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Protection of plant innovations by patents and plant variety rights (PVRs) in Europe

AGRO-IP DAY
1st Israeli Meeting for Agriculture Innovation and Intellectual Property

20 Jan 2020, Tel-Aviv
Dr. Hendrik Wichmann

Goals of Innovations in Plant Technology and Plant Breeding

- Creating new variations of plant characteristics, *e.g.*,
  - Higher yield (combined with quality)
  - Increased tolerance to environmental stress or increased disease or pest resistance
  - Increased levels of desirable components and/or reduced levels of unwanted components
  - Convenience aspects as well as mere aesthetic creations
- Creating of new processes for producing plants, *e.g.*, new breeding techniques
- The IP system provides protection for innovators by *inter alia* patents, plant variety rights and/or trademarks.

Update on the European Patent System (EPC)

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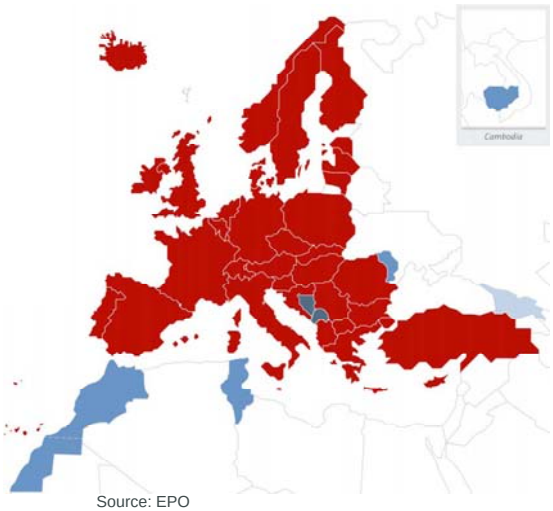

Source: EPO

Geographic coverage

- 38 Member States (red)
- 2 Extension states (grey)
- 5 Validation states (blue)

European Patent Office

- 174317 applications in 2018
- About 350 applications in plant technology (0.2 %)
- IP5 co-operation with patent offices in US, JP, KR and CN

Update on the Unitary Patent System (UPS)

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Principle

- Filing with and prosecution of EP applications before EPO for multiple contracting states of the EPC

Effect

- Granted European patent may be converted into a EP with unitary effect
- Enforcement and revocation of 'Unitary Patent' in all member states

Enhanced Cooperation

- 25 of 28 EU member states (excl. ES, HR and UK)

Proceedings before the European Patent Office - Patentability requirements and exclusions

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- Plant-related inventions are generally *patentable*, if they fulfill the requirements of novelty, inventive step, and industrial applicability (Art 52 EPC)
- However, European patents shall not be granted for
  - **Plant varieties**
  - Essentially biological **processes for the production** of plants

  (Art 53 b) EPC)

Proceedings before the European Patent Office - Exclusion of 'plant varities'

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- Exclusion of '**plant varieties**' (identical to UPOV definition)
  - Defines borderline between patent protection and plant variety protection
  - Is to be construed narrowly: *"A claim wherein plant varieties are not individually claimed is not excluded…, even though it may embrace plant varieties."* (G 1/98)
  - Decisive question is whether the substance of the claimed subject-matter (not the wording) is technically directed to a specific variety or a multiplicity of varieties, or fits the concept of *"an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part*" (G1/98)

Proceedings before the European Patent Office - Exclusion of an 'essentially biological process' I

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- Exclusion of 'an **essentially biological process** for producing a plant'
  - To exclude conventional breeding methods from patentability
  - Is to be construed widely: Any *"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…* ***as being "essentially biological""***
    G 2/07, G 1/08; Broccoli/Tomato I

Proceedings before the European Patent Office - Exclusion of an 'essentially biological process' II

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Conclusions for patenting

- Claims including a sexual crossing and selection where changes in the genes/genomes are only caused by meiosis are excluded ('classical breeding') – additional steps do not help
- Claims on additional technical steps before or after such a process are *per se* patentable (claims should not include crossing/selection process; e.g. T 2435/13) ('green biotech')
- Claims on breeding process which contains within the crossing/selection an additional technical step introducing or modifying a trait are not excluded ('green biotech')
- Claims on technical devices or means used in breeding processes (e.g. markers) are *per se* patentable in themselves

Proceedings before the European Patent Office - Exclusion of products of essentially biological process? I

