EU PARLIAMENT ON PATENTS FOR NGT-DERIVED PLANTS: PAWN SACRIFICE OR SACRIFICED TO THE PAWNS?

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1. Introduction

On 7 February 2024, the European Parliament adopted several amendments ('Parliament Amendments')[1] to the EU Commission's 'Proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed' ('the NGT Regulation').[2] On the one hand, the Parliament's decision is a first step in the direction of treating plants obtained by new genomic techniques ('NGT') essentially like conventional plants. On the other hand, the proposed amendments – if implemented – would fundamentally change the patentability and patent rights related to plants in the EU. Farmers' associations, national breeders' associations, and NGOs appear to be the primary drivers behind these changes. Their concerns are not without merit (discussed in section 3 below). Also, from a public perception perspective the position is understandable. While patentability and regulatory are separate legal areas in the minds of many they are interconnected. Plants which are 'conventional' from a regulatory perspective should be 'conventional' (that is, non-patentable) from a patent perspective. Plants which are 'technical' from a patent perspective should be considered genetically modified and regulated. In consequence, abandoning patents on NGT-derived plants can be considered a 'pawn sacrifice' or necessary evil to gain the necessary stakeholder support for the NGT regulation.

2. The Proposed Amendments

2.1 NGT Regulation: New Article 4a

Amendment 33 proposes a new Article 4a for the NGT Regulation which provides that 'NGT plants, plant material, parts thereof, genetic information and the process features they contain shall not be patentable'.

Besides a lack of clarity how the proposed exception from patentability should be implemented, its language ('process features') deviates from the common terminology in patent legislation. It must be assumed that the specific scope and implementation for the new Article 4a is expressed in the proposed new Article 33a. Therefore, Article 4a can be seen as a recital-like expression of a legislative intent.

2.2 NGT Regulation: New Article 33a

Amendments 69, 291cp1, 230/rev1 and 291cp3 propose a new Article 33a, which prescribes amendment of Articles 4, 8, and 9 of Directive 98/44/EC.[3] The proposed revised Articles look as follows (amended sections underlined).

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1) Amendments adopted by the European Parliament on 7 February 2024 on the proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))(1). ('Parliament Amendments'). Texts adopted 7 February 2024, Strasbourg. Doc. P9_TA(2024)0067. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.html.

2) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625. COM/2023/411 final. Document 52023PC0411. ('NGT Regulation') Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0411.

3) Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0044&from=EN.

Directive 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 Directive 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 revised Article 4 excludes '*plants, plant material, parts thereof, genetic information and process features they contain*' from patentability, if they are either created by an NGT (as defined in the NGT Regulation), or by '*techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B*'.[4] In consequence, not only NGT-derived plants are excepted from patentability but also random mutants,[5] and protoplast fusions.[6] In that the amendment goes beyond NGTs. It would change the current EPO practice set by the 2016 Commission Notice[7] and Rule 28(2) EPC,[8] which excepts from patentability plants obtained exclusively by essentially biological processes but sustains the patentability of plants resulting from mutagenesis and other technical processes. Remarkably, plants obtained by essentially biological processes are not specifically excepted, although this could have been managed by a simple addition to the current paragraph (b). While a decision of the CJEU is still outstanding on that matter, the parliamentarians likely saw this issue as settled by the Commission Notice and Rule 28(2) EPC. Also, plants with 'process features' are here excepted from patentability (see further, section 3.3 below).

Directive 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.

4) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018.

5) The term 'mutagenesis' in Dir. 2001/18/EC been construed by the CJEU (CIT) to mean random mutagenesis. Case C–528/16, Judgment of the Court (Grand Chamber) of 25 July 2018, *Confédération paysanne et al. v Premier ministre, Ministre de l' Agriculture, de l' Agroalimentaire et de la Forêt*. Available at : http://curia.europa.eu/juris/documents.jsf?num=c-528/16.

6) Meaning cell and protoplast fusions of plant cells of organisms which can exchange genetic material through traditional breeding methods

7) Commission Notice of 3 November 2016 on certain Articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJ 2016/C 411/03 – 14). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003.

8) Rule 28(2) EPC: '(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process'.

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.

In contrast to the amendment to Article 4, the amendments to Article 8 do not affect patentability but the rights resulting from a patent. They establish a full breeder's exemption for breeders which breed a new variety by using an essentially biological process without using the patented biological material. Remarkably, the proposed wording does not require the plants to be created 'exclusively' by an essentially biological process, as required by Rule 28(2) EPC and a similar provision in French Intellectual Property Code (see further, section 3.4 below).

Directive 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.

Plant-related innovations are always based on genetic information as every phenotype (that is, trait or characteristic) is based on a genotype. This applies to NGT-derived plants, which are based on modified (edited) DNA sequences, and also to plants obtained by mutation breeding, or resulting from essentially biological processes. In consequence, the limitations to Article 9 of Directive 98/44/EC are quite fundamental.

Paragraph 2 limits the protection of plants obtained by technical processes, noting that plants obtained by non-technical, that is essentially biological, means are excluded from patentability following the EPO's Enlarged Board of Appeal (EBA) decisions in G2/07–G1/8 (*Broccoli/Tomato I*)[9] and G 3/19 (*Pepper*).[10] However, the wording of paragraph 2 appears to be technically incorrect: it creates a derogation from patent rights (protection) but refers to patentability.

Paragraph 3 limits the protection conferred by claims on sequences on plants in which they are incorporated. Remarkably, in contrast to paragraphs 2 and 4, paragraph 3 does not refer to a technical process. It relates to '*a product containing or consisting of genetic information*' which would include all plants including plants with 'native traits' obtained by essentially biological processes. Paragraph 4 limits the protection conferred by method claims on resulting plants, which is provided not by Article 9 but by Article 8(2) of Directive 98/44.

9) Enlarged Board of Appeal (EBA), Decision G 2/07 – G 1/08 *Broccoli & Tomato I* (9 December 2010), OJ EPO 2012, 130, 206. Available at https://www.epo.org/law-practice/case-law-appeals/recent/g070002ex1.html.

10) Enlarged Board of Appeal (EBA), Decision G 3/19 *Pepper* (14 May 2020), OJ EPO 2019, A34. Available at http://documents.epo.org/projects/babylon/eponet.nsf/0/44CCAF7944B9BF42C125856800315O5A/$File/G_3-19_opinion_EBoA_20200514_en.pdf.

