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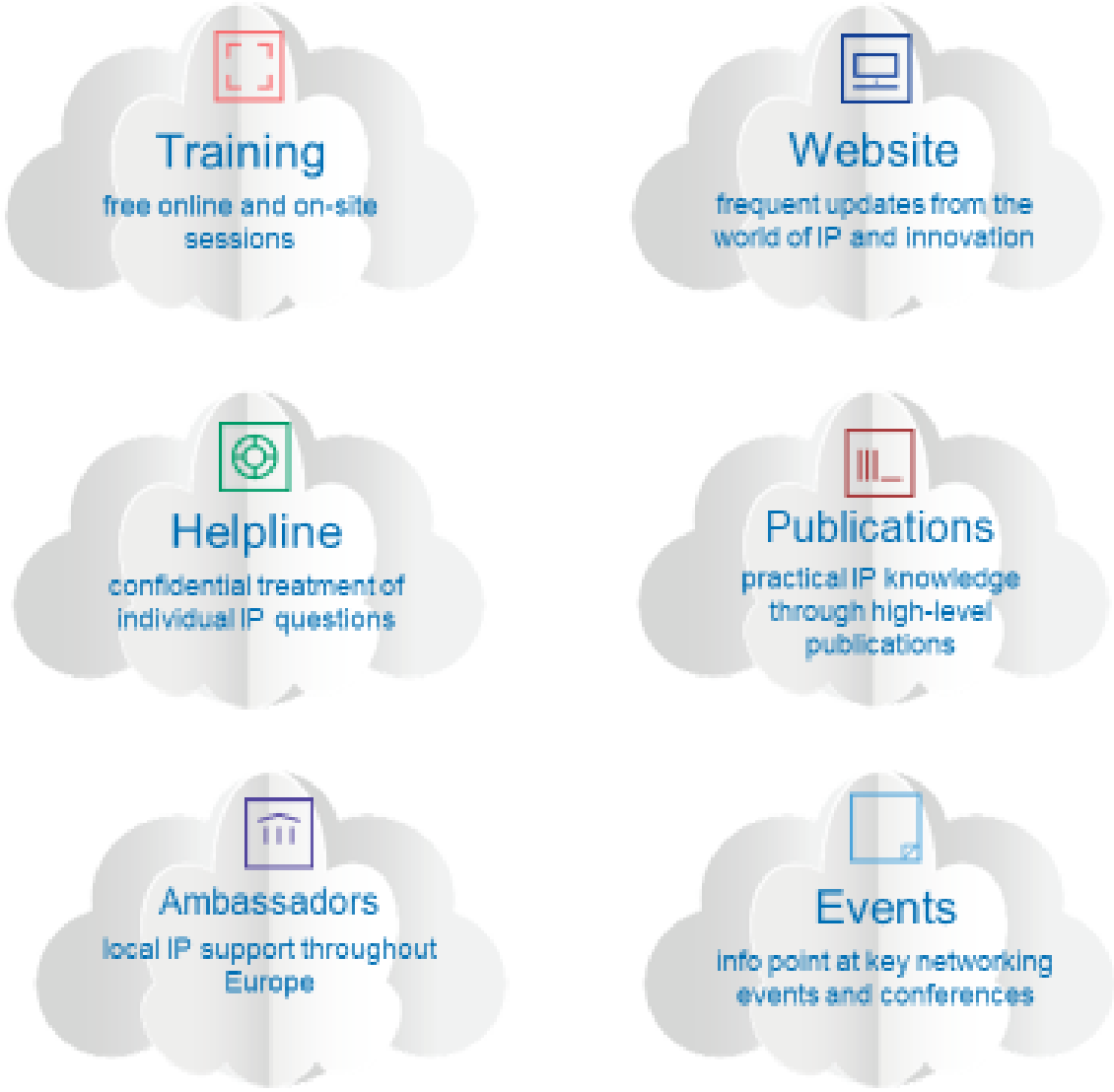
The interface between plant variety rights and patents

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CPVO

Community Plant Variety Office

The Interface between Plant Variety Rights and Patents

Montserrat García-Moncó – Head of Legal Unit
Ángela Martínez – Legal Advisor

IPR Helpdesk – 8 September 2022

The contents of this presentation are
the sole responsibility of the presenter
They do not necessarily represent the opinions of the
Community Plant Variety Office

Disclaimer:

This presentation contains information and elements stemming from the European Patent Office (EPO).

For the original source, please refer to the EPO.

The intention of the CPVO is to present the interface between plant variety rights and patents and for a comprehensive overview references to the EPO and its case law are required.

Outline

1. Introduction to Plant Variety Protection in the EU
2. Introduction to Patent Protection in Europe
3. Interface between Plant Variety Rights (PVRs) and plant-related patents
4. Case law of the Boards of Appeal of the European Patent Office (EPO)
5. Final considerations



1. Introduction to Plant Variety Protection in the EU

The value of plant innovation

- Products of plant breeding are of HIGH VALUE
- Developing new plant varieties is Time-Consuming and Costly
- Companies invest up to 20% of annual turnover on R&D
- Future R&D investments require incentives
- IP → allows a fair return on investment



Several forms of Intellectual Property (IP) protection available in plant breeding sector: patents, plant variety rights, trademarks, trade secrets…



WTO Obligation of plant variety protection

WTO members must implement the provisions of the Agreement on Trade-related Aspects of IPRs ("TRIPS Agreement")



Protecting plant varieties is a mandatory obligation for WTO members

Art. 27(3)(b) TRIPS Agreement:

Members shall provide for the protection of plant varieties ***either*** *by* ***patents*** ***or*** *by an effective* ***sui generis system*** ***or*** *by any* ***combination thereof.***

Legal Framework of the EU PVR system

The EU put in place the Community (EU) Plant Variety Rights (CPVR) system:

- A *sui generis* system for the protection of plant varieties in the EU territory
- In line with the TRIPS Agreement requirements [Article 27(3)(b)]
- Legal basis: Council Regulation No 2100/94 on Community plant variety rights ("Basic Regulation" or "BR")
- The Basic Regulation is modelled on and compliant with UPOV Convention
- The CPVR system is managed by the Community (EU) Plant Variety Office



Community (EU) Plant Variety Office (CPVO)

- EU Agency responsible for the management of the CPVR system
- Competent for the grant and management of Community plant variety rights (CPVRs)
- Seat in Angers (France) and operative since 1995, fully self-financed
- +55 employees of 14 EU nationalities – works in 24 EU languages
- Under the authority of the Administrative Council of the CPVO



Uniform EU protection

EU PVP has a uniform effect throughout the EU territory = 27 EU Member States (Art. 2 BR)

IP Principle of territoriality



- Grant, Transfer, Termination on a Uniform Basis



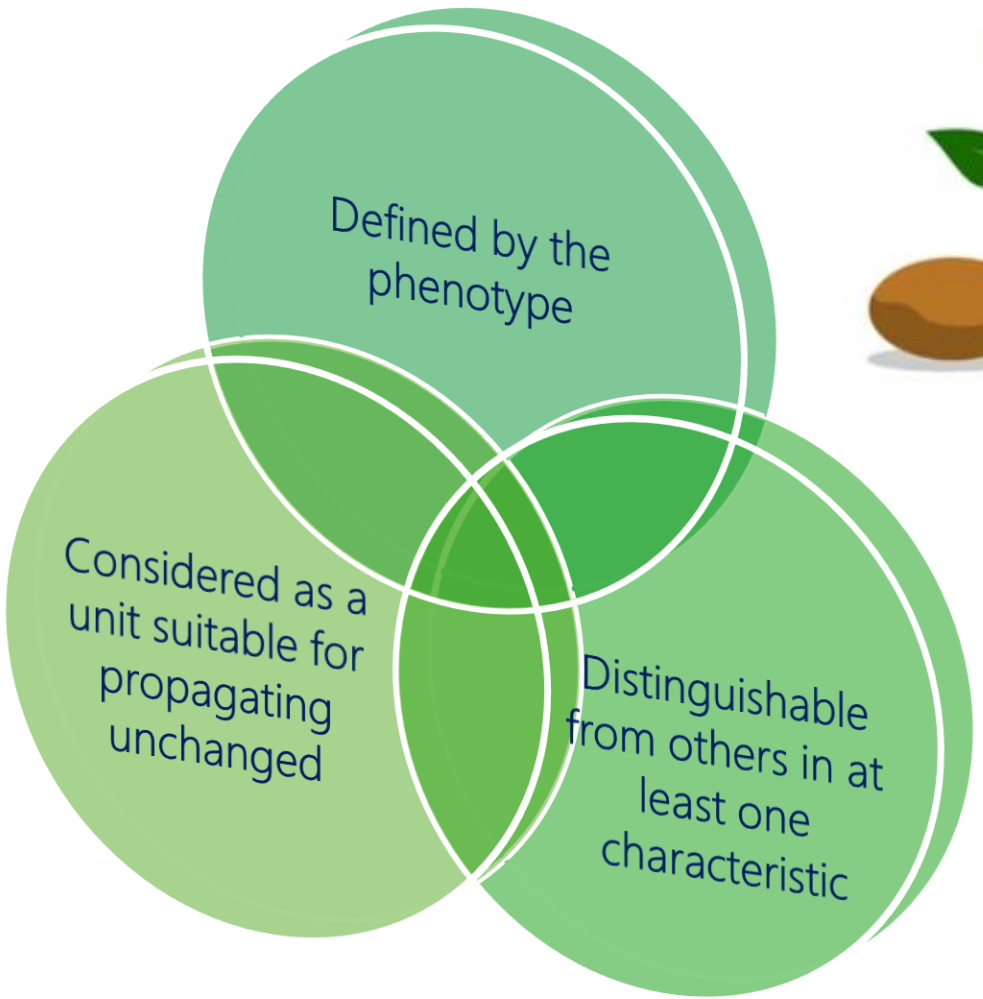
What is a Plant Variety?

