



Intellectual Property and Patenting

3502-440 Methods of Scientific Working for Crop Science

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Background

Introduction into patent law

Introduction into plant variety protection

Plant-related patents in the United States

The slides are based on a lecture
by
Dr. Eva Willnegger, European Patent Attorney.

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Outcomes of scientific research

- Materials, tangible things: e.g., Varieties, pesticides
- Procedures and methods: e.g., breeding methods, methods for chemical synthesis

If the results of scientific research are of commercial importance, the results represent an **intellectual property (IP)** and can be protected by the owner.

Two forms of publication of scientific results:

- Peer reviewed publications
- Patents

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National, supranational and international laws and agreements

The most important laws and agreements

- National level: **German Patent Act (PatG)**
- European level: **European Patent Convention (EPC)**
- International level: **Patent Cooperation Treaty (PCT)** and **Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)**

Implications of these laws:

- Harmonization of Substantial Law
- Essentially similar conditions and scope of protection in all Member States of the World Trade Organisation (WTO)

We focus on the European and German situation.

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Protectable subject matter

Patents are granted for any inventions, in all fields of technology provided that they are¹

- new
- involve an inventive step
- and are susceptible of industrial application

¹§1 I PatG, Art. 52 I EPC, Art. 27 I TRIPS

Protectable subject matter

Exempted subject matter: ²

- plant varieties
- animal varieties
- essentially biological processes for the production of plants or animals that consist entirely of natural phenomena such as crossing or selection
- But not microbiological processes (=any process involving or performed upon or resulting in microbiological material) or the products thereof

²§2a I, II PatG, Art. 53b EPC, Art. 27 IIIb TRIPS, however, the situation may vary from country to country, FRA: only certain plant species that are susceptible of plant variety protection are exempted from patent protection, Art. L. 623-3 du Code de la Propriété Intellectuelle

Protectable subject matter

Biotechnological inventions are patentable if they concern:³

- Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety
- A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety

³§2a II PatG, R 27 EPC

Question: Why are plant varieties exempted from patent protection?

Answer: Aspects to consider:

- Food security
- Dangers of monopolies
- Public interest

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Novelty

An invention is considered to be new if it does not form part of the state of the art⁴.

State of the art: everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application.

An invention is considered as involving an inventive step if,⁵

- having regard to the state of the art,
- it is not obvious to a person skilled in the art.

⁴§3 I, II PatG, Art. 54 I, II EPC

⁵§4 PatG, Art. 56 EPC

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Industrial Applicability

An invention is considered as susceptible of industrial application if it can be made or used in any kind of industry, *including agriculture*.⁶

⁶§5 I PatG, Art. 57 EPC

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Term of protection

20 years from the date the application is filed.

Provided that patent annuities are duly paid! ⁷

⁷§16 I PatG, Art. 63 I EPC, Art. 33 TRIPS

Question: Do you consider the term of patent protection too short for ensuring a reasonable return on investment?

Answer: Aspects to consider:

- Length of research and development (10-15 years for transgenic plants)
- Patent term starts at the beginning of research (usually 15 years before marketing)
- Length of field trials for GMO approval

Scope of protection⁸

- Determined by the claims (*the name of the game is the claim*).
- Description and drawings used to interpret the claims
- *First step:* Determining the literal understanding of the wording used in the claims, the description and drawings
- *Second step:* Doctrine of equivalence: equivalent means fall within the scope of a patent

⁸§14 PatG, Art. 69 I EPC

Extent of protection

A patent confers its owner the following exclusive rights:

- **Product claim:** to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;⁹
¹⁰
- **Process claim:** to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

⁹Decision of the Court of Justice of the European Union C-428/08

¹⁰§9 Nr. 1, 2, 3 PatG, Art. 64 II EPC, Art. 28, 34 I TRIPS

Exemptions of protection

Varieties are exempted from protection under the following circumstances:¹¹

- **Research exemption:** exempts from the patent right research relating to the subject matter of the invention
- **Breeders' exemption now in German patent law:** farmers are authorized to use protected varieties for propagating purposes - but: equitable remuneration which must be sensibly lower than the license fee