Remarkably, the scope of paragraph 2 and the other paragraphs 3 and 4 differs. While paragraph 2 refers to plants which 'are not distinguishable from plant products […] *obtained* by an essentially biological process', paragraphs 3 and 4 refer to plants which are 'not distinguishable from plant material *obtained* or which *can be obtained* by an essentially biological process' (*emphasis added*). No paragraphs require the plants to be created 'exclusively' by an essentially biological process as required by Rule 28(2) EPC. (For further discussion see 3.4 below.)

3. Discussion

3.1 The Legislative Intent

Currently, plants obtained by NGTs are patentable under the European Patent Convention (EPC) if they are novel and inventive, as they are not considered to be made exclusively by an essentially biological process.[11] While NGT-derived modifications of Category 1 can – in principle – exist in nature or occur during conventional breeding processes, the specific genetic change, for which an applicant will seek patent protection, will be unlikely to exist already as such in the breeding pool.[12]

If NGT-derived plants of Category I are treated essentially like conventional varieties, as foreseen in the current proposal for a NGT Regulation, rapid adaptation in the EU is likely. If NGT-derived plants remain patentable, the current low percentage of patented varieties in the EU – less than 3 per cent[13] – will rise quickly. It is well possible that within two decades most new plant varieties, at least in the major field crops, will be covered by patents. Also, patent complexity will increase: as new varieties always build on existing varieties, the number of patented characteristics in a single variety will increase.[14] This will make segregation of the patented elements practically impossible and may discourage the use of NGT-derived varieties for further breeding.[15] While at present breeders in the EU can use most commercialised varieties for breeding and commercialising new varieties without a licence, in future they would need multiple licences for commercialisation. Once NGT-varieties obtain a substantial market share (>50 per cent), access and exchange of plant biodiversity could practically cease, and breeders would only breed within their own collections. This would substantially narrow the genetic diversity available to breeders, affect breeding progress, and lead to industry consolidation. Eventually, the EU could face a similar situation to that in the United States, where two companies – Corteva and Bayer/Monsanto – control over 70 per cent of the corn seed market[16] and 85 per cent of corn-related intellectual property.[17] Together with BASF and ChemChina's Syngenta Group, these oligopolists own 95 per cent of corn-related IP, 97 per cent of canola-related IP, and 84 per cent of soybean-related IP.[18] The USDA traces this concentration to 'the expansion of intellectual property rights' in 'genetically modified (GM) varieties of seed'.[19] As 'biochemistry advanced', the industry became 'highly integrated'.[20]

While transparency measures (for example, the PINTO database[21]) and licensing platforms (for example, the ILP for

11) Rule 28(2) EPC excludes such plants from patentability. Rule 28(2) EPC: 'Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.'

12) Patentees will design their genome editing and patenting strategy to avoid any (known) novelty challenges. In consequence, most NGT-derived changes can and will be patented and there will be no ambiguity whether a certain variety infringes on a patent or not, if it comprises the specific genetic change claimed in the patent it will infringe the patent.

13) The PINTO (Patent Information and Transparency On-line) database of Euroseeds (http://pinto.euroseeds.eu/About/Home) in June 2023 listed 1274 varieties, which are associated with patents. This is a small fraction of about 47,000 varieties listed in the EU catalogues and currently marketed.

14) As new varieties are always based on existing varieties, the number of patented characteristics will increase in each breeding cycle. With a breeding cycle of about five years, as expected for NGTs, varieties can comprise four or more patented characteristics and be covered by dozens of patents.

15) MA Kock, 'Open intellectual property models for plant innovations in the context of new breeding technologies' (2021) 11(6) *Agronomy* 1218: https://doi.org/10.3390/agronomy11061218.

16) USDA Economic Research Service, *Two companies accounted for more than half of corn, soybean, and cotton seed sales in 2018–20*: https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=107516.

17) USDA Agricultural Marketing Service, 'More and better choices for farmers' (March 2023) at 53: https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf, at 77.

18) Ibid., at 42.

19) USDA, Note 17 above.

20) Ibid.

21) PINTO (Patent Information and Transparency On-line) database of the European Seed Association: https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/.

vegetables[22] and the ACLP[23] for field crops) may mitigate impact to some extent, these measures are not without problems[24] and will likely fail once the market share of NGT-derived varieties is higher than 50 per cent. Certain adjustments within the current legal framework may also reduce the impact on breeders. Suitable options are discussed by Kim *et al.*[25] and ALLEA, the European Federation of Academies of Sciences and Humanities.[26] Those options include clarifications to the scope of derived protection for process claims under Article 8(2) of Directive 98/44/EC, the requirements for a compulsory cross-licence under Article 12(1) of Directive 98/44/EC, and the limited breeder's exemption in the patent laws of several EU countries. Kim *et al.* summarise that such measures – while suitable ad interim – may not be sufficient once NGT-derived plants represent a major part of the commercial seed market and a more fundamental redesign of the IP systems for plants may become necessary.[27] ALLEA, however, sees an amendment of Directive 98/44/EC as an unlikely option.[28]

The concerns described above are expressed in the new Recital 1a[29] and Recital 45a[30] added by the EU Parliament. Recital 1a specifically mentions that 'allowing for new genomic techniques and their results to be patented risks giving multinational seed companies even more power over farmers' access to seeds' and 'deprive farmers of all freedom of action by making them dependent on private companies'. ALLEA summarises that:

> *the patentability of NGTs and their products raises several concerns among breeders and farmers, including (1) possible accidental infringement of patents, (2) monopolisation of technologies and traits, and (3) increased difficulties and costs of obtaining licences for use of these techniques and plant varieties.*[31]

National seed associations such as the German Breeders Association,[32] farmer's associations like copa-cogeca,[33] and NGOs advocate against patentability of NGT-derived plants. While largely subscribing to the benefits of NGTs, they see the above-mentioned patent complexity as a major threat. This author has heard several breeding companies clearly expressing that they would prefer not to open the EU to NGT-derived plants at all rather than allow for patented NGT-derived plants. In consequence, the proposed limitations to patents on NGT-derived plants can be seen as a 'pawn sacrifice' or maybe rather a sacrifice to the pawns, that is, to appease the concerns of farmers.

