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Patent Workshop, 23.5.2025

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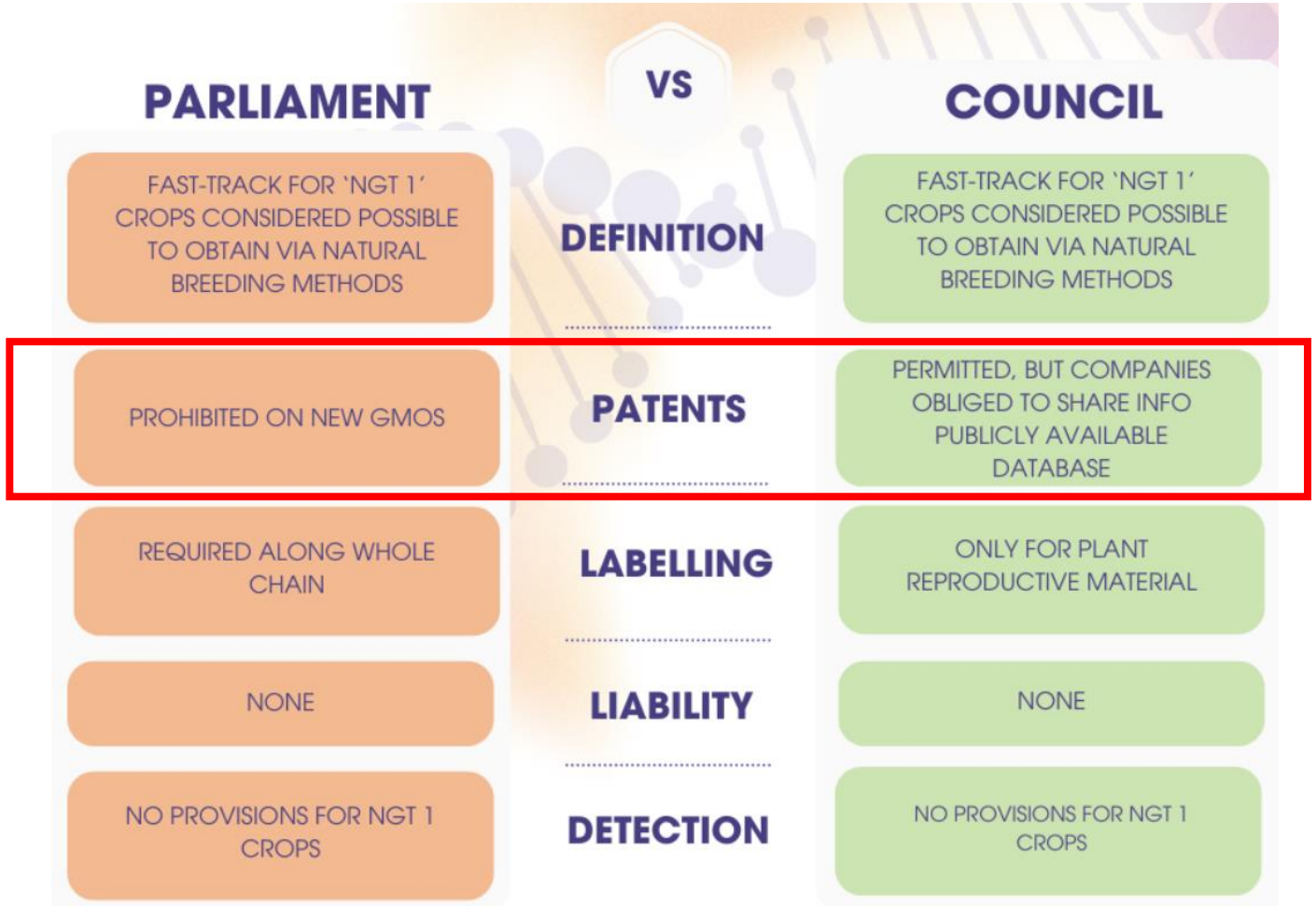
Trilogue Chronology

- **25.07.2018**: CJEU, C-528/16, Dir. 2001/18/EC (targeted mutagenesis, CRISP/Cas is „GMO“)
- **7. 2. 2023**: CJEU, C-688/21, Dir. 2001/18/EC (random mutagenesis is not „GMO“)
- **5.7.2023**: EU COM Proposal (COM/2023/411 final): Fast track verification for NGT1, defined by Annex I as “a plant is considered equivalent to conventional plants when it differs from the parent plant by no more than 20 genetic modifications’. GM is, for example, nucleotide deletion, targeted reversal of a DNA sequence, but also any other targeted modification, regardless of size, provided that the resulting DNA sequences already exist [...] in a species of the breeder's genetic heritage.”
- **7 February 2024**/confirmed 24.4.2024 (10952/24): EP supports simplified registration for plant varieties produced using NGTs that are deemed to be equivalent to conventional types, while retaining stricter controls for others that are not (plants resulting from targeted mutagenesis and cisgenesis), no patents on NGT1
- **7.3.2025:** Council (COREPER, 6426/25) agrees on negotiation mandate.
- **14. 5. 2025:** Trilogue started