Article 5(2) of Basic Regulation

Variety =

Plant grouping within a single botanical taxon

of the lowest known rank, which can be:





<u>In simpler terms</u>:

"Variety" = the most specific tangible unit of organisms of the taxonomy of Plant Kingdom

What is a Plant Variety?

Varieties of carrots

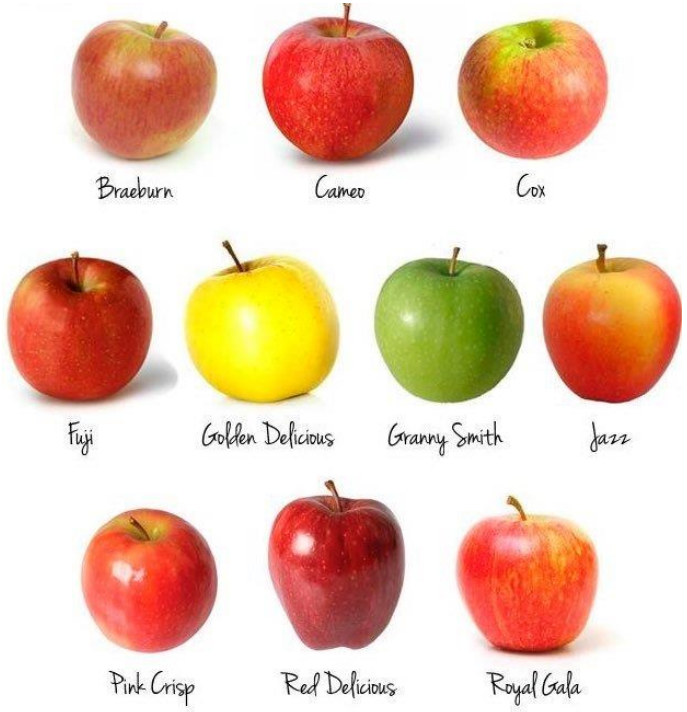




and lilies

What is a Plant Variety?

Varieties of apples





and rice

Which varieties can be protected?

Varieties of **all botanical genera and species** may be protected

The CPVO has received so far applications for ~**2300 plant species**







Benefits of application procedure for CPVR







One single application to cover the territory of all the EU Member States.



Less time and money spent in comparison to individual application filing in each EU Member State.



Easier management of the application and post-application processes thanks to a unique contact point.

Process of application for a CPVR



Registration of the application



Formal & Substantive examination of the application



Technical examination



Final decision: grant of the title or refusal of application

Requirements for protection



Distinctness



Uniformity



Stability



Novelty



Variety Denomination

Technical Examination

Examination of DUS requirements:

CPVO has no technical infrastructure

Growing trial carried out by Examination Office:
concludes with Technical Report

If Final Report positive: Variety Description issued



CPVO
Community Plant Variety Office

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DUS Examination Offices in the EU



The red dots represent entrusted Examination Offices carrying out DUS technical examinations on behalf of the CPVO

Period of Protection of CPVR

Duration of the right (Article 19 BR):

- 25 years
- 30 years:
  - Vines, trees and potato varieties
  - Since 2021, extension for asparagus and the species groups flower bulbs, woody small fruits and woody ornamentals



Possible provisional protection (Article 95 BR)

Scope of EU Plant variety Rights

Authorization of the holder required for the following acts [Art. 13(2) BR]:



Production or reproduction



Conditioning for the purpose of propagation



Offering for sale, selling or other marketing



Exporting from/Importing to the European Union



Stocking for any of the above mentioned purposes

The material scope of CPVRs



Variety constituents



Harvested material



Protection does not extend to: products obtained directly from material of the protected variety

Exceptions and Limitations to CPVRs



Exceptions to CPVRs

[Article 15 BR]:



Agricultural exemption

[Article 14 BR]



Private non-commercial acts



Acts done for experimental purposes



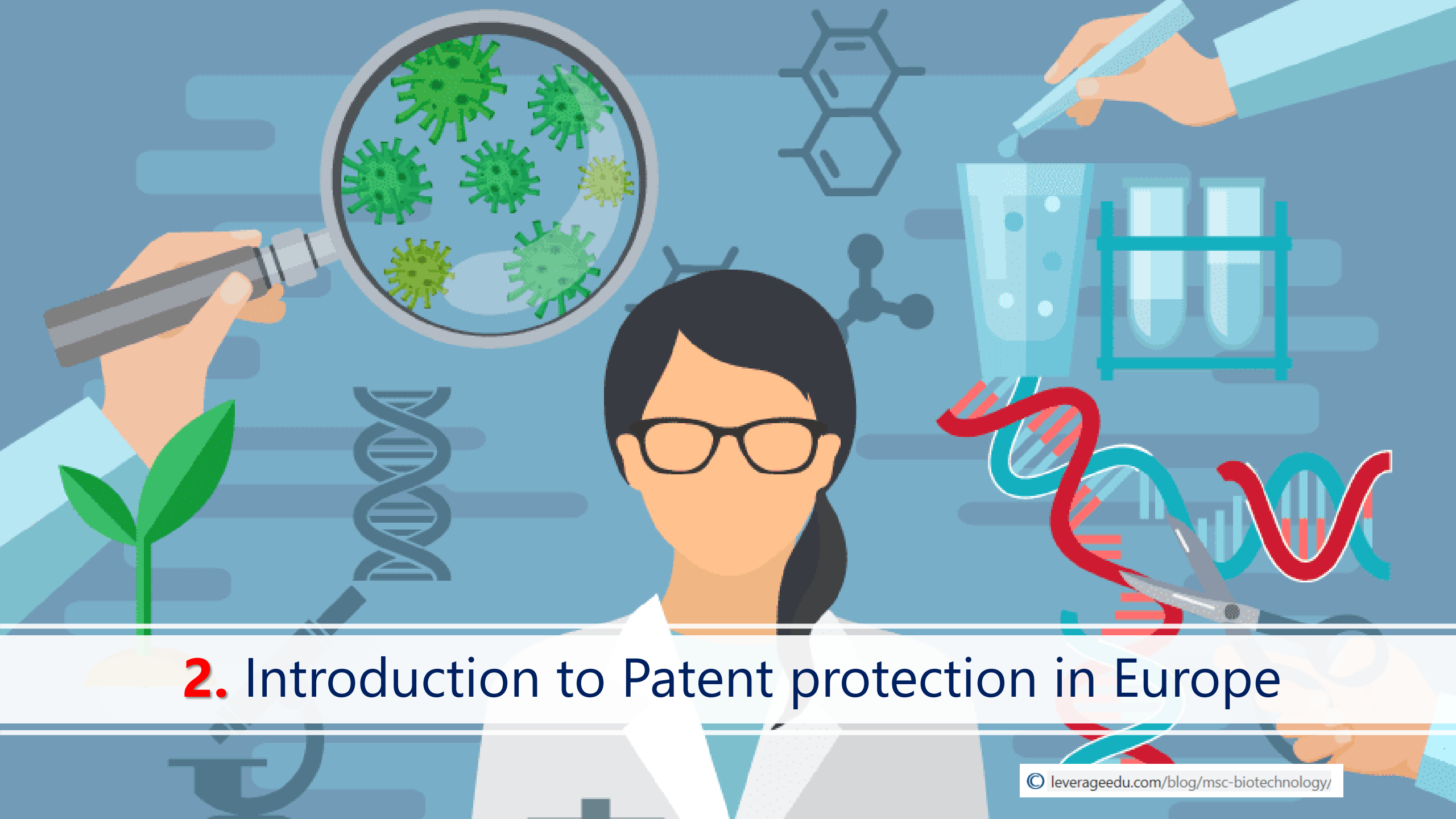
Breeder's exemption

Acts done for breeding, or discovering & developing new varieties

CPVO statistics (1995-2022)

