

NGT proposals by the EU Commission, European Parliament and Council – state of the trilogue

*with respect to
intellectual property rights*

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12TH GRUR MEETS BRUSSELS WORKSHOP




Image credit: Cold Spring Harbor Laboratory

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State of the trilogue

Calendar

05.07.2023	Commission legislative proposal
24.04.2024	Parliament position (first reading)
07.03.2025	Council position (Mandate for negotiations with the European Parliament)
03.04.2025	Council document: Initial positions of the institutions
08.04.2025	Mandate to start trilogue negotiations
06.05.2025	1 st Trilogue Meeting
 05/06.2025	9 informal tripartite meetings (ITM): NGT Cat. II → NGT. Cat. I → IP (June 23/25)
30.06.2025	2 nd Trilogue Meeting

Critical points:

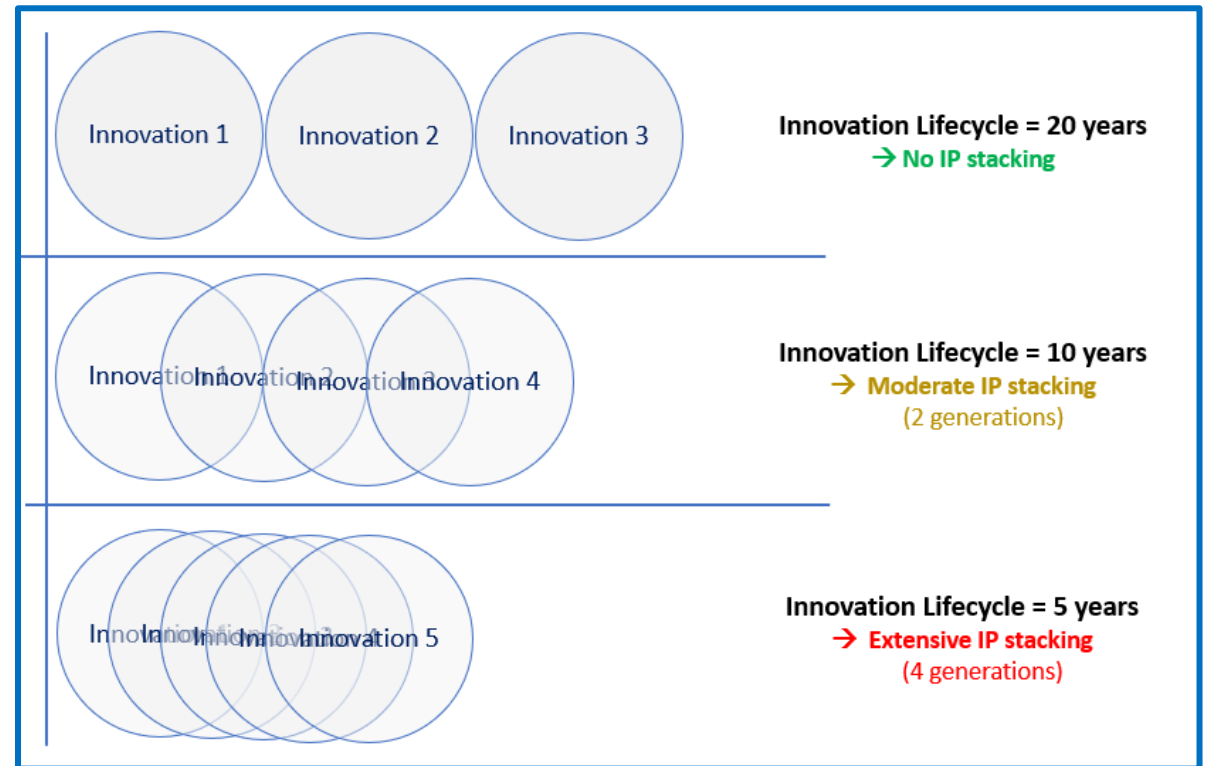
- **Traceability & labeling:** Only labelling of NGT-seed or also of products made therefrom?
- **Criteria for Cat.I:** Exclusion of herbicide tolerance, sustainability requirement, quantity of edits
- **Patents:** Study, transparency, exclusion from patentability or patent rights?