22) The International Licensing Platform – Vegetables (ILP; http://www.ILP-vegetable.org), launched in 2014, enables access to patented plant traits 'at fair and reasonable costs' determined by an independent expert committee based on baseball arbitration. The platform provides a global solution, including mutual non-assert, for breeding with patent-protected US varieties. It also includes patents for NGT-derived traits in countries where these traits are not considered GM. Reviewed in MA Kock and F ten Have, 'The "International Licensing Platform – Vegetables": a prototype of a patent clearing house in the life-science industry', (2016) 11(7) *Journal of Intellectual Property Law and Practice*. Available at: https://ilp-vegetable.org/uploads/Bestanden/News/Article%20ILP%20Journal%20of%20Intellectual%20Property%20Law%20&%20Practice%202016.pdf.

23) In Europe, the Agricultural Crop Licensing Platform (ACLP) was developed and launched in 2023 under the auspices of the European Seed Association: https://aclp.eu/.

24) The PINTO database lists several plant varieties with native traits in relation to patents filed after the effective date for Rule 28(2) EPC, which by law should not cover the respective variety. While legal disclaimers should mitigate the risk of a wrongful representation of patent coverage (*Patentberühmung*), such listing alone may have a deterring effect on third-party breeders. While some elements of the ACLP are similar to ILP, there are also differences which substantially limit the utility for breeders, including the scope of the licensed subject matter, the territorial coverage, and the types of licensing agreements.

25) D Kim *et al.* (2023) *New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector*, Max Planck Institute for Innovation & Competition Research Paper 23-16. Available at http://dx.doi.org/10.2139/ssrn.4537299.

26) ALLEA Statement on 'Measures to ease the impact of the IP system on new genomic techniques for crop development': https://allea.org/portfolio-item/allea-statement-on-measures-to-ease-the-impact-of-the-ip-system-on-new-genomic-techniques-for-crop-development/.

27) A Metzger and H Zech, 'Comprehensive approach to plant variety rights and patents in the field of innovative plant' in C Godt and M Lamping (eds), *A Critical Mind – In Honour of Hanns Ullrich* (Springer 2023) 619; MA Rapela, *Fostering Innovation for Agriculture 4.0. A Comprehensive Plant Germplasm System* (Springer 2019); MA Kock, *Intellectual Property Protection for Plant Related Innovation. Fit for Future?* (Springer 2022).

28) ALLEA Statement, Note 26 above, at page 9.

29) Parliament Amendments, Note 1 above, Amendment 167 Proposal for a regulation Recital 1a (new).

30) Parliament Amendments, Note 1 above, Amendment 23 Proposal for a regulation Recital 45a (new).

31) ALLEA Statement, Note 26 above.

32) BDP-Position: Position zur Ausgestaltung des Patentschutzes in der Pflanzenzüchtung. Bonn, 17 January 2023. https://www.bdp-online.de/de/Ueber_uns/Our_positions/BDP_Position_Ausgestaltung_des_Patentschutzes_in_der_PZ.pdf.

33) copa-cogeca. Position Paper on the Commission's proposal on plants obtained by certain new genomic techniques (NGTs) and their food and feed, and amending Regulation (EU) 2017/625, 16 October 2023: https://copa-cogeca.eu/Flexpage/DownloadFile/?id=13462320.

3.2 Limiting Patents on Plants: General Considerations

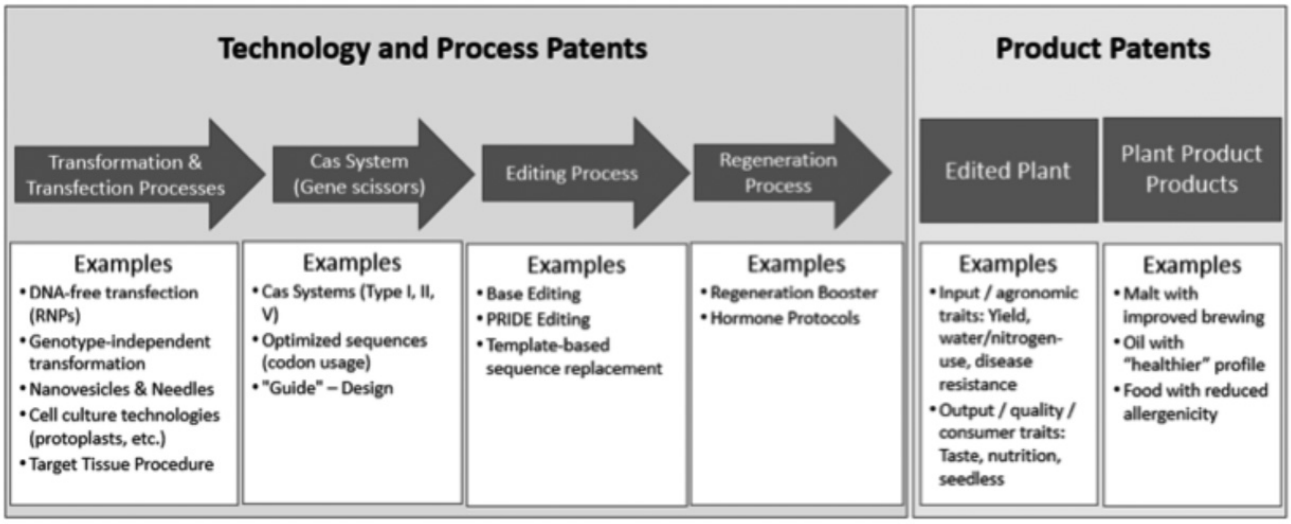
Limiting the effect of patents on NGT-derived plants in compliance with international legal frameworks and without negative side-effects on other innovations sectors is not a trivial task. The international framework for plant related innovation is provided by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs).[34] The TRIPs Agreement in Article 27(3)(b) provides flexibility to members when it comes to plant related innovations:

> *Members may also exclude from patentability: (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.*

In other words, members do not have to provide patent protection for plants as long they provide effective protection by plant breeders rights (PBR), that is, a sui generis system. While most countries implemented Article 27(3)(b) TRIPs by exceptions from patentability, implementation by an exemption from the rights resulting from the patent is not precluded. To the contrary: the original purpose of Article 27(3)(b) TRIPs was to enable countries to continue with the double protection requirement under the UPV 1978 Act. In consequence, Article 27(3)(b) TRIPs must be construed broadly, that is, from the perspective of its purpose to prevent double-protection or – in other words – to enable a sui generis system to be the *sole IP system* for the protection of plants. This can be implemented by exceptions from patentability or by exemptions from the rights resulting from a patent.