- ~ 77.000 applications for CPVR filed (~ 3.500 per year)
- ~ 61.000 CVPRs granted
- ~ 30.000 CPVRs currently in force

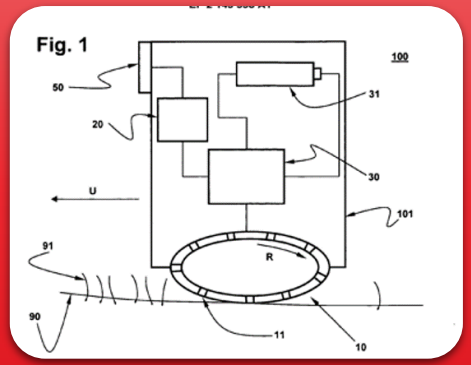




2. Introduction to Patent protection in Europe

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Article 27 of the TRIPS Agreement



Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application



Inventions in all fields of technology can be protected

Patents for products and for processes

Invention = technical solution to a technical problem!

Different routes for patent protection

NATIONAL

Código da Propriedade Industrial (CPI)



EUROPEAN

Munich Convention
1973.10.05
(European Patent Convention – EPC)



INTERNATIONAL

Patent Cooperation Treaty – PCT
1970.07.19



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European Patent Convention

The European Patent Convention (EPC) was signed in Munich in 1973

EPC established the intergovernmental European Patent Organisation (EPOrg)

EPOrg is composed of 38 contracting states (including all EU MS)

The European Patent Office is the executive arm of the EPOrg



Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office

- Responsible for examining applications and granting European patents –not an EU institution.
- Operative since 1973 and self-financed.
- 35 different nationalities and three working languages (English, French and German).
- Headquarters in Munich and offices in Berlin, The Hague, Viena and Brussels.
- Under the supervision of the Administrative Council.



Europäisches Patentamt
European Patent Office
Office européen des brevets

Bundle of national patents

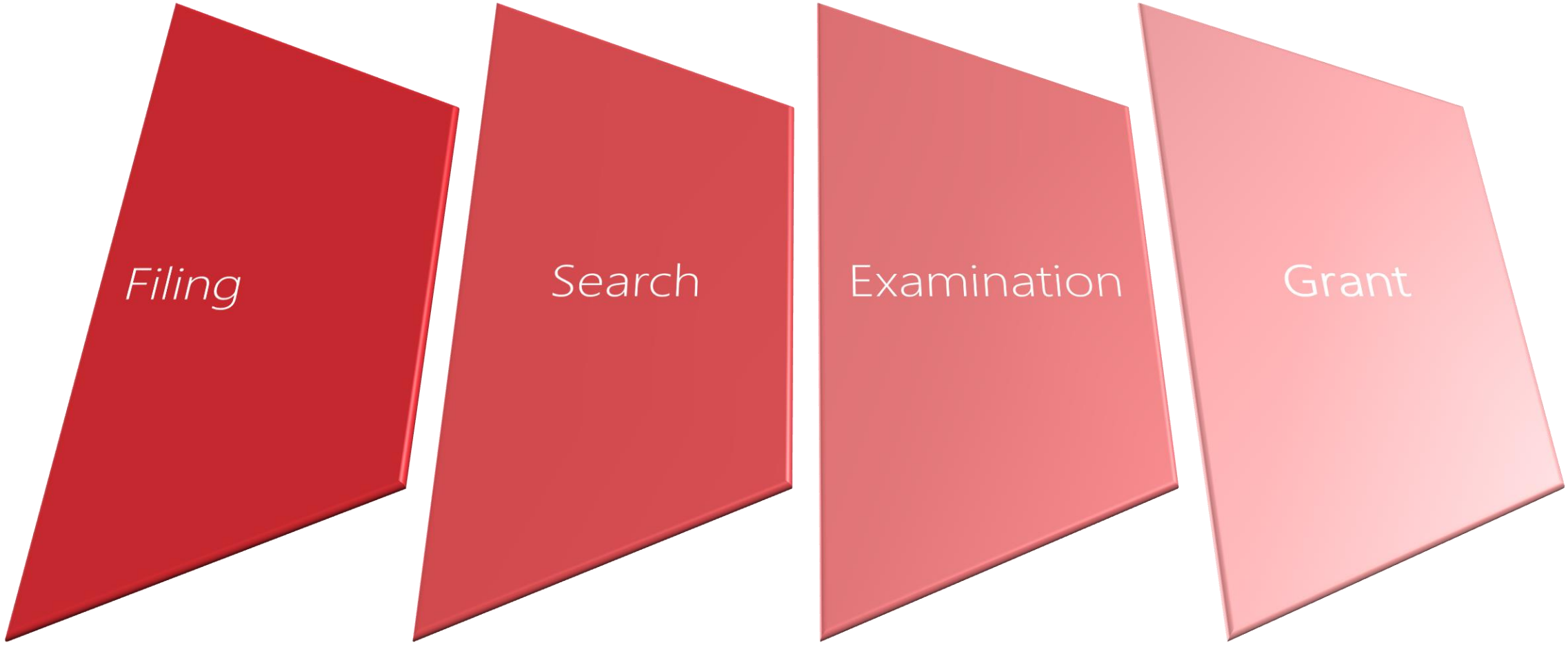
Centralized procedure to grant a European patent with a single application.

The European patent needs to be **validated** in the selected member states (translation might be needed).

Once validated, the European patents have the effects and are subject to the same conditions as a **national patent.**

It is possible to obtain patent protection in 44 countries based on a single application.

Procedure of application for European Patents



Patentability requirements

Article 52(1) EPC (Patentable inventions):
European patents shall be granted for any invention, provided that it is:



New



Involve an Inventive Step



Susceptible of Industrial Application

Effects of the European patent



Rights determined by the national patent law of the country where it is granted (Art. 64 EPC)

Scope of the patent: defined by the claims for which protection is sought





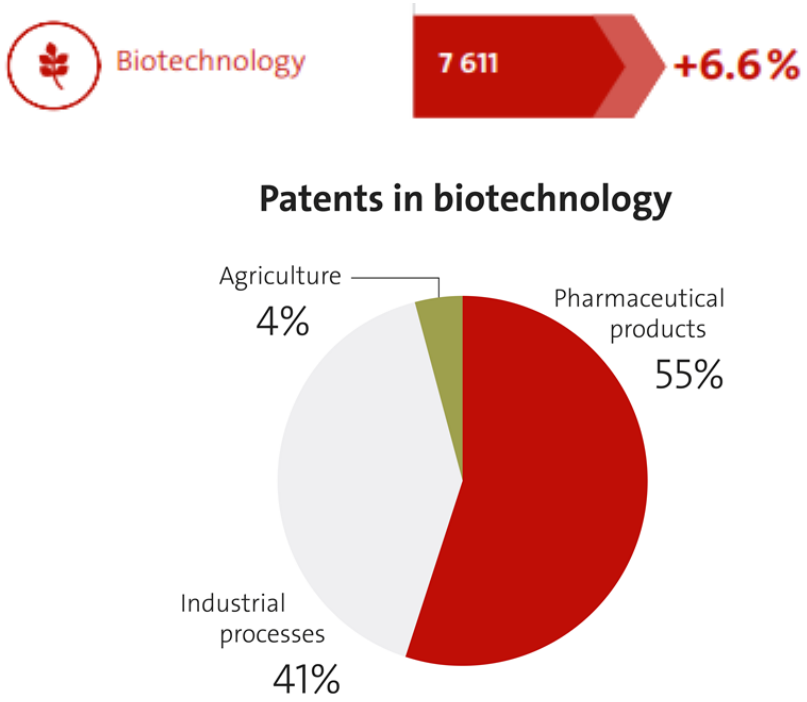
Term of the European Patent (Art. 63.1 EPC): 20 years from the date of filing of the application

Possible provisional protection since the publication of the application (Art. 67 EPC)

Statistics on Biotech patents

Around 300 patent applications for plant-related inventions per year.