NGTs and Patents

The WHY
The WHAT
The HOW

WHY a debate about patents on NGT derived plants?

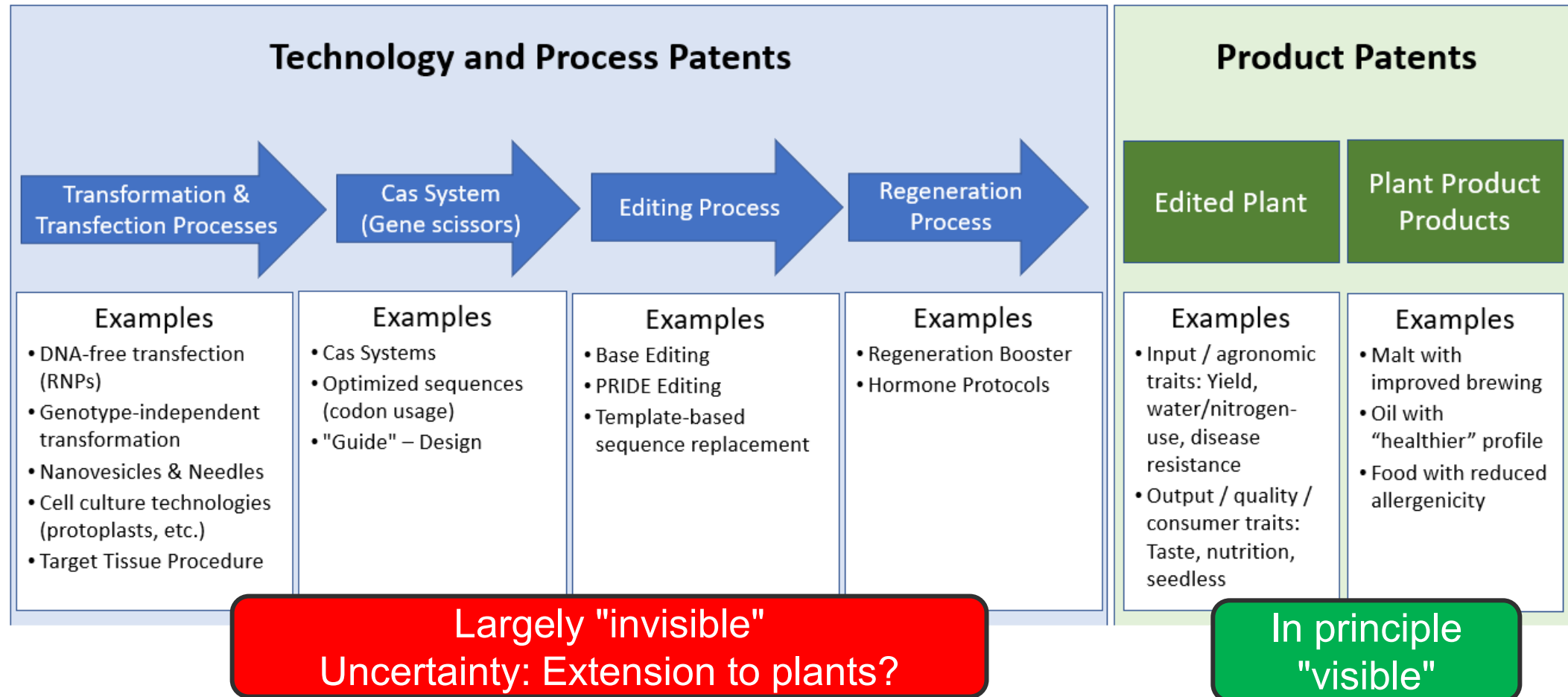
- NGTs enable precision breeding ("breeding-by-editing") with short development cycles. Complex breeding goals (e.g. climate resilience) are achieved by influencing several target genes in parallel ("multiplexing").
- NGTs are patentable, technical processes. Resulting plants are not excluded from patentability. While changes could occur naturally, most of them will be "new".
- Breeding of new varieties is based on existing ones. Through short NGT innovation cycles, patented properties MAY rapidly accumulate in plant varieties.