<https://www.arc2020.eu/eu-heads-towards-deregulation-of-new-gmo-technologies/>

European Parliament

Texts adopted :

P9_TA(2024)0067

P9_TA(2024)0325

Amendment 167
Proposal for a regulation
Recital 1 a (new)

(1a) *Allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds. In a context where large companies already have a monopoly on seeds and increasingly control natural resources, this would deprive farmers of all freedom of action by making them dependent on private companies. For this reason, patents on these products must be banned.*

Amendment 23
Proposal for a regulation
Recital 45 a (new)

(45a) *The European Parliament has called for grant patents on biological material and to saf breeders' exemption for varieties. It should be the genetic material of NGT plants, which by c to genetic materials can best be secured when in the hand of the breeder (breeder's exemptio not provide for a full breeder's exemption, it s restrict the use of NGT plants by breeders and subject to patent legislation, but should for th be subject to the Community Plant Variety Rig Council Regulation (EC) No 2100/94, which all NGT plants, their derived seeds, their plant ma genes and gene sequences, and plant traits sh patentability. The exclusion from patentability across legislation. Furthermore, in order to av applications being submitted between the dat and the application of its provisions, it should from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications coveri should be further limited. In addition, the Com forthcoming study, how the broader problem c indirectly, on plant material despite previous e further addressed. The assessment should ad patents on breeders' and farmers' access to p and affordable prices, as well as on innovation SMEs. The report of the Commission should b legislative proposals in order to ensure furthe intellectual property rights framework.*

Amendment 33
Proposal for a regulation
Article 4 a (new)

Article 4a

Exclusion from patentability

NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable.

Amendments 69, 291cp1, 230/rev1 and 291cp3
Proposal for a regulation
Article 33 a (new)
Directive 98/44/EC
Article 4, Article 8 and Article 9

Article 33a

Amendments to Directive 98/44/EC[1a]

Council of the European Union

Brussels, 7 March 2025
(OR. en)

6426/25

Interinstitutional File:
2023/0226(COD)

LIMITE

AGRI 67
AGRILEG 25
ENV 96
CODEC 162
PI 32
IA 11

PUBLIC

(14c) The balance between effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand should be maintained. Making patents on category 1 NGT plants available to breeders on ~~fair, reasonable and non-discriminatory terms is likely to~~ equitable conditions and providing information on the applicable licensing conditions, should contribute to the development of new varieties, and to further encourage the development and placing on the market of NGT plants and their products obtained by NGTs. To that end, it should be possible for the patent holder (irrespective of whether it is the requester) to announce their willingness to license their patent under certain terms and conditions, such as those referred to in licensing platforms, among others. This information should be provided by the requester, on a voluntary basis, in the context of category 1 NGT verification procedure.

(15) All NGT plants that are not category 1 NGT plants ('category 2 NGT plants') and their products (hereinafter 'category 2 NGT products') should remain subject to the requirements of the Union GMO legislation because they feature more complex sets of modifications to the genome.

Patent Issues

1. **Linkage** of „fast track market approval“ (NGT-1) and „non-patentability“ (NGT 1+2/Annex I B)

2. **Scope of patent exclusion** (*proposed* Art. 4 **lit. c** Dir 98/44/EC)

a) NGTs

b) Undirected/random mutagenesis

3. **Scope of protection**

proposed Art. 8 **sec. 3** Dir. 98/44 and Art. 9 **sec. 2-4** Dir. 98/44/EC

1. Linkage

1. **EP´s ´tit-for-tat ´deal:**

„fast track market approval“ (NGT-1) for „non-patentability“ (NGT 1+2/Annex I B)

➔ „Justifiable“ under the proportionality test?

Background

– CJEU 2018/2023 „targeted“ (+), „random“ (-) mutagenesis under Dir. 2001/18/EC

– COM **2023** „fast-tracks“ NGT-1 under Dir. 2001/18/EC

– EP **2024** approves „fast-tracks“ NGT-1, but excludes NGT 1+2 (both) and random mutagenesis and cell fusion from patentability

➔ Rationale?

- „Quid-pro-quo“?
- „A maiore ad minus“?