¹¹§11 II, IIa PatG

The structure of a patent text

1. Field of invention
2. Background art
3. Summary of the invention
4. Claims

National, supranational and international and agreements

- *National level:* German Plant Variety Protection Act (Sortenschutzgesetz, SortG)
- *European level:* Community Plant Variety Regulation No. 2100/94 (CPVR)
- *International level:* Union Internationale pour la Protection des Obtentions Végétales (UPOV 1991)

The laws and agreements have the following consequences:

- Harmonization of Substantial Law
- Essentially similar conditions and scope of protection in all UPOV 1991 Member States
- In the following: Focus on European, in particular German situation, cited source in bold letters

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Protectable subject matter

Plant variety means any plant grouping within a single botanical taxon of the lowest known rank which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:¹²

- Defined by the expression of the characteristics that results 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.

¹²§2a III Nr. 4 PatG, §2 Nr. 1a SortG, Art. 5 Nr. 2 CPVO, Art. 1 vi UPOV 1991

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Conditions of protection

The breeder's right shall be granted where the variety is:¹³

- new
- distinct
- uniform
- stable
- designed by a denomination

¹³§1 I SortG, Art. 6 CPVO, Art. 5 I, II UPOV 1991

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Novelty

The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety. ¹⁴

¹⁴§6 I SortG, Art. 10 CPVO, Art. 6 I UPOV 1991

Distinctness

The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. ¹⁵

¹⁵§3 I SortG, Art. 7 I CPVO, Art. 7 UPOV 1991

Uniformity

The variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics. ¹⁶

¹⁶§4 SortG, Art. 8 CPVO, Art. 8 UPOV 1991

Stability

The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.¹⁷

¹⁷§5 SortG, Art. 9 CPVO, Art. 9 UPOV 1991

Term of protection

25 years from grant, provided that the annuities are duly paid.¹⁸

¹⁸§13 SortG, Art. 19 No. 1 CPVO, Art. 19 II UPOV 1991

Question: What is the difference between patents and plant variety protection certificates concerning the term of protection?

Answer: Aspects to consider:

- Different term of protection
- Different starting point

Scope of protection

Authorization of the breeder is required for:

1. production or reproduction (multiplication),
2. conditioning for the purpose of propagation,
3. offering for sale,
4. selling or other marketing,
5. exporting,
6. importing,
7. stocking for any of the purposes mentioned in (1) to (6), above.

This also applies to harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.¹⁹

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¹⁹§10 I SortG, Art. 13 I, II CPVO, Art. 14 Ia, II UPOV 1991

Scope of protection

Scope extends to varieties which are essentially derived from the protected variety ("initial variety"), where the protected variety is not itself an **essentially derived variety** (EDV).²⁰

Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

²⁰§10 II SortG, Art. 13 Va CPVO, Art. 14 V UPOV 1991

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Scope of protection

A variety is an Essentially Derived Variety (EDV), when ²¹

1. it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
2. it is clearly distinguishable from the initial variety and
3. except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

²¹§10 III SortG, Art. 13 VI CPVO, Art. 14 V UPOV 1991

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1. **Breeders' exemption:** acts done for the purpose of breeding, or discovering and developing other plant varieties
2. **Research exemption:** acts done for experimental purposes
3. **The farm-saved-seed provision:** farmers are authorized to use protected varieties for propagating purposes - but: equitable remuneration which must be sensibly lower than the license fee

²²§10a I, No. 2, No. 3, II SortG, Art. 14 I, II CPVO, Art. 15 I ii, iii, II UPOV 1991

Question: Is the breeders' exemption an obstacle to innovation or does it foster innovation?