The complexity of the task is increased by the fact that NGT-derived plant varieties can be covered by multiple types of patents. Two major categories are relevant: first, technology and process patents which are often of a general nature and not plant-specific. Those patents are relevant for the making of the NGT-derived plants but their components (for example, a Cas enzyme) are usually no longer part of the final plant variety. Second, product patents which cover the resulting plant or a modified plant genetic sequence. Those patents are not usually limited to a specific NGT-technology (see Figure 1).

Figure 1. Categories of patents relevant for NGT-derived plants



34) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs): https://www.wto.org/english/docs_e/legal_e/27-trips.doc. 'WTO – intellectual property – overview of TRIPs Agreement': https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

An NGT-derived plant can be protected, directly or indirectly, by different types of patent claims, including but not limited to:

(i) Claims on plants or plant parts characterised by a characteristic conferred by a modified DNA sequence.

(ii) Claims on modified DNA sequences, which extend to plants where the sequence is contained and performs its function.[35]

(iii) Claim on methods of producing the plant with a specific characteristic which may extend to plants obtained by propagation or multiplication as long they comprise the characteristic.[36]

(iv) Claims on plant-derived materials with new properties (for example, barley with improved malting properties). Such claims may effectively preclude cultivation of the related plant.

An effective limitation of patent protection for NGT-derived plants needs to be comprehensive without causing collateral damage or legal ambiguity for other innovation areas. This is a challenge, as many patents on NGTs have applicability beyond plants, for example for therapeutic purposes, animals, or microbial engineering.

3.3 Exceptions from Patentability: Amendment to Article 4 Directive 98/44

Exceptions from patentability are implemented at the 'front end' of the patent life during the examination process. They ensure that patent claims do not cover the subject matter intended to be excluded. As plants could be covered directly, by claims on modified DNA sequences or plants, or indirectly, by claims on processes, designing effective exceptions is challenging.

Currently, the European Patent Convention (EPC) under Article 53 (b) EPC excepts 'plant or animal varieties or essentially biological processes for the production of plants or animals'. The scope of this exception has been interpreted in decisions G1/98 (*Transgenic Plant/Novartis II*)[37], G2/07–G1/8 (*Broccoli/Tomato I*)[38], G2/12–G2/13 (*Broccoli/Tomato II*),[39] and G3/19 (*Pepper*).[40] G2/07 clarifies if a process contains 'an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced … then the process is not excluded from patentability'. The current EPO guidelines define both random and targeted mutagenesis as technical and resulting plants as patentable as long as general requirements of patentability are fulfilled.[41]

The revised Article 4 of Directive 98/44 would exclude 'plants, plant material, parts thereof, genetic information and process features they contain' if they are covered by the NGT Regulation or by Annex IB of Directive 2001/18/EC. This formulation likely intents to prevent a circumvention of a plant-specific exception by claims on DNA sequences or method, which could indirectly cover a plant. Not addressed are plant-derived materials such as malt or oil with improved properties (see section 3.4). While at a first glance largely meeting the legislative intent, the proposed exception will face several challenges.

35) Dir. 98/44, Article 9, Note 3 above.

36) Ibid., Article 8(2). This also applies for characteristics which, as such, are not new.

37) EPO – Enlarged Board of Appeal (2000) Decision G 1/98 *Transgenic plant/NOVARTIS II*. OJ EPO 3/2000, 111. Available at https://www.epo.org/law-practice/case-law-appeals/recent/g980001ep1.html.

38) Decision G2/07–G1/08 *Broccoli & Tomato I*, Note 9 above.

39) EPO – Enlarged Board of Appeal (2015) Decision G 2/12 – G 2/13 *Broccoli & Tomato II* of 25 March 2015. OJ EPO 2016, 22. Available at https://www.epo.org/law-practice/case-law-appeals/recent/g120002ex1.html.

40) Decision G 3/19 *Pepper*, Note 10 above.

41) It is debatable whether random mutagenesis qualifies as 'technical' due to the inherent lack of reproducibility. Austria in its recent change of patent law defined random mutagenesis as an essentially biological process: Austrian Patent Law 1970, Version of 10 June 2023. BGBl. Nr. 259/1970 (WV) idF BGBl. Nr. 137/1971 (DFB). §2(2) 3. A process for the production of plants or animals is essentially biological if it is based entirely on natural phenomena such as crossbreeding, selection, non-targeted mutagenesis, or random genetic modifications occurring in nature. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002181.

(1) Implementation difficulty I (examination level). An exception from patentability can either be implemented by denying certain categories of claims in their entirety or in the form of a disclaimer. As in the present case multiple claim categories are affected, a disclaimer must not only be added to a specific claim but to the entire set of claims.[42] Apparently, such disclaimer would be a waiver of rights and largely inconsistent with the purpose of patent examination (see (5)). In addition, such disclaimer would raise questions in enforcement (see (6)).

(2) Implementation difficulty II (EPC level). In consequence of the amendment, plants obtained by targeted and random mutagenesis or protoplast fusion would be excepted from patentability. This is a fundamental change to the current EPO practice and would contradict G2/07 (*Broccoli I*), G3/19 (*Pepper*), and Rule 28(2) EPC. It is unlikely to be implemented by a simple change of the EPO's Implementing Regulations or another decision of the EBA. A revision of the European Patent Convention (EPC) by a diplomatic conference would be necessary, which is an onerous and lengthy endeavour. It requires unanimous consensus of the 39 EPC Member States, including several non-EU Member States. For some, limiting patents might be a red line which makes the required unanimity highly unlikely. A change only in the national patent laws of EU Member States would not be effective, as most plant-related patents in the EU are filed and granted through the EPO.

(3) Lack of retroactivity. For the fundamental reason of legal certainty, exceptions from patentability can only impact patents filed after the entry into force of the respective legal change.[43] This substantially limits their usefulness for NGT-derived plants as many relevant NGT patents have already been filed and would not be affected. In contrast, exemptions from patent rights affect every granted patent and pending application (see section 3.4 below).

(4) Potential spill-over effects. Even if there is reason to limit the effects of patents on NGT-derived plants there is no legitimate reason to limit patentability of NGT-related technologies as such. For process claims especially, it will be challenging to limit only the derived (indirect) protection without affecting the direct protection of the process. Further, many patented NGTs are multi-purpose and can be used in plants, human therapies, animals, microorganisms and so on. Patent offices would have to make a careful assessment where claim limitations or disclaimers are demanded. As examiners can hardly foresee whether an invention could have utility in the plant field, a vast majority of patents in the life science field would likely become affected. This increases the risk of collateral damages and spill-over effects.