- consequential argument, but legally restricted (Art. 27 sec. 2 TRIPS)…

Article 27 TRIPS
Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, 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. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, **provided that such exclusion is not made merely because the exploitation is prohibited by their law.**

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

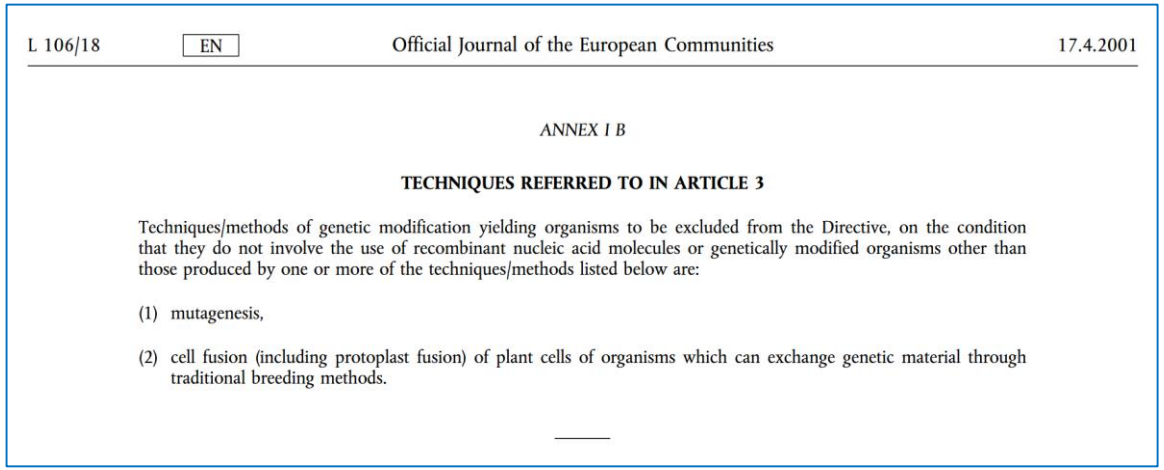
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement

➔ Rationale Art. 27 sec. 2 TRIPS

- Language: patent exclusion cannot be based on regulatory prohibition
- **Here:**

(1) „NGT-1 gets *de-regulated* (**inverse direction**)

(2) Random mutagenesis was never prohibited,
it was excluded from scope: Art. 3 Dir. 2001/18, Annex I B:



L 106/18 EN Official Journal of the European Communities 17.4.2001

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Conclusion (ad 1)

Against a broadly understood rationale of Art. 27 TRIPS („no synchronism“),

- Random mutagenesis was never prohibited + Art. 4 EU Biopatent-directive exempts: Therefore, **clarification** is welcome. Yet, the language of Art. 33 lit d EP-proposal should be revised (no linkage of patent law and Dir. 2001/18).

- As to the exclusion of NGTs, **the legislative reasoning** must be based on a **consistent** public policy reason (e.g. included or added to Art. 4 Dir. 98/44 ➔ Art. 53 lit. b EPC-exemptions). Yet, the reasoning must be clear: The exclusion of „technical“ NGTs can be justified as „remedy to civil procedure problems of proof“ or as „protection of the bio-sector“ e.g.), but not only as „tit-for-tat“ !

2. Scope of patent exclusion

EP position
Jan./April 2024

30.7.98 EN Official Journal of the European Communities L 213/13

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 July 1998
on the legal protection of biotechnological inventions

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.

a) NGT →

b) Random mutagenesis →

'(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation];

(d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.'

b) Random mutagenesis

30.7.98 EN Official Journal of the European Communities L 213/13

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 July 1998
on the legal protection of biotechnological inventions

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.

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.

Article 53 (40), (41) EPC
Exceptions to patentability

European patents shall not be granted in respect of:

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(40) Amended by the Act revising the European Patent Convention of 29.11.2000.

(41) See decisions/opinion of the Enlarged Board of Appeal G 3/95, G 1/98, G 1/03, G 2/03, G 1/04, G 2/06, G 1/07, G 2/07, G 1/08, G 2/08, G 1/16, G 3/19 (Annex I).