EU framework: Directive 98/44



Advent of modern biotechnology: proliferation of patents, led to adoption of EU Directive 98/44 (“Biotechnology Directive”)



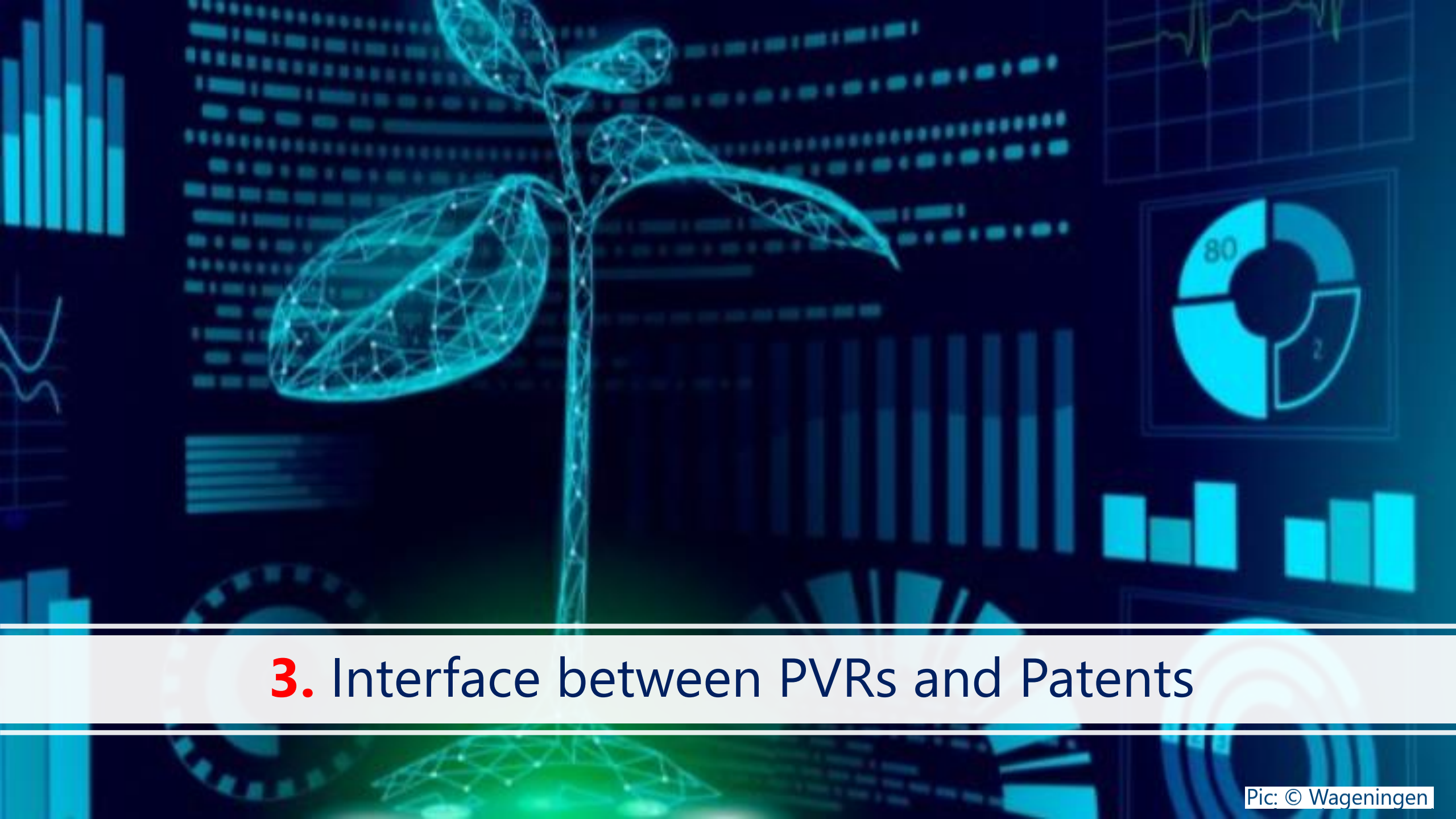
Harmonisation at EU level of national legislation on patentability of inventions on biological material



Biotech Directive was incorporated into the EPC in 1999 by the Implementing Rules to the EPC 26 to 34 to ensure harmony between EU legal order and European patent system



Biotech Directive must be used as a supplementary means of interpretation when applying the provisions of the EPC



3. Interface between PVRs and Patents

Pic: © Wageningen

Eligibility Requirements



PATENT	PLANT VARIETY RIGHT
Subject matter: Technical Invention	Subject matter: Plant Variety
Novelty (absolute) ⇔	Distinctness
	Uniformity
	Stability
Inventive Step	
Industrial Applicability	
	Novelty (commercial)
	Denomination



The "Distinctness" requirement under PVP systems can be compared to the "novelty" requirement under Patent systems: a variety is distinct when it is added to the Plant Kingdom (varieties of common knowledge = state of the art).

The notion of "novelty" under PVP law refers to "commercial novelty", so it is narrower than under patent law ["absolute novelty": the invention must not form part of the state of art"].

Scope of the right



The scope of the right under a patent is larger than under a PVR: no equivalent to the breeders' exemption



Some European jurisdictions foresee a limited breeders' exemption in their patent laws [Germany, Netherlands, Switzerland, France]



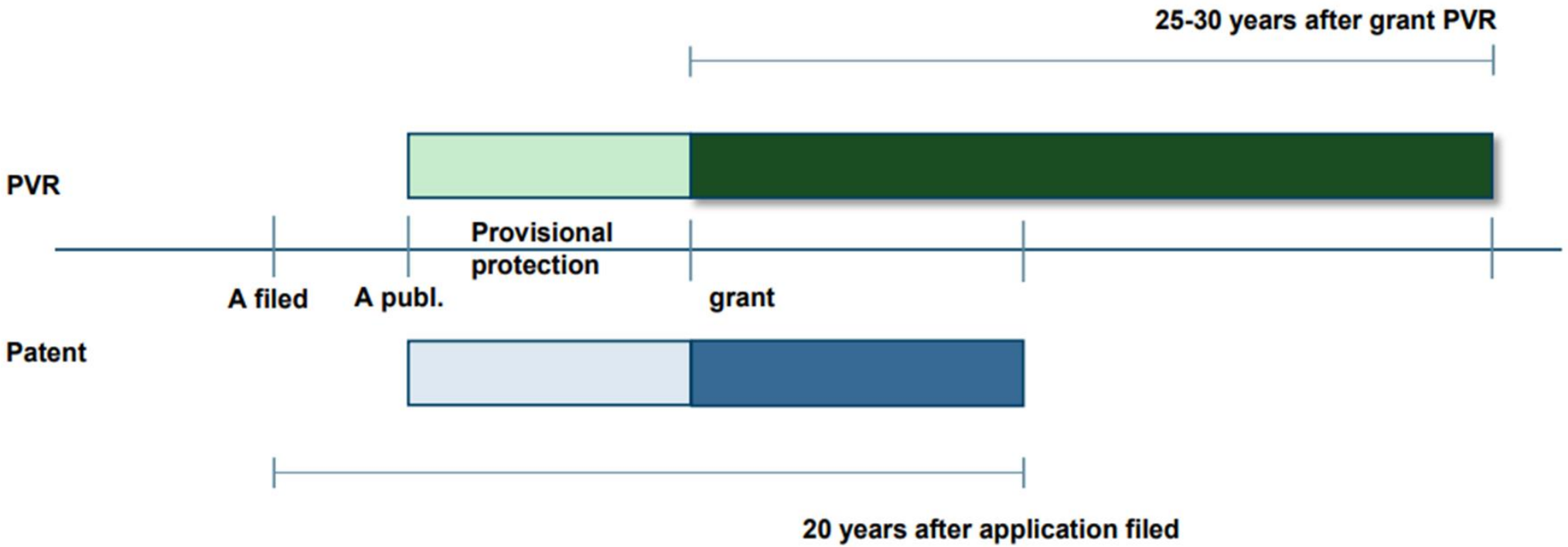
Limited breeders' exemption: breeders can use patented biological material for developing new varieties, patent holder authorisation not needed.

However, for commercialising the new variety including the patented trait, a licence is needed from the patent holder.



