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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Subject: Informal VTC of the members of the WP Innovation in Agriculture – 1 December 2023 – Item 1: Biotechnology patents in plant breeding - Presentation of the Commission services

Following the informal videoconference of the members of the of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 1 December 2023, delegations will find in annex the presentation given by the Commission on the above subject.


European Commission
New genomic techniques
IP issues
Informal VTC of the WP Innovation in Agriculture – 1.12.2023
European Commission, DG GROW, IP unit (C4)

Background

- Biotech Directive (98/44/EC): Harmonised conditions for the patenting of biotechnological inventions
- Transposed into national law of EU Member States, reflected in the EPC
- Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (2013-16)
- Commission Notice on certain articles of the Biotech Directive (2016)
- Continuous monitoring of biotech-related IP matters by the Commission
- Commitment re-iterated in the IP Action Plan of 2020
- Biotech among key priorities for the Commission in 2024 (cf. SOTEU)

The planned Commission's assessment (1)

- Announced in the Communication of 5 July 2023
- Preparatory work on the assessment is underway; launch in 2024
- Evidence-based approach and comparative analysis to identify the potential issues and the possible follow-up measures, if any
- Need for collecting evidence from all relevant stakeholder categories and the Member States
- Need for quality at all stages (preparation, execution, etc.)

The planned Commission's assessment (2)

Possible aspects to be covered:

- Landscape of the plant breeding and seeds markets in the EU and the potential effects of the IP system in shaping these markets
- Potential challenges and opportunities to the various agritech market players in relation to patent rights on NGT plants and techniques, matters relating to their licensing and transparency
- Potential challenges to the various agritech market players with regard to patent-related disputes concerning NGT plants and techniques
- The existing public and private mechanisms/tools facilitating the transparency and/or access to patented biological material
- Potential impact on plant innovation, EU agritech competitiveness, SMEs, etc;
- Identifying and analysing potential issues of IP awareness in agritech

Patentability of NGT plants

- NGT plants are **technically** produced and thus **patentable** under the principles of the Biotech Directive; the EBP exclusion does not apply
- The **regulatory** status of an NGT plant under product law does not and should not influence its **patentability**
  - Equivalence of a cat. 1 NGT plant to a conventionally produced plant under product law does not have an impact on whether that plant is patentable or not
  - The possible or intended use of a product generally does not and should not influence its patentability
  - Parts of the production chain, e.g. manufacturing equipment, (technical) manufacturing processes or related chemicals may be patented

Patent law concepts (1/2)

- '**Farmer's privilege**' (Art. 11.1 of the Biotech Directive (98/44/EC)):

  "[…] *the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm* […]."

- **Exhaustion principle** -- e.g. in the UPC Agreement (Art. 29):

  "*The rights conferred by a European patent shall not extend to acts concerning a product covered by that patent after that product has been placed on the market in the European Union by, or with the consent of, the patent proprietor, unless there are legitimate grounds for the patent proprietor to oppose further commercialisation of the product.*"

Patent law concepts (2/2)

- **Cross-licences** are (usually voluntary) licences exchanged by two companies regarding mutually-relevant technologies (e.g. in improvement situations).
- **Compulsory cross-licences** in respect of biotechnological inventions are defined in Art. 12 of the Biotech Directive (98/44):
  - "1. *Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.* […]"
  - "2. *Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty.* […]"

Commission

Patent law concepts – Exemptions

- Art. 27 UPC Agreement (currently applicable to 17 MSs) states that **the rights conferred by a patent shall not extend to**:
  - acts done for **experimental** purposes relating to the subject-matter of the patented invention, nor to ('experimental exemption')
  - the use of biological material for the purpose of **breeding**, or discovering and developing other plant varieties ('limited breeders' exemption')
- The 'experimental exemption' is also found in the national patent law of all MSs.
- The limited breeders' exemption does not extend to the commercial exploitation of the new plant variety. In case of commercialization, a licence from the patent holder is required (cf. compulsory cross-licensing).

Patent law concepts – Patent infringement

- Launching patent infringement is decided by the patent holder:
  - Evidence of infringement to be provided
  - Typically, the first step is a warning letter → the potential infringer can show (provide evidence) that it did not use a patented technology
  - In court, parties to provide evidence on the facts they rely upon
- No plant-related patent infringement or revocation cases brought to the attention of the Commission (MS input welcome)
- No cases of accidental infringements known to the Commission (MS input welcome)
  - Proportionality requirement

SME-specific rules in patent law

- Patent law includes no SME-specific rules as regards the patentability criteria
- Operational rules:
  - Under the farmers privilege (as defined in Council Regulation (EC) No 2100/94), small farmers are not required to pay remuneration to the rights holder
  - SMEs enjoy a 40% rebate on the procedural fees of the Unified Patent Court
  - EU SME Fund offers dedicated financial support for patent and plant variety registration
  - Fee reductions available under the EPC



Thank you
for your attention