Answer: Aspects to consider:

- Food security
- Return on investment/amortisation of research costs
- Alternative: biological protection mechanisms (hybrids)

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Intellectual property protection in the US

Plant Patent Act (1930):

- Administered by US Patent and Trademark Office
- Covers asexually reproduced plants (mostly ornamentals and fruits)
- No yearly maintenance fee required
- Can exclude others from importing any part of a protected plant

Plant Variety Protection Act (PVP) (1970):

- Administered by US Department of Agriculture
- Weaker than plant or utility patents: Breeder's exemption and farmer's exemption

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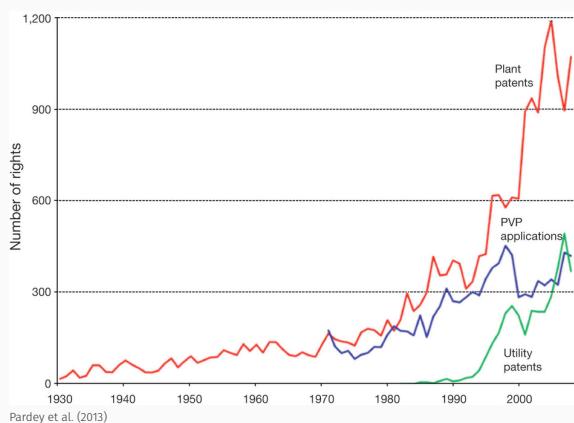
Intellectual property protection in the US

Utility patents (*Diamond v. Chakrabarty*) (1980)

- *Anything under the sun that is made by man* is patentable subject matter
- This includes plant varieties, parts of plants, genetically engineered organisms and gene products
- Plants covered by plant patent or PVP can additionally be covered by a utility patent
- ⇒ **Dual IP protection is possible for plants in the US!**

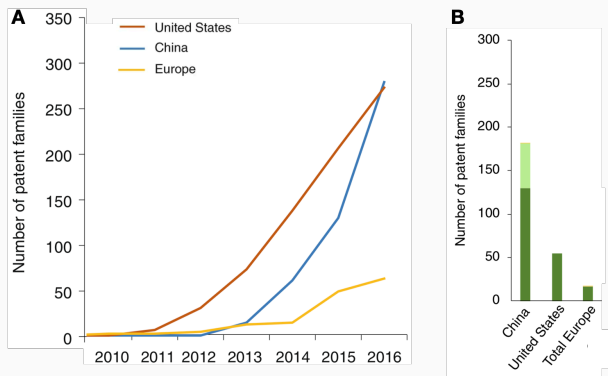
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Plant varietal rights in the United States, 1930-2010



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Patents related to CRISPR/Cas9 genome editing



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Summary

- Intellectual property (IP) is an important outcome of scientific research
- Patenting is the most important legal tool to protect IP
- Patenting is a contract between the inventor and the society: A time-limited monopoly is traded for a publication of the invention.
- Plant variety protection (PVP) is for protecting the products of plant breeding and is more liberal than patenting.
- The legal landscape for patenting in the context of biological processes and products is dynamic and complex.

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Further Reading

- Cornish/Llewelyn, Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights, 6th ed., 2007
- Würtenberger/Kiewit/van der Kooij, European Community Plant Variety Rights, 2006

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Review questions

1. What are the key requirements that a patent can be granted?
2. Which plant-breeding related matters are exempted from patenting?
3. Which biological inventions are patentable?
4. Why are plant varieties exempted from patent protection?
5. How long is a patent granted? Why is this period possibly too short for biotechnological inventions?
6. What part of a patent defines the scope of protection of an invention?

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References i

Pardey, P., Koo, B., Drew, J., Horwich, J., and Nottenburg, C. (2013). The evolving landscape of plant varietal rights in the United States, 1930–2008. *Nature Biotechnology*, 31(1):25–29. Number: 1 Publisher: Nature Publishing Group.

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