The WHY: NGTs and patents – legal complexity

Two types of patents:

- General technology and process patents (not limited to specific plant characteristics)
- Patents on plants with new specific characteristics

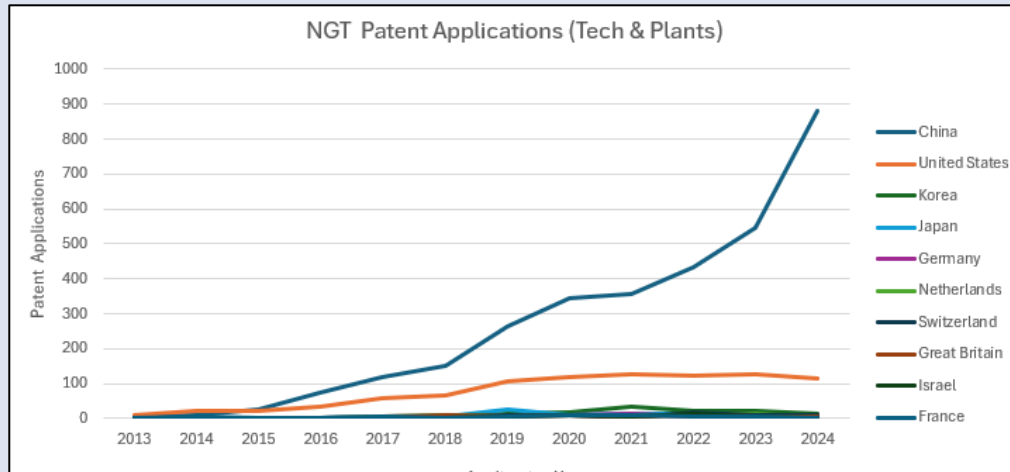


The WHY: NGTs and patents - quantitative complexity

NGT Process Patents

with relevance to plants

- Steady increase: Currently ~5000 families (28.4.24)
- Trend: Increase will plateau in the medium term.



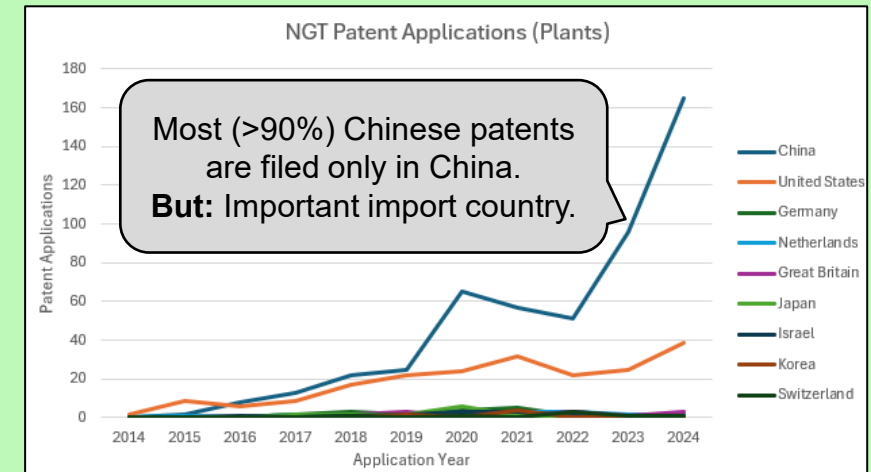
Applicant country:

	CN	US	KR	JP	DE	NL	CH	UK	IL	FR
2024	880	114	12	3	10	3	8	7	2	2
2013 - 2024	3213	925	129	77	68	67	61	51	46	49

Patents on NGT plants

>1 Example with CRISPR on plants

- Slow increase: Currently ~800 families (28.4.24)
- Trend: Increase with falling regulatory hurdles.