Article 27(b) Unitary Patent Court Agreement: *The rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding, or discovering and developing other plant varieties.*

Duration of protection under a patent and a PVR



© Source: Houthoff

Exceptions to Patentability

Article 53(b) EPC

[= Art. 27(3)(b) TRIPS]

European patents shall not be granted in respect of: […] Plant varieties or essentially biological processes for the production of plants

Implementing Rule 28(2) EPC

Under Article 53(b), European patents shall not be granted in respect of plants exclusively obtained by means of an essentially biological process

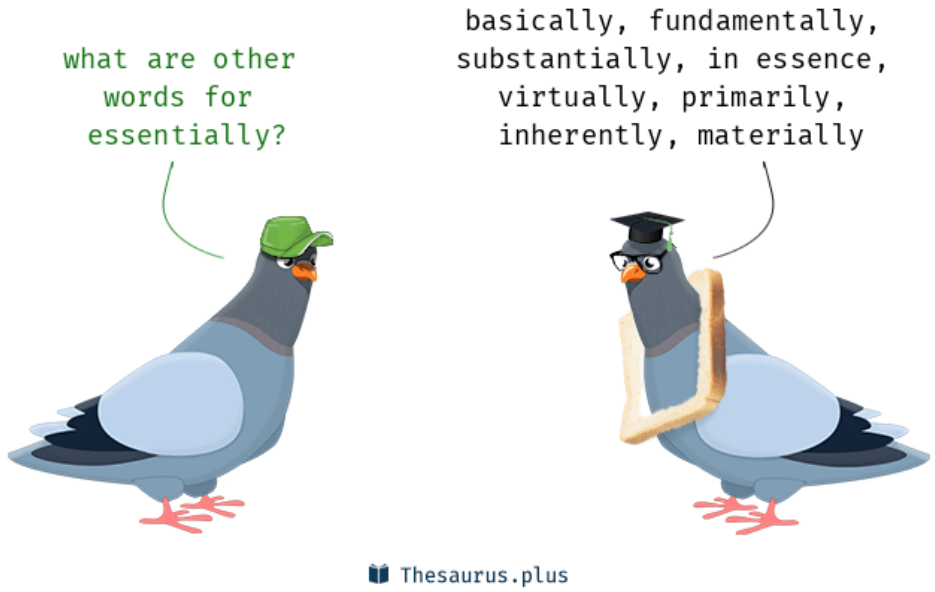


The notion of “Essentially Biological Process”

Rule 26(5) EPC

Essentially Biological Process = process for the production of plants consisting entirely of natural phenomena

= Conventional methods for producing plants not involving use of technologies to bypass natural biological mechanisms





4. Case law of the Boards of Appeal of the European Patent Office (EPO)

Outline of Landmark Case Law Saga



1. *Novartis II* (G1/98)



2. *Tomato & Broccoli I* (G 2/07 & G 2/13) and *II* (G 2/12 & G 2/13)



3. *Pepper* (T 1063/18)

4. *Opinion G 3/19*

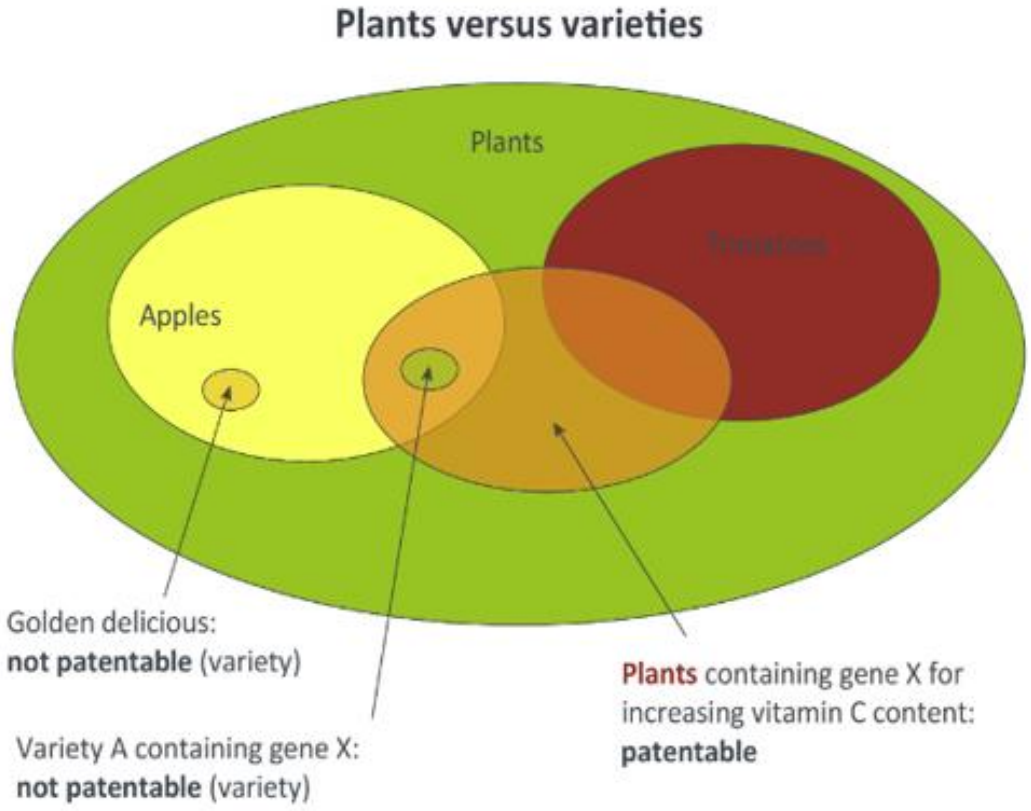
EPO Boards' case law (1): *Novartis G 1/98* Plant varieties excluded from patentability

"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 can be patented if the technical feasibility of the invention is not confined to a particular plant variety

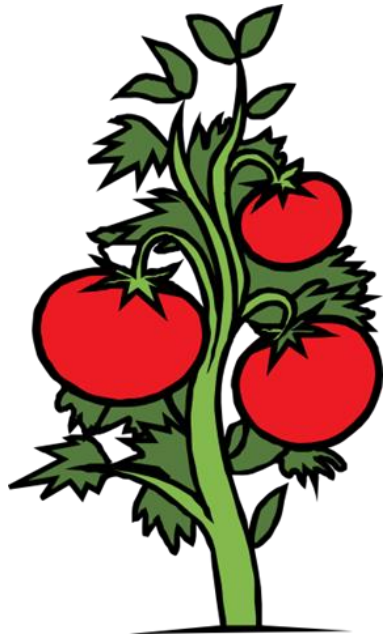
[Rule 27(b) EPC]

Hence, although plant varieties are NOT patentable, they can be covered under the scope of a patent.



Illustrative Example

PVR

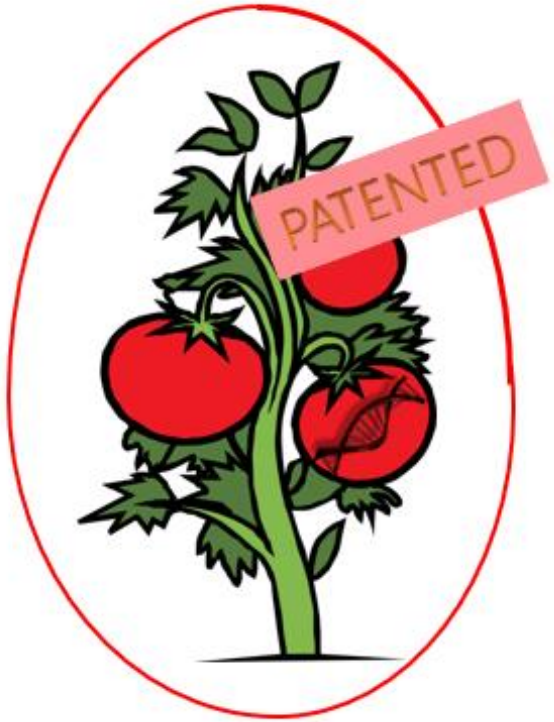


A Plant variety = phenotype resulting from a specific combination of genetics

A plant which has been inserted a gene that makes it herbicide-resistant does not fall under the definition of plant variety:

that plant grouping would not be defined by its whole genome, but by an individual characteristic (herbicide resistance)

The invention could be patented



A gene / trait

Private Initiatives in the plant breeding sector

International Licensing Platform Vegetable

ILP vegetable

ACLP AGRICULTURAL CROP LICENSING PLATFORM

PINTO

EPO Boards' case law (2): *Tomato & Broccoli I* (G 2/07 & G 1/08) Essentially Biological Processes excluded from patentability

Two patent applications: Tomato, and Broccoli

- Process claims for a conventional method for the production of Tomatoes with reduced fruit water content comprising a step of "screening for reduced fruit water content as indicated by wrinkling of the fruit skin".
- Process claims for a conventional method for the production of Broccoli with elevated levels of glucosilonate comprising a step wherein molecular markers are used in two steps to select hybrids.