(5) Legal ambiguity I. The term 'process features' contained in a NGT plant is unusual. It probably means the 'specific characteristics' as a result of process invention under Article 8(2) of Directive 98/44/EC. If so, it mixes patentability with scope of rights: the extension of process claims to products is a consequence of the rights resulting from the patent. A corresponding limitation should usually be addressed on the level of rights and not on the level of patentability.

(6) Legal ambiguity II (enforcement level). An NGT disclaimer will include a reference to a NGT process. This, from a legal perspective, converts the claim into a product-by-process claim. Under current EU case law, product-by-process claims are 'absolute' and not limited by the process steps. This could render the disclaimer useless.[44]

(7) Legal ambiguity III (scope defined by reference). The scope of the proposed exception is defined by reference to the NGT Regulation and Regulation 2001/18. However, the technical definitions in these regulations are subject to change. In the NGT Regulation in particular, the threshold for

42) This is currently the practice in Argentina. By Resolution No 283/2015 the Argentinean patent office implement a moratorium for patents which directly or indirectly cover plants and plant material. Method claims are only granted if narrowed by a disclaimer which waives extension to plant material: https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-283-2015-252851/texto.

43) G 3/19, Note 10 above, at page 66. To 'ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants', the EBA decided that the opinion and thereby the effect of Rule 28 (2) EPC has no retroactive effect on European patents granted before the Rule came into effect (1 July 2017) or on applications filed, or claiming a priority, before that date.

44) One could argue that the disclaimer is a 'waiver of rights' or estoppel which overrules the usual interpretation of product-by-process claims.

change is rather low: the Commission is empowered to adopt delegated acts amending the criteria of Category I NGT plants in Annex I.[45] As change is very possible, the scope of the exception would become a moving target, which creates legal uncertainty for innovators and patent offices.

In summary, the proposed exception from patentability will not only be difficult (or impossible) to implement, it will also not achieve the legislative objective, at least not for 20 years until current patents expire.

3.4 Exemptions from Patent Rights

Limiting the effect of patents on NGT-derived plants can also be achieved by a limitation to the scope of rights resulting from a patent, that is, an exemption from the patent right: irrespective of whether a claim refers to a plant, a modified DNA, or a process, the exempted plant is not covered by the rights and effects of the patent. Plant-related exemptions do already exist like, for example, the limited breeder's exemption. The Agreement on a Unified Patent Court (UPCA)[46] provides: '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'. Similar provisions exist in several EU Member States, Switzerland, and the UK.[47] France provides an additional exemption for independently developed plant varieties,[48] and some EU countries exempt materials where the alleged infringement is accidental and unavoidable.[49]

Exemptions become effective from the date they enter into force and affect all existing patents and pending applications. This is especially relevant for the new Article 9(3) which also covers plants with 'native traits'. The new paragraph 3 may achieve what Rule 28(2) EPC was unable to achieve: retroactivity, that is, affecting patents on native traits filed before the entry into force of Rule 28(2) EPC (1 July 2027). Exemptions do not require a change to the EPC but can be implemented in the national patent laws of EU Member States and the UPCA.

While the proposed exemptions are more effective and easier to implement than the suggested exceptions, there is room for improvement.

Directive 98/44 New Article 8(3)

(i) Ambiguity I: 'Obtained independently of the patented biological material'. While copied from the corresponding French legislation the wording remains unclear. It is formally quite broad and could mean '*without material covered by the patent*'. However, this would make the exemption an empty shell as material which is not covered would anyway not infringe. It likely means '*without material created by the patentee or its licensees*' or maybe '*without material created using the teaching of the patent, that is, the specific process disclosed in the patent*'. Clearer language would be desirable.

(ii) Ambiguity II: 'Obtained by an essentially process'. The amendment approved by the Parliament exempts products independently created by essentially biological processes. It does not include the limitation 'exclusively' as foreseen in Rule 28(2) EPC or the corresponding exemption in the French Intellectual Property Code.[50] The difference is significant. The EPO Examination Guidelines explain:

> *The term exclusively is used here to mean that a plant or animal originating from a technical process or*

45) Parliament Amendments, Note 1 above, Amendment 35. Article 5 – paragraph 3: The Commission is empowered to adopt delegated acts in accordance with Article 26 amending the criteria of equivalence of NGT plants to conventional plants laid down in Annex I, taking into account potential associated risks and functional consequences in the verification procedure in order to adapt those criteria to the latest scientific and technological developments as regards the types and extent of modifications which can occur naturally or through conventional breeding.

46) Agreement on a Unified Patent Court (2013/C 175/01), Article 27(b): https://www.unified-patent-court.org/sites/default/files/upc_documents/agreement-on-a-unified-patent-court.pdf.

47) German Patent Act §11 No 2a, French Intellectual Property Code Art L 613-5-3, Dutch Patent Act Article 53b(2).

48) Article L613-2-3, Article 10 para 3. At https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000033033605/.

49) German Patent Act §9c(3) (3); Swiss Patents Act Article 9 (1f); Austrian Patent Act Article 22c(4).

50) See Note 48 above.

> *characterised by a technical intervention in the genome is not covered by the exclusion from patentability even if in addition a non-technical method (crossing and selection) is applied in its production.*[51]

If the term 'exclusively' is not included, a technical process could be initially used as long as the final step in creating the final variety is essentially biological. This could enable using an alternative technical process to establish the patented characteristic and introgressing it into the target variety by sexual crossing. As this is unlikely to be intended, adding the term 'exclusively' would be desirable.

Directive 98/44 New Article 9 (2), (3) and (4)

(i) Ambiguity I: 'obtained' vs 'can be obtained'. The difference in scope between paragraph 2 and paragraphs 3 and 4 is substantial. While paragraph 2 refers to plants 'obtained by an essentially biological process', paragraphs 3 and 4 refer to plants 'obtained *or which can be obtained* by an essentially biological process' (*emphasis added*).

The definition in paragraphs 3 and 4 is quite comprehensive and likely covers all NGT-derived plants (at least of Category I) based on the assumption of the NGT Regulation that such plants 'are indistinguishable with analytical methods from natural mutations or from genetic modifications introduced by conventional breeding techniques'.[52] In contrast, paragraph 2 appears to require a clear evidence that the plant obtained by an essentially biological process already exists at the filing date of the patent on the NGT-derived plant.[53] A hypothetical probability that such plant 'can be obtained' is obviously not included. It must be assumed, that this omission is unintentional and an addition of '*can* be obtained' would be meaningful.

