

# Patentability of plants and animals

Report on EPO practice - GRUR Annual Meeting



## Legal basis

- According to Article 53(b) EPC European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals.
- According to Rule 28(2) EPC, enacted by the Administrative Council with effect from 1 July 2017, plants and animals exclusively obtained by means of an essentially biological process are excluded from patentability under Article 53(b) EPC.
- G 1/98 (exclusion of plant varieties), G 2/07 G 1/08 (definition of essentially biological process), G 3/19 (exclusion from patentability)

# Non-patentable plants and animals (as from 1.7.2017)

#### Plant / animal

- Incl. propagation material (seed, fertilised ova)
- Explicitly covered: plant cells (totipotent)

# Essentially biological breeding process

- As defined in "Tomato/Broccoli I": "Crossing and selection"
- "exclusively" obtained: Claimed feature not result of technical process

No European patent

# Plant / animal varieties

- G 1/98 continues to apply: Exclusion of inventions confined to varieties
- No circumvention by claiming large number of varieties

### Non-excluded plants/animals

# Technically produced plant/animal

- Genetic change result of technical process
- Genetic engineering techniques ("Tomato/Broccoli I")
- Mutagenesis (e.g. CRISPR, radiation)
- No variety (see before)

#### Offspring

- Mutation / transgene originates from technical process
- Additional crossing / selection steps not decisive (not "exclusively" obtained by crossing and selection)

#### Parts / products

- All parts of technically produced plants/animals
- Plant products which are not propagation material (irrespective of method to obtain plant)

In principle patentable, since 1.7.2017 only with "disclaimer"

### **EPO Disclaimer Solution**

# Limitation of European patent to technically-produced plant/animal

- Required in all cases in which feature of claimed plant/animal may be the result of either a technical intervention or an essentially biological process
- Explicit limitation in patent claim required

#### **Established means**

- Use of disclaimers established in patent practice
- Clear requirements based on case law of the EPO's Enlarged Board of Appeal

"with the proviso that the plant is not exclusively obtained by means of an essentially biological process"

#### **Binding requirement**

- Detailed explanations in EPO Guidelines for Examination
- Non-observance ground for refusal of application

#### **Cut-off date 1.7.2017**

- Disclaimer only enforceable for applications with filing/priority date on/after 1.7.2017
- Prohibition of retroactive application (G 3/19)

## Implementation of retroactivity ban from G 3/19

#### No retroactive effect

- Patent exception cannot be applied to European patent application/patents with filing/priority date before 1.7.2017
- Binding for EPO examining and opposition divisions (see, e.g., T 452/19 et al.)

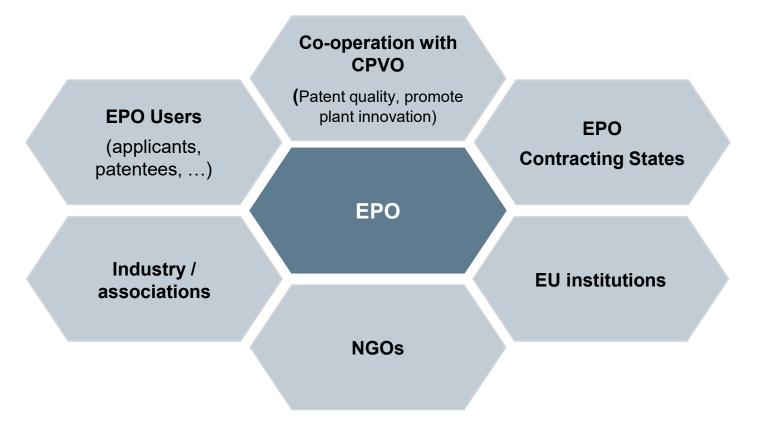
#### Cases concerned

- Around 300 in examination; dozen cases in opposition.
- "Conventional" plants: No patent exception
- Technically-produced plants: No disclaimer

#### **Procedure**

- Scrutiny of general patentability requirements such as:
  - Clarity
  - Sufficient disclosure
  - Novelty
  - Inventive step
- < 20 patents granted so far</li>

# **Consultation and co-operation**



# **Summary and outlook**

- Implementation of Opinion G 3/19 has increased legal certainty for applicants/patentees and the public at large.
- EPO remains committed to dialogue with all stakeholders on this sensitive and complex issue with legal, societal and economic implications.

### Thank you for your attention!