Applicant country:

	CN	US	DE	NL	UK	JP	IL	KR	CH	FR
2024	165	39	2	2	3	0	0	0	1	1
2013 - 2024	504	207	19	16	14	13	11	7	7	5

The WHY: Patents on NGT plants: Consequences for breeders and farmers

Challenge	Consequences / Concerns
Transparency Which patents are relevant?	Lack of transparency → Increased due diligence & costs <ul style="list-style-type: none">• Patent identification and valuation
Legal certainty Do I need a license?	Legal uncertainties → Deterrence, unnecessary licenses <ul style="list-style-type: none">• Patent: Scope of process claims, cross-license, breeder's exemption• PBR: DUS criteria and EDV definition for NGT varieties
Guaranteed Access Secure licenses (i) Patented characteristics (ii) Patented technologies (?)	Limited access → Reduced competitiveness <ul style="list-style-type: none">• Transaction cost• Risk of license denial, financial losses• Restricted genetics for further breeding
Farmers	<ul style="list-style-type: none">• In principle: Farmer's exemption applies to patents• Short term: Uncertainty for farm-saved-seed royalties (several holders)• Mid term: Reduced competition – fewer offers – higher prices

Can existing (or improved) transparency, access, and legal clarity solve these issues and be more than a transition?

Towards the WHAT: Categories of plants

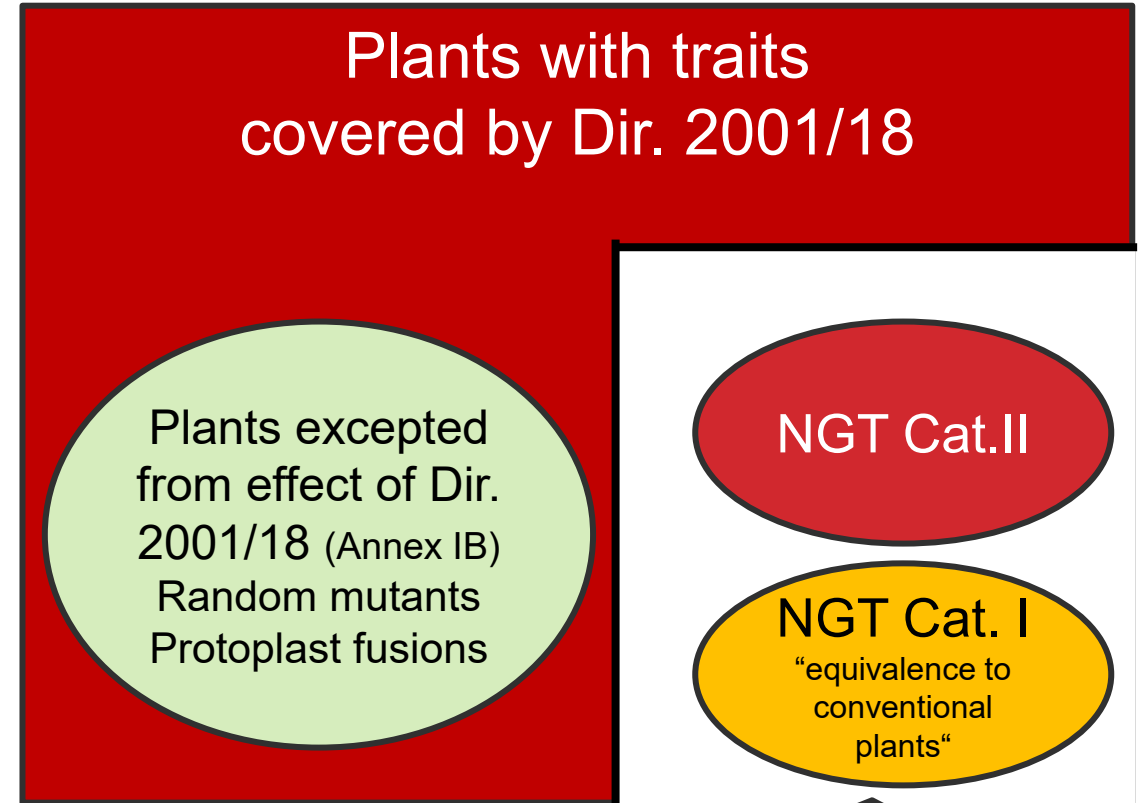
Impacted by patents

Non-GMO



Plants with naturally existing traits introgressed by essentially biological processes (crossing and selection)

GMO



Plants which could be made by essentially biological processes?