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Defined as:

EPC Rule 26
General and definitions
(1)
(2)
(3)
(4)
(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

5.4.2 Essentially biological processes for the production of plants or animals

A process for the production of plants or animals which is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals is considered to be essentially biological and so excluded from patentability. This applies even if the process comprises human intervention, including the provision of technical means, that enables or assists with the performance of the process steps or if other technical steps relating to the preparation of the plant or animal or its further treatment are mentioned in the claim before or after the crossing and selection steps (see G 1/08 and G 2/07). *Rule 26(5)*

To take some examples, a method of crossing, interbreeding or selectively breeding, say, horses that involves merely selecting for breeding and bringing together those animals (or their gametes) with certain characteristics would be essentially biological and therefore excluded from patentability. Selfing of a transgenic plant is also excluded from patentability because, like crossing, it is the mixing of entire genomes. These methods remain essentially biological and thus excluded from patentability even if they contain an additional feature of a technical nature, for example the use of genetic molecular markers to select either parent or progeny. Patent protection is available for any such additional technical steps per se which are performed either before or after the process of crossing and selection. However, such steps are ignored when determining whether or not the process as a whole is excluded from patentability under Art. 53(b) EPC (see G 1/08, G 2/07).

However, if a process of sexual crossing and selection includes an additional step of a technical nature that by itself introduces a trait into the genome of the produced plant or modifies a trait in its genome, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Art. 53(b) but qualifies as a potentially patentable technical teaching (see G 1/08, G 2/07).

Genetic engineering techniques applied to plants which differ profoundly from conventional breeding techniques in that they work primarily through the purposeful insertion and/or modification of one or more genes in a plant are patentable (see T 356/93). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.

EPC-guidelines 2025

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Random mutagenesis is still listed as patentable in EPC-guidelines 2025 !

filing ~~filing date~~ and/or a priority date after 1 July 2017. It does not apply to patents granted before 1 July 2017 or to pending patent applications with a date of filing ~~date~~ and/or a priority date before that date (see G 3/19, OJ EPO 2020, A119).

The exclusion covers plants and animals exclusively obtained by means of an essentially biological process that does not involve any direct technical intervention in the genome of the plants or animals, as the relevant parental plants or animals are merely crossed and the desired offspring is selected for. This is the case even if technical means are provided that enable or assist with the performance of the essentially biological steps. In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.

The term **exclusively** is used here to mean that a plant or animal originating from a technical process or characterised by a technical intervention in the genome is not covered by the exclusion from patentability even if a non-technical method (crossing and selection) is additionally applied in its production.

Determining whether a plant or animal is obtained by exclusively biological means entails examining whether there is a change in a heritable characteristic of the claimed organism which results from a technical process going beyond mere crossing and selection, i.e. one that does not merely enable or assist with the performance of the essentially biological process steps.

Transgenic plants and technically induced mutants are therefore patentable, while the products of conventional breeding are not.

Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical processes. If the offspring of transgenic organisms or mutants also have the transgene or mutation, they are not produced exclusively by an essentially biological method and are thus patentable.

~~For living matter to be patentable, it must also be possible to reproduce it in~~ a way that has exactly the same technical features. For example, reproducibility can be ensured:

(1) by a deposit of the living matter (seeds, microbiological strains). The deposited material must be publicly available and such that the invention can actually be reproduced starting from it. If, for example, a novel and inventive trait is due to a single transgene, a skilled person can reproduce the invention from a living sample. If, instead, the claimed trait is dependent on a large number of structurally undefined loci in the genome, these will segregate in subsequent generations and it will be an undue burden to reproduce the invention from the deposited sample (T 1957/14).

(2) by disclosing in the application as filed the gene sequence responsible for the claimed trait together with instructions on how to

reproducibly introduce by technical means such an altered sequence in a target organism (e.g. by CRISPR-Cas).

If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of either a technical intervention (e.g. directed mutagenesis) or an essentially biological process (a natural allele), a disclaimer is necessary to limit the claimed subject-matter to the technically produced product in order to comply with the requirements of Art. 53(b) and Rule 28(2). Otherwise the subject-matter is directed to excluded subject-matter and is to be refused on the basis of Art. 53(b) in conjunction with Rule 28(2). A disclaimer is required in all cases and, in particular, even if the description only mentions a technical method of production and is silent on the use of an essentially biological process. If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a transgene, no disclaimer is needed.

This should apply also if such a disclaimer relates to subject-matter that was not disclosed in the application as filed. In such a case the disclaimer fulfils the requirements laid down in G 1/03, G 2/03 and G 1/16 because it is introduced to exclude subject-matter not eligible for patent protection (for the general principles governing disclaimers, see also H-V, 4).

Such a disclaimer is needed only for patent applications with a date of filing ~~date~~ and/or a priority date after 1 July 2017. A disclaimer is not required for patents granted before 1 July 2017 or for pending patent applications with a ~~filing~~ date of filing and/or a priority date before that date (see G 3/19, OJ EPO 2020, A119).

The technical character of a claimed plant or animal product may lie in a non-heritable physical feature imparted directly to the claimed organism, e.g. a seed coated with a beneficial chemical.