EPO Boards' case law (2): *Tomato & Broccoli I* (G 2/07 & G 1/08) Essentially Biological Processes excluded from patentability

The Enlarged Board of Appeal (EBA) found that a process for producing plants which contains or consists of the steps of crossing the whole genomes of plants and of subsequently selecting plants is excluded from patentability as being "essentially biological" within the meaning of Art. 53(b) EPC.

However, if such process contains within the steps of crossing & selecting an additional step of technical nature, which step by itself introduces/modifies a trait into the plant's genome, and the trait's introduction/modification does not result from the mixing of the genes of the plants, then the process could be patentable.

So, when does a technical step render a process patentable?

The word “essentially” (as opposed to “purely”) indicates that the mere use of a technical device in a process is not sufficient to confer such process a technical character.

A technical step serving only to enable or assist the process of cross and selection does not render such process patentable.

However, a process is patentable if it comprises an additional technical step which by itself introduces or modifies a trait in the genome, and the change in the genome does not result from the sexual crossing of whole genomes.

Examples of Technical steps not rendering process patentable

Tools to assist with pollination

Special greenhouses

Molecular markers to facilitate trait selection







EPO Boards' case law (2): *Tomato & Broccoli* II (G 2/12 & G 2/13) Products of Essentially Biological Processes (EBPs): excluded from patentability?

New questions addressed to the Enlarged Board

Question on patentability of products obtained from EBPs:

- Product claim for Tomato fruit naturally dehydrated obtained from EBP
- Product claim for Broccoli plant/seed obtained from EBP

EBA ruled that the patentability exception of EBPs had no bearing on the patentability of EBP's products

So: Products of EBPs were considered patentable





Reactions to *Tomato & Broccoli II* at EU level: Commission Notice

European Parliament reacted to *Tomato* and *Broccoli II: issued* in 2015 a Resolution asking the Commission to clarify scope of Art. 4 BD [= Art. 53(b) EPC]

Commission adopted in 2016 the "Commission Notice" on interpretation of Biotech Directive

Commission affirmed that the EU legislator's intention was to exclude from patentability both EBPs and their products

European Parliament and the Council of the EU endorsed the Commission Notice

Call for the alignment of the EPO practice with the Commission Notice

> The Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

Rule 28(2) EPC: entry into force on 1 July 2017

In the light of the EU developments, the EPO Committee on Patent Law issued in 2017 a favourable opinion on the amendment of the Implementing Regulations to the EPC for aligning the EPC with the Biotechnology Directive as interpreted in the Commission Notice.



Administrative Council of EPO approved the introduction of Rule 28(2) EPC, which entered in force on 1 July 2017:

"Under Article 53(b), European patents shall not be granted in respect of plants [...] exclusively obtained by means of an essentially biological process"

Application of Rule 28(2) EPC in practice

Rule 28(2) excludes from patentability plants exclusively obtained by an EBP (i.e.: non-technical process)

Rule 28(2) also excludes plants obtained by an EBP where additional steps of a technical nature were used to enable or assist the process

However, Rule 28(2) does not exclude: plants with modified (heritable) traits as a result of a technical process

EPO Boards' case law (3): *Pepper* (T 1063/18)



The Technical Board of Appeal (TBA) questioned the validity of Rule 28(2) by considering it to conflict with Art. 53(b) EPC as interpreted in *Tomato* and *Broccoli II*.



The TBA recalled that the EBA is the EPOrg's judicial body competent for deciding on points of law of fundamental importance.



The TBA ruled that the Commission Notice was irrelevant because it had not been confirmed in a legally binding manner (i.e.: by EU Court of Justice).



The TBA considered that the entry into force of Rule 28(2) had no impact and reiterated the findings in *Tomato* and *Broccoli II* (i.e.: EBP's products could be patentable).

EPO Boards' case law (4): Opinion G 3/19

Situation of impasse:

in April 2019 and to restore legal certainty, the EPO President lodged with EBA Referral G3/19 (pursuant to Art. 112(1)(b) EPC).

2 Questions in Referral G 3/19:

Q1.

Can Art. 53 EPC be clarified in the Implementing Regulations without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards?

Q2.

Is the patentability exclusion of EBP's plants pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC?



EPO Boards' case law (4): Opinion G 3/19

First part of EBA's Opinion:

- Wording of Art. 53(b) EPC: unclear if article should be subject to narrow or broad interpretation.
- Commission Notice: does not qualify as legal act within the EU legal order.
- National developments in some EPC Contracting States resulting in the exclusion from patentability of EBP's products: irrelevant because did not concern all EPC Contracting States.

EBA could not find reasons to extend the patentability exception in Article 53(b) EPC and endorsed its findings in *Tomato* and *Broccoli II*.

EPO Boards' case law (4): Opinion G 3/19

Second Part of EBA's Opinion: application of "Dynamic Interpretation" method

- "A particular interpretation which has been given to a legal provision can never be taken as carved in stone, because the meaning of the provision may change or evolve over time"

Consequently, *Tomato and Broccoli II* did not settle the meaning of Art. 53(b) EPC

The EBA considered that it could not ignore the introduction of Rule 28(2)

- Most of the EPC Contracting States in the Administrative Council of EPO voted in favour of Rule 28(2) + many of them had aligned their national provisions to Rule 28(2)

The EBA concluded that the exception of Art. 53(b) EPC extends to EBP's products

i.e.: EBP's products are NOT patentable

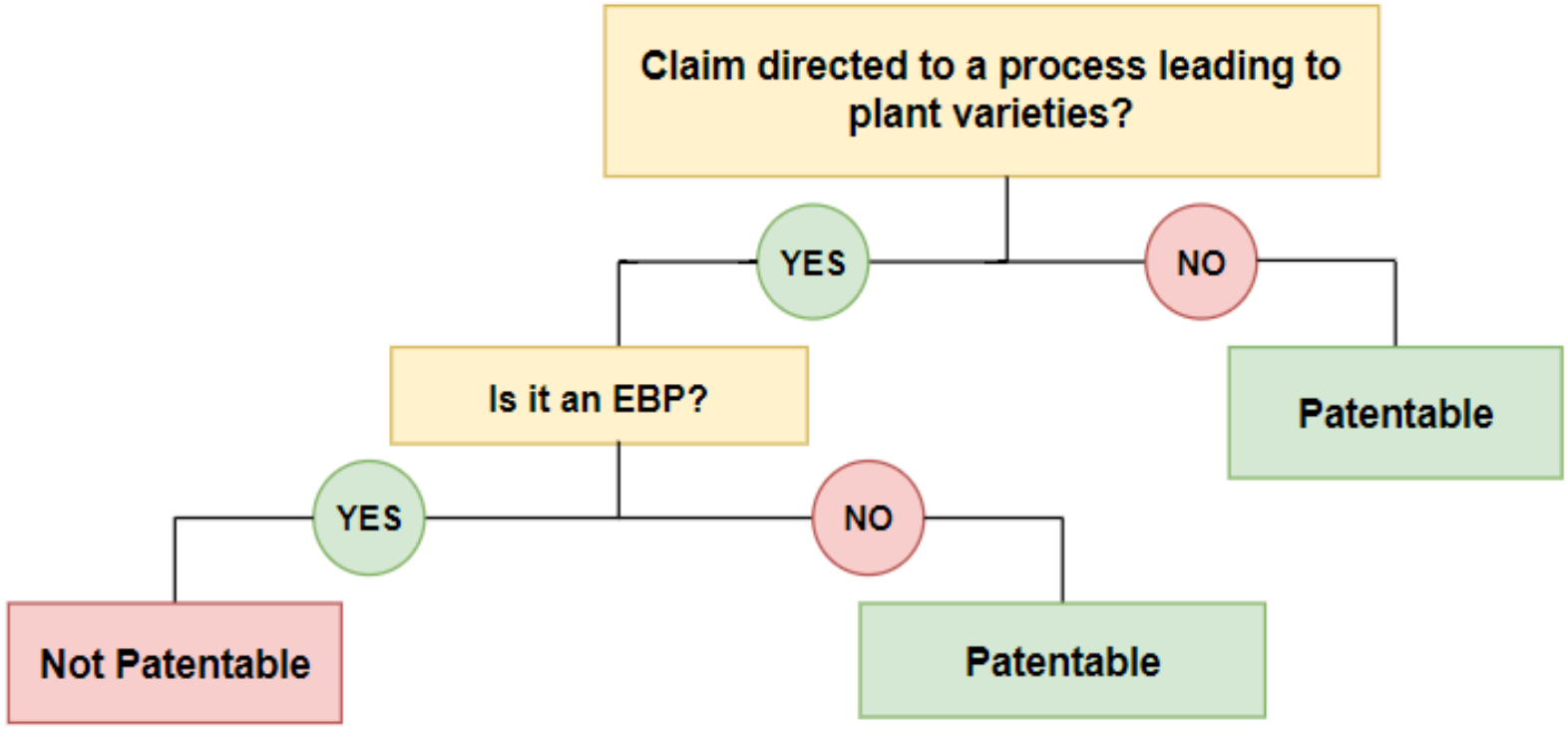
EPO Boards' case law (4): Opinion G 3/19