The WHAT: EU NGT Regulation and Patents

Parliament's Approach I : Patentability - Proposed amendments of Art. 4 Dir.98/44

Article 4

1. The following shall not be patentable:
 - (a) plant and animal varieties;
 - (b) essentially biological processes for the production of plants or animals.
 - (c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) [.../...];
 - (d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Dir. 2001/18/EC as listed in Annex I B to that directive.'
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.
4. Paragraph 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.

The WHAT: EU NGT Regulation and Patents

Parliament's Approach I : Patentability - Proposed amendments of Art. 4 Dir.98/44

Article 4

1. The following shall not be patentable:

- (a) plant and animal varieties;
- (b) essentially biological processes for the production of plants or animals.
- (c) NGT plants, plant material, parts thereof, genetic information and **process features** they contain, as defined in Regulation (EU) [.../...];
- (d) plants, plant material, **genetic information** that can be yielded by techniques excluded from the scope of Directive 98/44 as noted in Annex I B to that directive.'

Definition not harmonized with EPO
"Consist entirely of natural phenomena."
No extension to plants.

Cat. I + II NGTs

What is a process feature?
Art.8(2): Specific characteristics as a result of the invention.?

- 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
- 3. Paragraph 1(b) shall be without prejudice to the patentability of any product obtained by means of a technical process or a
- 4. Paragraph 2 and 3 shall be without prejudice to the patentability of any product obtained by means of a technical process or a

What is the effect on patentability
for the different categories of plants ?

The WHAT: Patentability of Plants

		Native Traits (no change)	Transgenics (no change)	NGT Cat. I & II (targeted mutants, cisgenesis)	Random mutants, protoplast fusions (Dir. 2001/18 Annex IB)
Claim	Legal Basis	Rule 28(2) EPC	Dir. 98/44	NGT Reg. → Dir.98/44 Amendment	
Plants		Non-patentable	Patentable	Not patentable	Not patentable
Plant material		Partially Patentable (Dead material: wort, silage)			
Plant parts		Partially Patentable (Technically treated seed)			
Genetic information		Patentable			
Process features		Partially Patentable (Selection processes)			
Implementation		Disclaimer for plant claims	-	Requires change of Dir. 98/44 and EPC! ?? Disclaimer for the entire patent ??	
Effect		Patents filed after July 1, 2017	-	Patents filed after a future change of the EPC enters into force.	

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendment of Art. 8 Dir.98/44

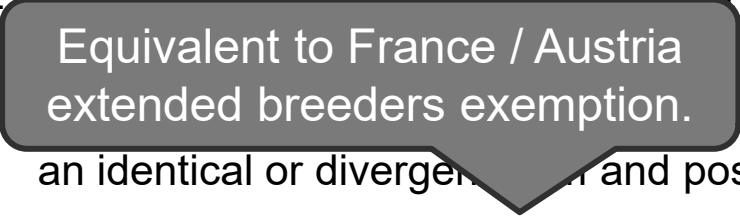
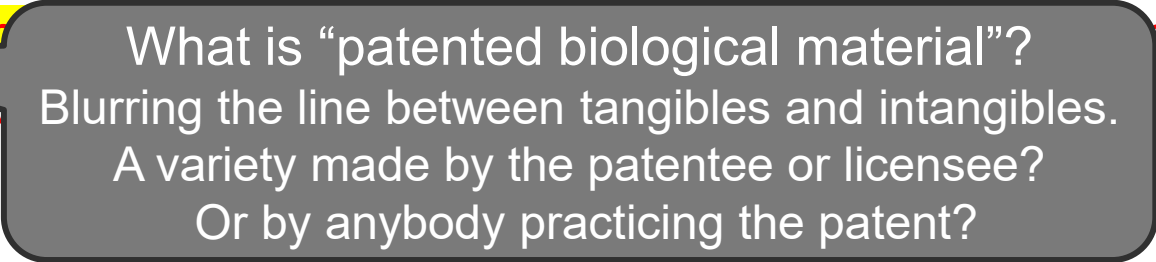
Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
3. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.'

