.12; G-II, 5.2, 5.4 and 5.5).

Committee on Patent Law - 12 May 2016

- Findings of the PLC Chair on the results of the questionnaire by the Contracting States

- The situation in the contracting states may be grouped in 3 categories
 - i. Law and practice consistent with G 2/12 and G 2/13
 - ii. Law and/or practice differs from G 2/12 and G 2/13
 - iii. No clear position/not enough cases.

- Presentation of the EPO legal framework and practice

- The legal framework: Exclusions of
 - Varieties and
 - Essentially biological processes
- Implementation of the legal framework into the practice
 - Patentability of products of essentially biological processes

Committee on Patent Law - 21 November 2016

- The Contracting States to the European Patent Organisation were invited by the EPO to give clear orientation on the Commission Notice on certain articles of Directive 98/44/EC - C(2016)6997.
 - i. A significant number of delegations in favour of the Commission's interpretation;
 - ii. Several delegations in favour of an amendment to the EPC Implementing Regulations;
 - iii. Few delegations of the view that no action should be taken until a judgement of the CJEU on the matter is issued.

- The EPO intends to submit to its governing bodies, early in 2017, a discussion paper setting out options, including a proposal for an amendment of the Implementing Regulations.

- In the meantime: Stay of proceedings in which the decision depends entirely on the patentability of a plant or animal obtained by essentially biological processes.

EPO/CPVO Administrative Arrangement

signed in Munich on 11.02.2016

▪ **Actions**

- Bilateral workshop, 21-22.09.2016, Angers
- Overall better understanding of each other's systems in respect to the notion of "variety" (DUS test and patentability requirements)
- Further focus on use of available data.

▪ **Continuation of the co-operation**

- Second bilateral workshop will take place in Munich (March 2017)
- Joint public conference EPO-CPVO foreseen in May 2017.

Thank you for your attention

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