The technical method of producing the plant or animal may be included in the claims, in the form of product-by-process claims (see F-IV, 4.12).

Plant products that are not propagation material, such as flour, sugars or fatty acids, have to be considered on the basis of their chemical properties only. As long as the general patentability requirements are fulfilled, it will therefore be irrelevant whether the subject-matter (e.g. a sugar molecule) is isolated from a product (e.g. a living plant) of an essentially biological process or is produced in a laboratory.

Examples are provided in G-II, 5.4.2.1 below.

This exclusion of plants and animals exclusively obtained by means of an essentially biological process does not apply to patents granted before 1 July 2017 or to pending patent applications with a date of filing ~~date~~ and/or a priority date before that date (see G 3/19, OJ EPO 2020, A119).

For these applications and granted patents, the exclusion from patentability of essentially biological processes for the production of plants does not adversely affect the allowability of a product claim directed to plants or plant

Conclusion (ad 2)

The **EU legislator** shall **insist** on and **(clarify)** the patent exclusion of **random mutagenesis,** since it is already caught by the patent exclusion of Art. 4 Dir. 98/44, Art. 53 lit. b EPC.

➔ as stipulated in § 2 sec. 2 sentence 3 Austrian Patent Act,
➔ EU Commission shall commit to push for adapting the EPO-guidelines to EU law.

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3. Scope of protection

– *proposed* Art. 8 **sec. 3** Dir. 98/44 and Art. 9 **sec. 2-4** Dir. 98/44/EC

2. In Article 8, the following paragraph is added:

'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.'

3. In Article 9, the following paragraphs are added:

'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

contained and performs its function but which is not distinguishable from plant

Full support!
(the result is the reversal of proof)
(judicial argumentation is published 2021)

As „minus“ to the EP-proposal

Pdp-claim or only method-claim?

EPC-guidelines 2025

4.12 Product-by-process claim

Art. 53(b)
Rule 28(2)
Art. 64(2)

A claim defining a product in terms of a process is to be construed as a claim to the product as such. The technical content of the invention lies not in the process *per se*, but rather in the technical properties imparted to the product by the process. Claims defining plants or animals produced by a method including a technical step which imparts a technical feature to a product constitute an exception in so far as the requirements of Art. 53(b) as interpreted by Rule 28(2) are concerned. The exclusion under Rule 28(2) regarding plants and animals exclusively obtained by means of an essentially biological process does not apply to patents granted before 1 July 2017, nor to pending patent applications with a ~~filing date~~ date of filing and/or a priority date before 1 July 2017 (see G 3/19, OJ EPO 2020, A119).

…al feature of a claimed plant or animal, e.g. a single nucleotide …n the genome, can be the result of both a technical intervention …d mutagenesis) and an essentially biological process (a natural …claimer is necessary to delimit the claimed subject-matter to the …oduced product (see examples in G-II, 5.4.2.1 and G-II, 5.4). …other hand, the feature in question can unambiguously be … technical intervention only, e.g. a transgene, no disclaimer is …For the general principles governing disclaimers see H-V, 4.1 …2.

…ss through which the claimed plant or animal is defined does not …tifiable and unambiguous technical features to the plant or … the genetic information present in the genome, the claim …a plant or animal lacks clarity.

Clarify that NGT-process claims are „working method claims“ only,
Axel Metzger, NGT-Expert opinion, 5. Dec. 2024, p. 51
<https://www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere_Dokumente/Rechtsgutachten_Biopatentrechtsreform_Gruene_Bundestag.pdf>

Council of the European Union

Brussels, 7 March 2025
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(14c) The balance between effective protection of invention and stimulation of research and development on the one hand and wide access to varieties serving the development of new varieties on the other hand should be maintained. Making patents on category 1 NGT plants available to breeders on ~~fair, reasonable and non-discriminatory terms is likely to~~ equitable conditions and providing information on the applicable licensing conditions, should contribute to the development of new varieties, and to further encourage the development and placing on the market of NGT plants and their products obtained by NGTs. To that end, it should be possible for the patent holder (irrespective of whether it is the requester) to announce their willingness to license their patent under certain terms and conditions, such as those referred to in licensing platforms, among others. This information should be provided by the requester, on a volu…

(15) All NGT … products … of the Un… the genom…

Upgrade „transparency and access“ (only) by „statutory use right“

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ANNEX LIFE.3 **LIMITE** **EN**

Conclusion (ad 3)

– A reduction of protective scope makes sense as identified by individual experts (Metzger 2024; Kim et al 2023; Godt 2021/2025 *forthcoming*) and expert groups (ALLEA 2024), based on various reasons (including civil procedure).