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendment of Art. 8 Dir.98/44

Article 8

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2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics shall extend to biological material directly obtained through that process and to biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
Equivalent to France / Austria extended breeders exemption.
3. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from which the biological material is obtained from such material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
What is “patented biological material”?
Blurring the line between tangibles and intangibles.
A variety made by the patentee or licensee?
Or by anybody practicing the patent?

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendments of Art. 9 Dir.98/44

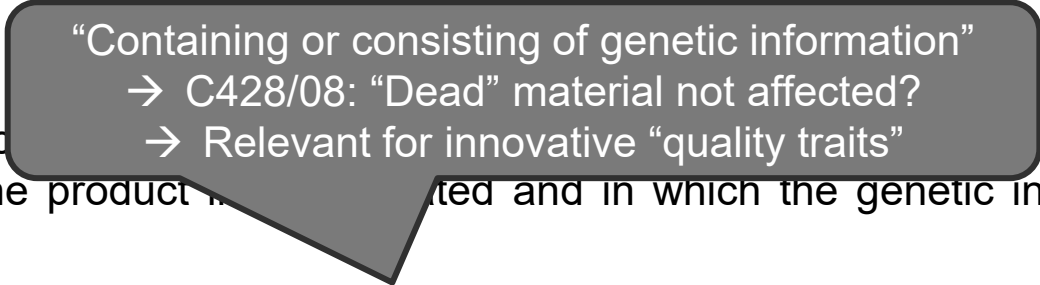
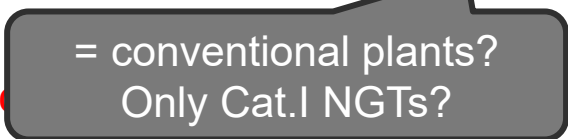
Article 9

1. The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.
2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.
3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.
4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendments of Art. 9 Dir.98/44

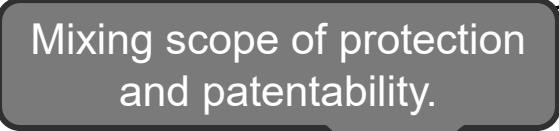
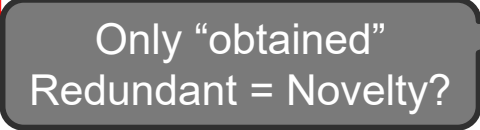
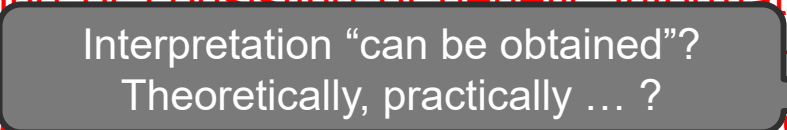
Article 9

1. The protection conferred by a patent on a product containing or consisting of genetic information shall not extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.
 "Containing or consisting of genetic information"
→ C428/08: "Dead" material not affected?
→ Relevant for innovative "quality traits"
2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.
3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.
 = conventional plants?
Only Cat.I NGTs?
4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendments of Art. 9 Dir.98/44

Article 9

1. The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 10, in which the genetic information is incorporated and in which the genetic information is contained and performs its function.

2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.

3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.
4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.


What is the effect on patent rights
for the different categories of plants ?

EU NGT Regulation and Patents

Parliament's Approach II: Scope of patent rights - Proposed amendments of Art. 8 & 9 Dir.98/44

Claim ↓	Native Traits	Random mutants	Protoplast fusions	NGT Cat. I	NGT Cat. II	Transgenics
Plant	Exempted if (independently) developed by an essentially biological process	Unclear: Is random mutagenesis essentially biological? → AT Patent Law ≠ EPO Practice Exempted if independently developed by essentially biological process	Not exempted (likely: not obtainable by essentially biological process)	Exempted	Not exempted (likely: not obtainable by essentially biological process)	Not exempted
Plant part						
DNA						
Process						
Plant material (dead, quality traits)	Not exempted	Not exempted		Not exempted		
Implementation	Dir. 98/44 → UPC & National Patent Law of all EU Member States					
Effect	Retroactivity: All unexpired patents and patent applications					

EU NGT Regulation and Patents

Council's Approach: Transparency

Article 6

3x. The requester shall, **acting to the best of their knowledge**, submit a written statement identifying **patents claiming modifications of biological material of the NGT plant resulting in particular traits**, or published applications for granting such patents, or declaring the absence of such patents or published applications for granting such patents (patent information).