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- European patents shall not be granted for
  - Plant varieties
  - Essentially biological **processes for the production** of plants
- Processes and products are separate claim categories
- In the absence of a solid basis, the process exclusion cannot be construed widely to extent directly to a **product claim** directed to plants or plant material (e.g. fruits) or to plant parts other than plant varieties
  (G 2/12, G2/13; Broccoli/Tomato II)
- Political issue
  - Plant varieties obtained by conventional breeding may be covered by generic product claims directed to existing 'native traits' – this might hinder SMEs in the breeding area

Proceedings before the European Patent Office - Exclusion of products of essentially biological process? II

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- Following an initiative of the EU commission, the EPO introduced a new paragraph in Rule 28 EPC:
  *"(2) Under Article 53 b), European patents shall not be granted in respect of **plants** or animals **exclusively obtained by means of an essentially biological process**."*
- Applying the Broccoli/Tomato II decisions, appeal board decision **T1063/18** declared that new Rule 28(2) EPC is in conflict with Article 53 b) EPC, as interpreted by the Enlarged Board, and that there is no reason to deviate from its findings

Proceedings before the European Patent Office - Exclusion of products of essentially biological process? III

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- Following decision T1063/18, on 4 April 2019, the **President of the EPO** referred two legal questions to the Enlarged Board (**case G 3/19**)
  - Aim of seeking clarification of Article 53 b) EPC
  - Questionable whether referral is admissible, and, if so, how the Enlarged Board may come to different conclusion
  - **Stay of examination and opposition proceedings**, in which the decision depends entirely on the outcome of the referral (about 250 cases)
- Meanwhile, the EPO applies **stricter standards** in examination of applications on native traits
  (e.g. T1957/14; lack of clarity, because essential sequence information not disclosed; deposited material not sufficient)

The EU System of Plant Variety Rights - Introduction

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- The **Community PVR (CPVR) system** was established in 1994 – co-exists with national systems in 24 Member States
- The **Community Plant Variety Office** (**CPVO**) has been operational since 1995, based in Angers, France
- Community Plant Variety Rights (PVRs) granted under this system as **valid throughout the (27) Member States** of the EU
  - More than **67,600 applications processed**
  - More than **28,200 titles in force** (by 14.11.19)
- **Duration** of the Community PVR: 25 years
  (30 years for vines, trees and potato varieties)
- **Provisional protection**: as of publication of the PVR until grant
- **National courts** competent to hear infringement cases

The EU System for Plant Variety Rights - Applications per crop sector

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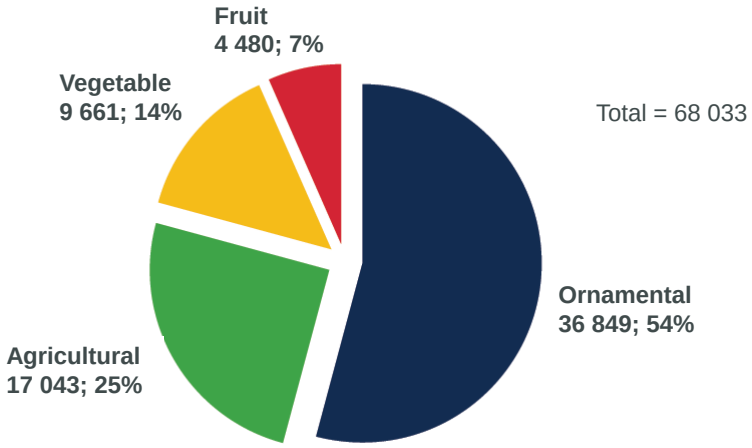
Period: 27.04.1995-14.11.2019



Source: CPVO

The EU System of Plant Variety Rights - Application procedure

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- One application, one procedure, one technical examination, one decision, one right for <u>all</u> EU member states
- **Conditions**: Novelty, Distinctness, Uniformity, Stability (DUS), suitable denomination, entitlement
- **Technical examination** ('DUS test'): Carried out by an entrusted Examination office
  (here shown for apples)

Source: CPVO

The EU System of Plant Variety Rights - Distinctness I

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- Main issue: **Distinctness**

COUNCIL REGULATION (EC) No 2100/94

of 27 July 1994

on Community plant variety rights

Article 7

Distinctness

1. A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application determined pursuant to Article 51.

Source: CPVO

The EU System of Plant Variety Rights - Distinctness II

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- Which characteristics ?
  - All characteristics listed in respective test guidelines are observed (additional characteristics possible)
  - *Any* single characteristic may be sufficient to establish distinctness (no need for intrinsic value)
- What is a clear difference? Depends on type of expression of characteristic (qualitative, pseudo-qualitative, quantitative)
- Which varieties belong to common knowledge?
  - Existing in a publicly accessible collection (e.g. botanical garden)
  - Registered in official register
  - Commercialized
  - ➢ worldwide