To safeguard the legitimate interests of patent proprietors and applicants, the EBA introduced "ban on retroactivity"

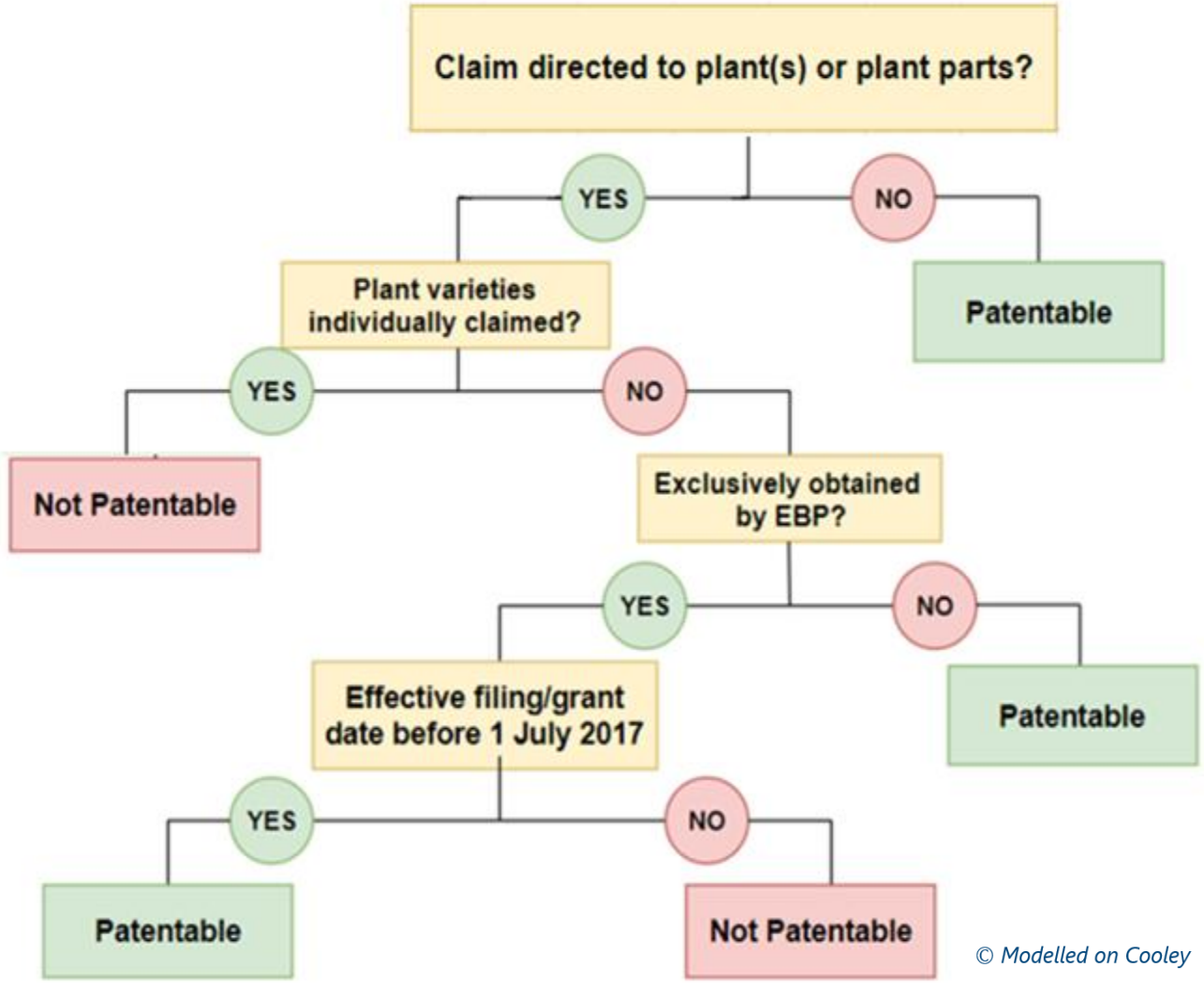
The EBA ruled that the new interpretation of Art. 53(b) EPC has no retroactive effect on European patents containing claims on EBP's products and having been granted before 1 July 2017, or on pending European patent applications filed before that date.



Patentability of Claims directed to processes relating to plants



Patentability of Claims directed to plant-related products



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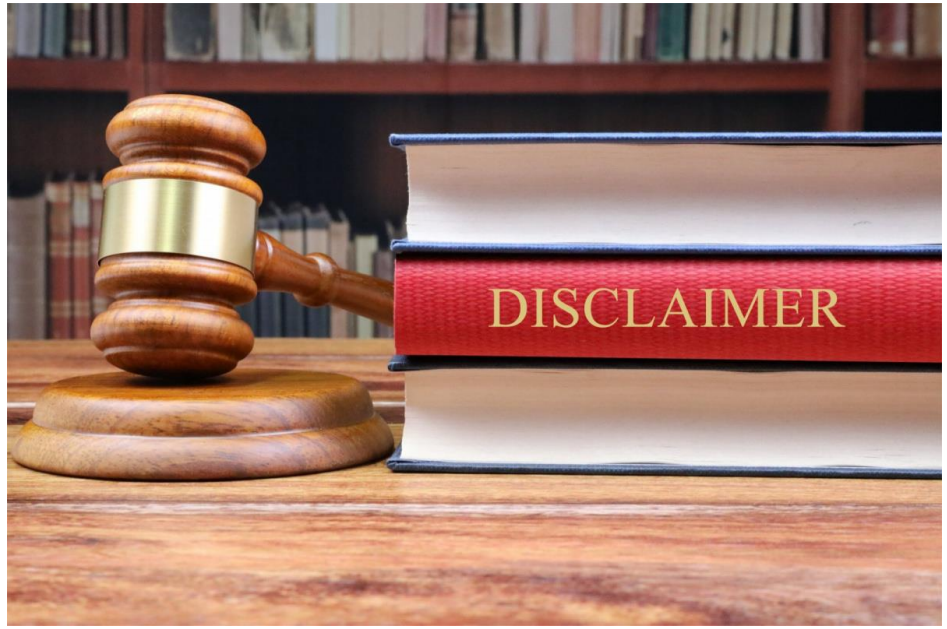
Opinion G 3/19: Implications for the Disclaimers' practice in applications

If a technical feature can be achieved both by a technical process and an EBP, a disclaimer is required to exclude the EBP and limit the claimed subject matter to the technically produced product