The formulation 'can be obtained' will likely be the basis for endless debates during patent examination.[54]

(ii) Ambiguity II: mixing 'rights' and 'patentability'. The new paragraph 9(2) creates a derogation from the patent rights conferred by paragraph 1. On the other hand it provides that certain subject matter 'shall not be patentable'. This mixes patent rights and patentability.

(iii) Ambiguity III. It is also arguable whether the proposed wording is comprehensive and exempts plant-derived materials like meal, or oil and method of use claims. Non-viable plant-derived materials are still deemed patentable under current EPO practice, irrespective of whether the related plants were made by an essentially biological or technical process, provided that they are novel and inventive as such (for example, oil with a new fatty acid profile).[55]

In view of the above challenges and ambiguities, a simpler, more comprehensive, and technically more 'precise' wording could be considered:

> *Article 10bis: By way of derogation from Articles 8 and 9, the rights conferred by a patent shall not extend to … a plant, its parts, or any use*[56] *thereof if such plant does not contain any genetic material from outside the plant's gene pool*[57] *introduced by a technical process.*

51) Guidelines for Examination in the EPO (March 2023), Part G – Chapter II-40 5.4: https://link.epo.org/web/epo_guidelines_for_examination_2023_hyperlinked_en.pdf.

52) NGT Regulation, Note 2 above, Recital 7.

53) In that case a claim on the plant as such would already lack novelty as the process plays no role when it comes to assessing novelty of a composition matter claim.

54) NGT-practising entities, like breeders, will be unlikely to argue that their plant cannot be obtained by an essentially biological process, as this may contradict with the verification applications under the NGT Regulations. However, non-practising entities may not shy away from using such arguments.

55) EPO Guidelines for Examination, Note 51 above, Part G – Chapter II-40 5.4.2.1 'Examples: The following subject-matter is not excluded from patentability under Art. 53(b) … Flour or oil produced from plant X (even if it is apparent from the description that said plant was exclusively obtained by means of an essentially biological method).'

56) The term 'plant' means a plant in any stage of its development. The term 'parts of a plant' means macroscopic parts (for example, seeds, leaves, and fruits), microscopic parts (for example, DNA, proteins), and any material directly obtained from a plant (for example, meal, oil, juice and so on). The term 'use' means any use of a plant or a harvested material for food, feed, and industrial purposes by breeders, farmers or other users within the value chain.

57) The 'gene pool' means all genetics which, in principle, could be introgressed by sexual crossing. See also NGT Regulation, Note 2 above, and Parliament Amendment, Note 1 above, Article 3(1) No 2. Amendment 25 Article 3 – paragraph 1 – point 2(2): '"NGT plant" means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the gene pool [for conventional breeding purposes] that temporarily may have been inserted during the development of the NGT plant.'

This wording incorporates the broadest possible definition for NGT-derived plants from the NGT Regulation. It exempts all NGT-derived plants from the patent right, including products derived therefrom and any uses. It also covers random mutations. It is independent of any future changes to Annex I of the NGT Regulation. It not only creates a full 'breeder's exemption' but also protects the interests of farmers and down-stream users like brewers. This exemption does not include the 'making' of the plant and thereby sustains patent rights for innovative NGT-processes.[58] It further sustains patent protection of transgenic plants.

While there are arguments that such exemption is consistent with the legislative intent of Directive 98/44 and could be immediately implemented in the patent laws of EU Member States,[59] a change of Directive 98/44 will create higher legal certainty.[60] The exemption should be implemented in the UPCA[61] and national patent laws of EU Member States. It does not require an amendment to the EPC.

4. Next Steps

While there seems to be a broad cross-party consensus in the EU Parliament to limit the patents on NGT-derived plants, the position in the Council is less decisive. So far the Council has only tightened the Commission proposal by setting 31 December 2025 instead of 2026 as a shorter deadline to

> … *conduct a study on the impact that the patenting of plants and related licensing and transparency practices may have on innovation in plant breeding, on breeders' access to plant genetic material and techniques and on availability of plant reproductive material to farmers as well as the overall competitiveness of the EU plant breeding industry.*[62]

A similar requirement is part of the Parliament Amendments.[63]

It appears that the lack of clear position against patents in the Council is the primary stumbling block to achieve a qualified majority in support for the NGT Regulation. Poland in particular seems to be reluctant to proceed based on a position which does not comprise more than a commitment to a study. This is not surprising, as in the subsequent trialogue the position of the Parliament may not prevail against a joint pro-patent position of the Council and the Commission. So the patent issue appears to be the most critical point which could make or break a deal on the NGT Regulation. The reason why the Council does not want to follow the Parliament is unclear. While several Member States have voiced clear concerns about patents, for some abandoning patents appears to be a line they do not want to cross (yet).

If the current Belgium presidency is unable to find a resolution for the current impasse prior to the last plenum session of the EU Parliament (22–25 April 2025), the

58) There is no legitimate reason to limit patents on NGT processes as long as the related claims do not limit the use of the resulting plants. In consequence, a party who wants to use a patented NGT process outside of the statutory research exemption has to take out a licence. However, breeders or farmers who merely use the NGT-derived plant for breeding or farming without practising the patented process do not require a licence.

59) The Directive's legislative history shows that at the time when the Directive was drafted (1995–1998) the view on plant-related innovations tended to be binary: there was the world of conventional breeding, plant varieties, and essentially biological processes on one side, and the world of genetically engineered (transgenic) plants on the other. A scenario where these two worlds could blur was not foreseeable. It is apparent that the legislator when drafting Directive 98/44 intended to provide protection for 'transgenic plants', that is, plants which comprise DNA which was previously isolated or technically made (see Dir. 98/44 Article 3). Several statements in the legislative history of Dir. 98/44 refer to 'genetic engineering' and 'biotechnological inventions'. At that time these terms referred to the emerging field of transgenic organisms. It is also clear from the legislative history that the legislator did not intend to provide protection for plants resulting from conventional breeding. There is a clearly expressed intent to preserve the full benefits of the plant breeder's rights system.

60) Whether a change of Directive 98/44 can be implemented by the NGT Regulation alone without having to follow the usual process for a revision, is another story.

61) For example, as a new paragraph to Article 27 (Limitations of the effects of a patent) to the UPCA (Note 46 above): 'The rights conferred by a patent shall not extend to any of the following: … (c-bis) a plant, its parts, or any use thereof if such plant does not contain any genetic material from outside the plant's gene pool introduced by a technical process'.