The EU System of Plant Variety Rights - Assessing distinctness – case study T-177/16

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- Distinctness will be assessed
  - within the technical examination (DUS test) – Art 56 BR
  - in accordance with the 'Technical Protocol', i.e. the guidelines for the DUS test for the respective species (e.g. TP/14/2 for apples)
  - These guidelines describe, i.a., the plant material required for the test, the methods to be applied, and a table listing the relevant characteristics, and they define, in particular, how and when the characteristics listed are to be examined

  "Observations on the fruit should be made … at the time of ripeness for eating"

The EU System of Plant Variety Rights - Case study T-177/16 – Mema vs CPVO II

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- Determination of the 'time of eating maturity' and the ‚time for harvest' according to TP/14/2:

  Ad 57: Time of eating maturity
  Time of eating maturity is the period **when a fruit has reached optimum** color, firmness, texture, aroma and flavor **for consumption**. Depending on the type of fruit, this period can occur directly after removal from the trees (e.g. early varieties) or after a period of storage or conditioning (e.g. later varieties)

  Ad 56: Time for harvest
  Time for harvest is the **optimum time** of picking **to achieve fruit in peak condition for eating** (see Ad. 57)

The EU System of Plant Variety Rights - Case study T-177/16 – Mema vs CPVO III

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– For late apple varieties such as Braeburn,

(i) picking of the fruit of the respective variety (candidate/reference variety) must be carried out at the optimum time and

(ii) the characteristics must be recorded when the fruit has reached eating maturity, i.e. optimum color, etc.

-> If (i) and (ii) are not fulfilled, *"no correct comparative assessment"* of candidate and reference varieties (para. 49 of T-177/16)

The EU System of Plant Variety Rights - Case study T-177/16 – Mema vs CPVO IV

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- However, important data were missing/ questionable

In 2012: first significant fruit harvest

Variety/ Characteristic	Date of harvest	Starch regression	Firmness (kg/cm²)	Refractometric index (%)	Acidity (g/l malic acid)	Shade (spectrocolorimetry)*
Candidate variety	11/10	5.5	9.2	12.8	7.39	18.64
Royal Braeburn	11/10	-	-	-	-	20.19
X9466 (1)	11/10	6.3	9.3	12.8	7.31	18.71

In 2013: second significant fruit harvest

Variety/ Characteristic	Date of Harvesting	Starch regression	Firmness (kg/cm²)	Refractometric index (%)	Acidity (g/l malic acid)	Shade (spectrocolorimetry)*
Candidate variety	11/10	5.5	10.5	11.7	7.8	22.49
Royal Braeburn	11/10	6.0	10.0	11.6	8.08	23.55
X9466 (1)	11/10	5.7	10.2	11.2	7.53	22.07

- Decision of Appeal Board to confirm refusal of application by CPVO was declared null and void

The EU System of Plant Variety Rights - Distinctness – Additional characteristics

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- 'Additional characteristics' may be inserted in the test guidelines
  - if helpful in establishing distinctness
  - subject to payment of an extra fee
  - special tests will be undertaken, provided a technically acceptable test procedure can be devised
- Examples: New varieties of medicinal cannabis
  - *"THC content: 0.065%"*
  - *"The variety has a low percentage of CBD (2)"* (THC content absent or very low)

The best of both worlds? - Outlook

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- In principle, Community PVR protection may be less demanding to obtain than a European patent
- In practice, to avoid lengthy and costly legal proceedings against the CPVO, it is (highly) recommendable to monitor the technical examination and scrutinize the data in the DUS report
- Patent protection for plants other than varieties may still be desirable in terms of scope of protection
- Ideally, plant variety protection and patent protection would be complementary, and conflicts be resolved by way of a limited breeder exemption for breeding or discovering and developing new plant varieties (cf. Art 27 (c) UPCA)

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Thank you for your attention!

Feel free to contact me with any comments or questions.

wichmann@wuesthoff.de

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Annex I
- Definition of a ‚variety‘

UPOV 91 Convention

Article 1 – Definitions

(vi) “**variety**" means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged

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Annex II
- Examples of limited breeder exemptions

Unitary Patent Court Agreement (UPCA)

ARTICLE 27
Limitations of the effects of a patent
The rights conferred by a patent shall not extend to any of the following:
…
(c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties

See, e.g, also

German Patent Act § 11 Nr. 2a

Swiss Patent Act Art. 9 G.I.e