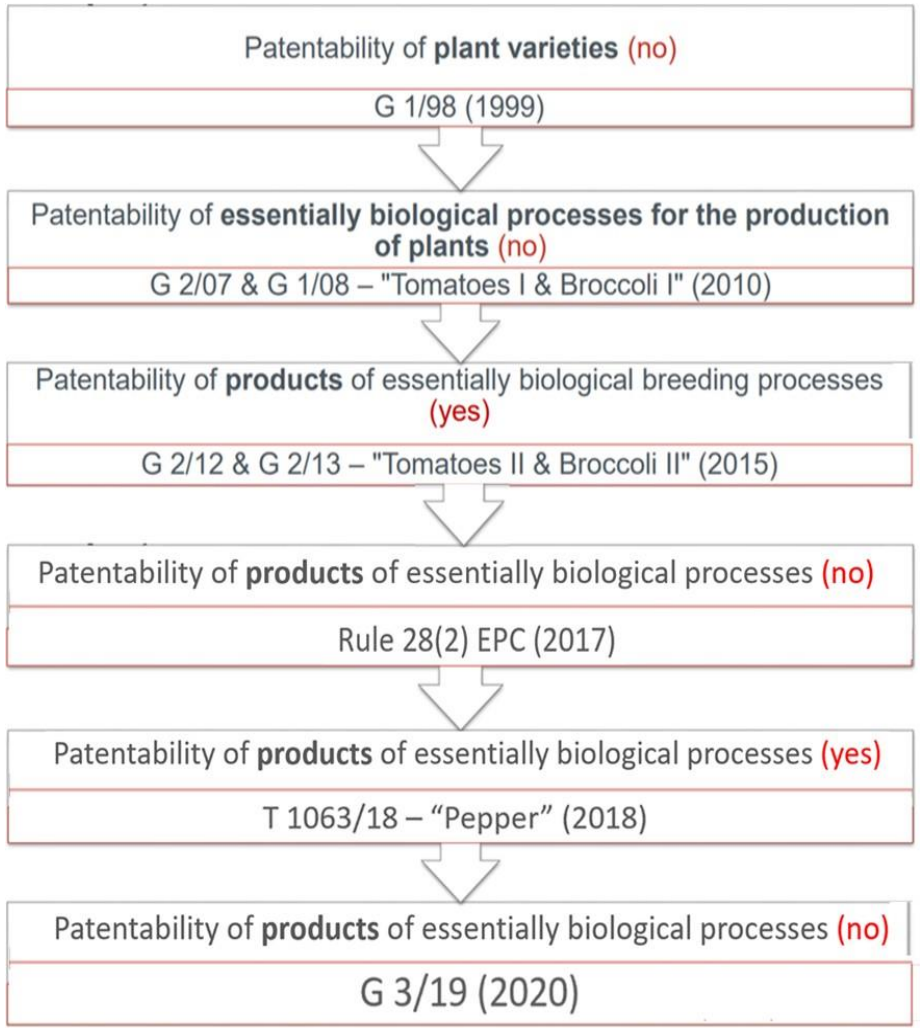
- "wherein said plant is not exclusively obtained by an essentially biological process"

Otherwise, application considered to concern excluded subject-matter (EBP) and is refused

After Opinion G 3/19, Disclaimer only needed for patent applications with a filing date and/or a priority date after 1 July 2017



Wrap-up 1: EPO case law

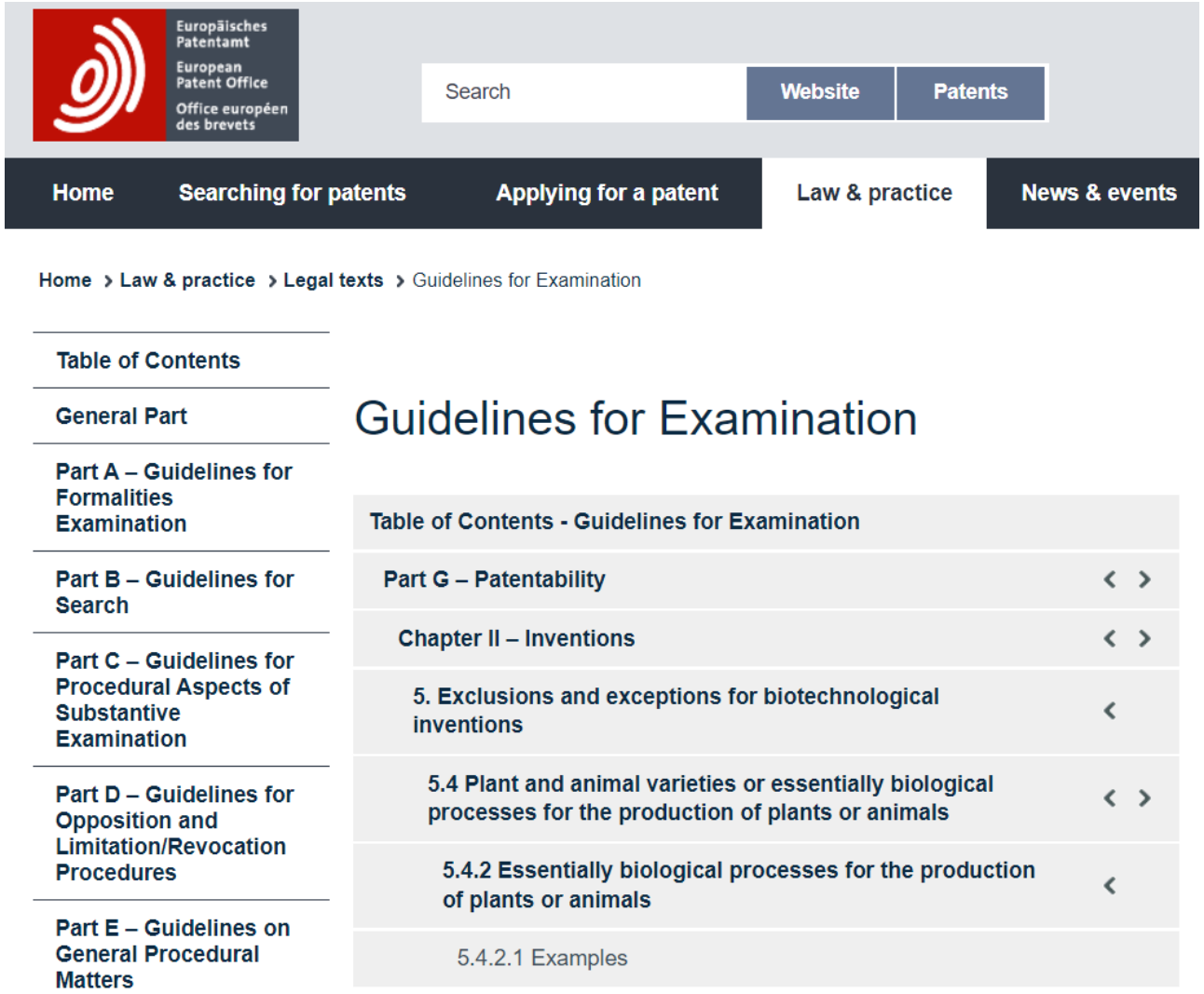


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Wrap-up 2: Patentable vs Non-Patentable Subject Matter

Non-patentable	Patentable
Plant varieties (propagatable material)	Plants produced by technical processes, provided that the technical feasibility of the invention is not confined to a particular plant variety
Essentially Biological Processes (EBPs)	Genetic engineering methods for introducing new traits into a plant
	Microbiological processes and products (plant cells or cell populations)

EPO Examination Guidelines





5. Final Considerations

Bilateral cooperation between the CPVO and EPO



On 31 March 2022, the "Administrative Arrangement No 2022/01373 on bilateral cooperation between the EPO and the CPVO" was signed, renewing cooperation for 5 years.

- Follows on former Adm. Arrangement No 2016/0009, signed in February 2016.



Adm. Arrangement No 2022/01373 is focused on the exchange of data and in the sharing of work practices on the use of databases and other work tools.

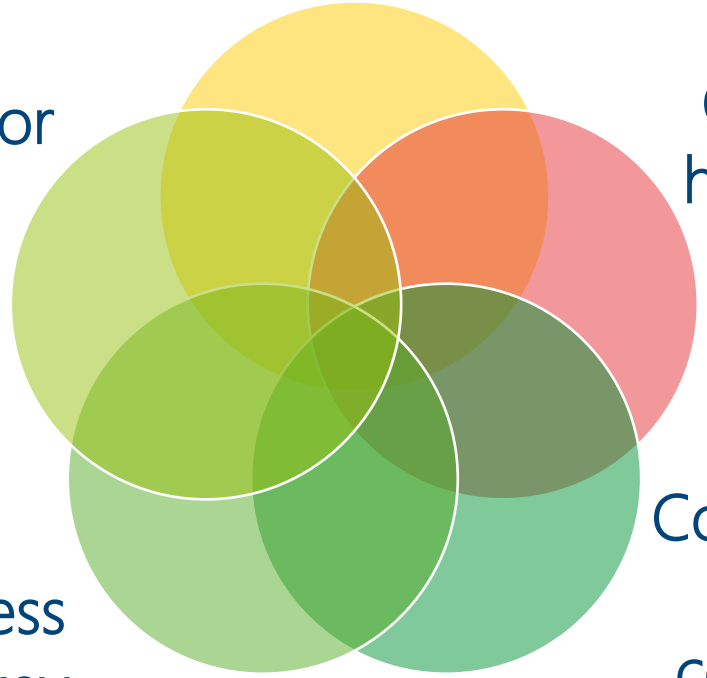


The CPVO and EPO engage in regular dialogues essential to the protection of plant-related innovations and which will play a key role in facing the 21st century challenges.

Final Considerations

Patents and PVRs have a different scope of protection

Innovation provides a means for future-proof plants against threats



Opinion G 3/19 of EPO's EBA has brought legal certainty on Art. 53(b) EPC

Transparency and access to genetic material is key

Cooperation necessary to ensure peaceful coexistence of patent systems

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