62) See 'Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 – General approach'. Brussels, 7 December 2023 (OR. en) 16443/23. Interinstitutional File: 2023/0226(COD). Recital 46(a) and Article 30bis. At: https://data.consilium.europa.eu/doc/document/ST-16443-2023-INIT/en/pdf.

63) Parliament Amendments, Note 1 above. See Amendment 66 Proposal for a regulation. Article 30 – paragraph 5a (new) 5a.

finalisation of the NGT Regulation will be substantially delayed. The EU parliamentary elections (6–9 June 2024), the reconstitution of the Parliament and the Commission, the EU presidency of Hungary (second half of 2024) and Poland (first half of 2025) – both currently opposed to the NGT Regulation – may defer a re-start of the negotiations to the Danish presidency in the second half of 2025. If subsequently a qualified majority in the Council and a successful trialogue can be achieved within six to 12 months, the NGT Regulation may enter into force in 2026. It will, however, only become applicable after the 'sunrise' period of 24 months, that is, in 2028.[64] By this time NGT-derived plants will likely be cultivated in North and South America.

While such delay might be acceptable for cultivation of NGT-derived crops in the EU, it may impact feed importation and with that meat production in the EU. No genetically modified food or feed shall be placed on the Community market unless it is covered by an authorisation.[65] As the CJEU decision C–528/16[66] declares all NBT-derived plants GM,[67] their import arguably requires a product safety assessment based on Directive 2001/18.[68] If a GM product is not approved, a 'zero tolerance' rule applies[69] and consignments shall be re-dispatched to the country of origin or destroyed unless accompanied by an analytical report proving the absence of the unauthorised GM.[70]

As in many cultivation countries NGT-derived crops are considered 'conventional', their adaptation will progress rapidly. In the United States alone, 156 approvals have been granted under the former A.I.R. ('am I regulated') process[71] and 41 under the new RSR (Regulatory Status Review) process.[72] It is unlikely that these countries will slow down the adaptation of NGT-derived crops to accommodate the EU legislative process. It is also unlikely that producers will spend on average €35 million for a GM import approval[73] solely for the EU, notwithstanding that the approval process in the EU takes at least five years to conclude.

How the annual EU import of 14 million tons of soybeans[74] and 4 million tons of corn[75] can continue remains to be seen. At least the EU Parliament is aware of the disruption potential

64) NGT Regulation, Note 2 above, Article 34(2). The Regulation will only shall apply from 24 months from the date of entry into force of the Regulation. This 'sunrise' period shall enable the Commission to establish the necessary Implementation Acts and the verification process.

65) Reg. 1829/2003 Articles 4(2) and 16(2). Article 2 incorporates the definition for GMOs from Directive 2001/18/EC, Note 4 above. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed: https://eur-lex.europa.eu/eli/reg/2003/1829/oj.

66) Court of Justice of the European Union. Judgment in Case C–528/16. Press release No 111/18 of 25 July 2018. Available at https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf. Decision available at: https://curia.europa.eu/juris/document/document.jsf;jsessionid=CA6833BDA64164C36800D0498D7CB7E7?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=10186143.

67) E Callaway, 'CRISPR plants now subject to tough GM laws in European Union', (2018) *Nature* 560:16.

68) Articles 4(3) and 16(3) of Reg. 1829/2003 state that no genetically modified food and feed shall be authorised unless it has been adequately and sufficiently demonstrated not to have adverse effects on human health, animal health or the environment.

69) Article 53 of Regulation (EC) No 178/2002 provides for emergency measures for food and feed imported from a third country to protect human health, animal health or the environment. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178.

70) See, for example, 2013/287/EU Commission Implementing Decision of 13 June 2013 amending Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China Text with EEA relevance.

71) Under the previous regulations, APHIS offered an inquiry process for developers to determine if their NBT-derived organism met the definition of a regulated article. This process was discontinued on 17 June 2020, and replaced with the SECURE rule's confirmation process beginning on 17 August 2020: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table.

72) See under https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/rsr-table/rsr-table. See also Kock (2021), Note 15 above.

73) In 2011 the costs for regulatory science were on average $17.9 million and those for registration and regulatory affairs $17.2 million. Most of these costs would occur irrespective of the number of countries. Meanwhile the costs should be substantially higher. Phillips McDougall (2011) 'A consultancy study for Crop Life International: the cost and time involved in the discovery, development and authorization of a new plant biotechnology derived trait'. Available at: https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf.

74) https://ec.europa.eu/commission/presscorner/detail/en/IP_19_161. See also: https://agriculture.ec.europa.eu/document/download/661daad3-92df-4d44-a357-51f00ea33330_en?filename=monitoring-agri-food-trade-jan2023_en.pdf.

75) https://www.gro-intelligence.com/insights/brazil-seen-ramping-up-corn-production-as-global-trade-flows-shift.

and has added a new Article which makes clear that 'the implementation, enforcement and application of this Regulation shall not have the object or effect of preventing or impeding imports from third countries of NGT plants and products that meet the same standards as those laid down in this Regulation'.[76] However, for this provision to become effective, the NGT Regulation first needs to be approved. Absent an approval, feed import and meat production in the EU may face uncertainties, which would primarily affect countries where meat production is of high economic importance, including Poland.

Consequences for EU Breeders

If the amendments are implemented as suggested, patents would play no role for plants cultivated in the EU. Breeders would have to rely solely on plant breeder's rights (PBR). As the exemptions will have a retroactive effect, not only future NGT-derived plants but also existing plants would be affected, including those with random mutations and native traits. Breeders which relied solely on patents will be deprived of IP protection, which may disrupt current business models. This may raise concerns whether such interference in established rights complies with constitutional rights.[77] However, without retroactivity – at least for NGT method claims – the limitations will lack effectiveness, as many important patents on foundational NGT-process have already been filed and will stay for the next two decades.

Looking forward, breeders are well advised to use PBRs for the protection of their products. The resulting protection may be sufficient for a reasonable return on investment. NGTs enable efficient, fast, and cost-effective breeding. With a product lifecycle of five years or less, the importance of patents might be overrated, especially if they take five or more years to grant. For the majority of breeders, the expanded 'freedom-to-breed' may weigh more heavily than the loss of protection. Only large companies, which can conduct their breeding programme solely within their own germplasm collection without accessing third party genetics, may still see a benefit.