3xx. The requester **may submit** a written declaration of the holder of a patent identified under paragraph 3x confirming his their willingness to licence the protected subject under equitable conditions in all Member States where the patent holder is entitled to grant such a licence (licence declaration).

3xxx. The patent information and the licence declaration shall not be subject to verification and shall only have declaratory value.

(Similar in Article 7; 2x.-2xxx)

EU NGT Regulation and Patents

Council's Approach: Transparency

Article 6

3x. The requester shall, **acting to the best of their knowledge**, submit a written statement identifying **patents claiming modifications of biological material of the NGT plant resulting in particular traits**, or published applications for granting such patents, or declaring the absence of such patents or published applications for granting such patents (patent information).

Not holistic: Does not include process patents which extend to plant material.

3xx. The requester **may submit** a written declaration of the holder of a patent identified under paragraph 3x confirming his entitlement to grant such a licence under equitable conditions in all Member States. The holder is entitled to grant such a licence (licence declaration).

No legal consequences.
Forfeiture of rights?
Patent-Mismatching?

3xxx. The patent information and the licence declaration shall **not be subject to verification and shall only have declaratory value.**

(Similar in Article 7; 2x.-2xxx)

EU NGT Regulation and Patents

Council's Approach: Expert Group & Study

Article 30 bis NGT patent expert group and the study on the impact of patenting practices

1. Commission to establish **an expert group** on the effect of patents on NGT plants: Effect of patent law on access to genetic resources, innovation in the field of NGT plants, incl. patent licensing practices, [...] and patent enforcement practices vis à vis farmers.
2. Commission to conduct **a study** on impact of patenting of plants, licensing and transparency practices and impact on innovation in plant breeding, breeders' access to plant genetic material and techniques, and availability of plant reproductive material to farmers, competitiveness of the EU plant breeding industry.
3. If no follow-up is deemed necessary, the Commission shall conduct **another study** no sooner than 4 years and no later than 6 years after the first report.

NGT Regulation and Patents

Conclusions

Approach	Assessment
Parliament: Exceptions to patentability	<ul style="list-style-type: none">• Unclear situation for "native traits"• Unclear implementation for process patents. Risk of collateral damage.• Amendment to Dir. 98/44 <u>and</u> the EPC (Unanimity 38 Member States)• No retroactivity → Conclusion: Not holistic, limited effect, uncertain implementation
Parliament: Limits to patent rights	<ul style="list-style-type: none">• Amendment Dir. 98/44 → Amendment of national patent laws/Unitary Patent• Unclear wording and scope → Conclusion: Conceivable (in principle), not holistic, unnecessary complex.
BE/PL Presidency: Patent waiver (withdrawn)	<ul style="list-style-type: none">• Mixing private and public law.• Arbitrary trade barrier (WTO); legal uncertainty for users (trade)• "Mission Impossible" for third-party patents, especially universities (NPEs) → Conclusion: Interesting idea, not effective, uncertain implementation, risks.
Council: Patent transparency License readiness	<ul style="list-style-type: none">• Declaratory character: No consequences for incorrect naming or "non-naming" → Conclusion: No change in the status quo (limitation of forfeiture/mismatching?)

NGT Regulation and Patents

Summary

- **IF** there is desire/need to limit patents on NGT plants, limitations to patent rights could be an effective approach with limited risk of collateral damage.
 - **WHAT:** Clear(er) solutions are possible → “Full breeders exemption” („Humboldt Whitepaper“)
 - **HOW:** Regulation → Direct effect for member states (see CPVR Reg. 2100/94 Art.91)
 - **WHEN:** (i) Now or (ii) if and when patented NGT-varieties obtain a certain market share?
- **Important:** Adapt PBR system to precision breeding (DUS, EDV)

THANK YOU VERY MUCH!



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