Two elements remain important: (i) NGT processes as such should still have effective patent protection; and (ii) NGT-derived varieties are entitled to equitable PBR protection. Equitable PBR protection for NGT-derived varieties seems, prima facie, obvious but is in fact not trivial. Two issues need to be addressed: (1) the distinctness criterion as requirement for protection; and (2) the scope of protection and applicability of the breeder's exemption in the context of the definition of 'essentially derived varieties' (EDVs).

The protectability of new plant varieties is based *inter alia* on 'distinctness'. Usually, the characteristics for distinctness are unrelated to the agricultural performance and are more of a 'side-effect' of the crossing process.[78] With NGTs precision is greatly increased, leading to enhanced agricultural performance often without visible 'side-effects'. It would contradict the purpose of PBRs – to provide incentives for new and improved varieties – if varieties with enhanced agronomic performance cannot be protected solely because the related characteristics is not 'on the list'.[79] Thus, the distinctness criteria need to be adapted to ensure that NGT-derived varieties are equally incentivised by the PBR system.

The PBRs protection extends to essentially derived varieties (EDVs).[80] An EDV needs to be predominantly derived from the initial variety and retain its essential characteristics.[81] As NGT-derived varieties only differ in a few nucleotides from the initial variety, they are usually considered predominantly derived. However, they can differ substantially in their

76) Parliament Amendments, Note 1 above, Amendment 32 Article 4 – paragraph 1a (new).

77) BVerfG (07.07.1971) BVerfGE 31, 229/238-11 'Schulbuch'; BVerfG (07.07.1971) BVerfGE 31, 275/287 – „Leistungsschutzrecht'; BVerfG (25.10.1978) BVerfGE 49, 382/392 -„Kirchenmusik'; BVerfG (03.10.1989) BVerfGE 81, 12/16 f. – „Tonträger'; BVerfG (31.05.2016) NJW 2016, 2247 – 11 'Sampling'.

78) The characteristics for determining distinctness are specifically defined for each plant species and usually comprise phenotypical characteristics that are not influenced by environmental factors, such as the colour of the stem or petals.

79) While new characteristics can be added, the approval of such addition is at the discretion of the president of the Community Plant Variety Office (CPVO). This creates substantial legal uncertainty for breeders using NGTs whether their variety would be protectable or not.

80) Reg. 2100/94, Article 5(a).

81) Reg. 2100/94, Article 6.

phenotype. It is debated whether NGT-derived varieties should be *per se* considered EDVs, that is, solely on the genotype similarity.[82] The revised 2023 UPOV Explanatory Notes on EDVs (EXN-EDV) creates ambiguity as it indicates that also 'essential characteristics' may be excluded from the assessment which could render all NGT-derived varieties EDVs.[83] If this were the case, NGT-derived varieties would face two negative consequences: (1) dependency, that is, consent by the breeder of the initial variety would be required for commercialisation of the EDV;[84] and (2) a reduced scope of PBR protection, as there cannot be an EDV from an EDV.[85] The issues have been discussed in detail elsewhere.[86]

In particular, if patents for NGT-derived plants are limited, a full and equitable PBR protection for innovative varieties needs to be ensured. A reasonable solution requires a clear and appropriate definition of an 'essential characteristic' to avoid discrimination between classic and new breeding techniques. An essential characteristic should be determined based on its added value. If a significant value is added to the derived variety, it should not be considered an EDV.

5. Summary and Conclusion

Patent on NGT-derived plants appears to be the most critical point which could make or break a deal on the NGT Regulation. The 'pawn sacrifice' proposed by the EU Parliament may not be sufficient unless the Council follows with a corresponding move. A substantial delay or even derailing of the NGT Regulation might be the consequence, which could lead to a 'check mate' for EU agriculture. Short-term imports and meat production in the EU may be affected. Mid-term EU breeders and farmers would be deprived of an important tool to mitigate climate change and reduce inputs like fertiliser, water, and pesticides.

While many stakeholders – farmers and national breeders' associations – have taken a clear position against patents on NGT-derived plants,[87] the position of Euroseeds – the voice of the European seed industry – remains vague.[88] The resulting 'position vacuum' could be one reason why EU Member States hesitate to take a clear position against patents. Another reason is potentially lobbying by multinational companies which may still believe they can have both: a favourable NGT Regulation, which treats NGT-derived plants as conventional, and strong patent protection. Such a view not only ignores the political reality in the EU, it also overemphasises the importance of patents while ignoring the economic importance of a timely, favourable NGT Regulation for importations and cultivation in the Americas, where it is likely that the majority of the value from NGT-derived plants will be created. It can only be hoped that in the remaining very short time window until April 2024, countries but also stakeholders make the 'right move'.

82) From a dogmatic perspective, making genetic similarity the sole decision criterion for essential derivation is hardly compatibility with the UPOV 1991 Convention and the CPVR. It would be in conflict not only with the requirements for the grant of PBRs but also with how breeding progress is evaluated, which are both based on the phenotype.

83) While the EXN-EDV do not single out NGT-derived plant varieties, they still include a statement (§19) that the characteristics which may be ignored in the assessment of an EDV 'may also include essential characteristics'. This could be interpreted as creating flexibility to render all NGT varieties EDVs. UPOV, 'Explanatory notes on essentially derived varieties under the 1991 Act of the UPOV Convention' (UPOV/EXN/EDV/3), 27 October 2023: https://www.upov.int/edocs/expndocs/en/upov_exn_edv.pdf.

84) This would diminish the PBR's breeders' exemption for breeders using NGTs. The breeders' exemption is considered a cornerstone of PBRs as 'access to germplasm to provide the initial source of variation in breeding programs … deemed essential from the outset': MS Clancy and GC Moschini, 'Intellectual property rights and the ascent of proprietary Innovation in Agriculture' (2017) 9 *Annual Review of Resource Economics* 53, at 63.

85) In consequence, the PBR of the NGT-derived variety can be easily circumvented by even a small, commercially irrelevant (for example, somaclonal) variation.

86) D Kim *et al.*, Note 25 above); MA Kock (2021) 'Essentially derived varieties in view of new breeding technologies – plant breeders' rights at a crossroads' (2021) GRUR Int. 70:1, 11–27. Available at: https://doi.org/10.1093/grurint/ikaa156.

87) See Notes 32 and 33 above.

88) Euroseeds statement on IP and NGTs (2 November 2023). Available at: https://euroseeds.eu/news/euroseeds-statement-on-ip-and-ngts/.