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Legal options for changing the patent protection of plants in Germany, Europe and in international law

Legal study commissioned by the

parliamentary group of Bündnis 90 / Die Grünen in the German Bundestag

submitted by

Prof. Dr. Axel Metzger, LL.M. (Harvard), Humboldt University Berlin

Revised machine translation from the original authoritative German version

Table of contents

Executive Summary

Breeders who create new plant varieties in Europe today are faced with an increasingly confusing landscape of numerous, overlapping patents and plant variety rights. Today, the examination of possible infringements of property rights prior to breeding ("freedom to operate" or FTO analysis) is complex and costly. The same applies to obtaining any necessary licenses. The food and animal feed plant industry is aware of the problems caused by the thicket of property rights and has taken measures to improve patent transparency and rights clearance. However, these measures do not yet offer any comprehensive solutions. Critics of the growing patent practice fear that the liberalization of regulatory law proposed by the European Commission for genetically modified plants produced by using new genetic engineering methods such as CRISPR/Cas in particular (NGT plants) could lead to a further increase in patents in the area of food and feed plants and, as a result, to negative effects for small and medium-sized breeders, farmers and biodiversity. Against this backdrop, the European Parliament and the Belgian Council Presidency have adopted proposals aimed at excluding NGT plants from patent protection and restricting the protective effects of plant patents. This is opposed by the industry associations of the biotechnology sector, which fear a weakening of the innovation activities and competitive position of the biotech industry and predict that the development of innovative plants required for climate pro - tection and sustainability will be hindered.

In light of this, the parliamentary group of Bündnis 90/Die Grünen in the German Bundestag has commissioned the preparation of a legal opinion on the legal possibilities for amending biopatent law in Germany, Europe and related treaties with the aim of securing comprehensive and unrestricted access to the genetic material of plants for breeding, farmers and research." In accordance with this mandate, the report examines the possibilities for the legally secure implementation of the various proposals for limiting patent protection for plants, but does not make any policy recommendations.

The patentability of innovative plants, plant characteristics, gene sequences and breeding methods is regulated in detail at various levels of law, from WTO law and the TRIPS Agreement, the European Patent Convention (EPC), which is also anchored in international law, to the Biotechnology Directive 1998/44, which is based in EU law, and national law, in Germany the Patent Act of 1981 (PatG). For the protective effects of patents, the Agreement on a Unified Patent

Court, which is based on international law, must also be taken into account, although it is bound by EU law. The currently discussed changes to the regulations on patentability and the protective effects of patents in the Biotechnology Directive must comply with the requirements of international law. This must be observed in particular with regard to the EPC, as this is decisive for the granting practice of the European Patent Office. The provisions of the Biotechnology Directive are binding for possible amendments to national law.

The expert report shows that, despite the dense network of regulations at international, European and national level, there is certainly scope for restricting patent protection for plants. However, this scope lies less in the patentability of plants or in exclusions from patent protection, but rather in the scope of protection.

With regard to the proposed regulations on patent exclusions and patentability requirements, the study shows that various measures would be possible by amending the Biotechnology Directive without violating the TRIPS Agreement or the EPC, in particular an exclusion of natural plants and gene sequences, an exclusion of patented plants from the NGT liberalization, a tightening of the ordre public exception and an obligation to disclose the origin of biological material. On the other hand, an exclusion of NGT plants and mutagenesis plants from patent protection would not be compatible with the EPC. The same applies to an even more far-reaching full exclusion of all plants, plant parts, gene sequences and processes. At the level of national law, no changes with significant effects would be possible without a revision of the Biotechnology Directive or European genetic engineering law.

With regard to the proposed restrictions on the scope of protection , the following measures would be possible by amending the Biotechnology Directive without violating the TRIPS Agreement or the EPC: A clarification that biological offspring are not covered by product patents, a clarification that general NGT process patents are to be classified as working processes and not as manufacturing processes, a change to the burden of proof rule for derivative products from specific NGT processes, a clarification of the regulations on compulsory licenses based on the Swiss model to the effect, that the breeding of a new variety eligible for authorization under the seed law constitutes a "significant technical progress of considerable economic interest"; a clarification that sanctions the patent holder's refusal to cooperate in an FTO analysis by restricting his claims and the introduction of a mandatory transparency register. On the other hand, a restriction of the scope of protection with regard to plants that have the same properties as plants that

have been or can be produced in the traditional way would not be compatible with the EPC. A full breeders' privilege would not be free from doubt with regard to Art. 30 TRIPS. At the level of national law, without amending the Biotechnology Directive, it would be possible to exclude natural offspring, clarify the rules on derivative products of general NGT working methods, adapt the compulsory licensing system along the lines of the Swiss model and introduce a mandatory transparency register.

A. CURRENT LEGAL POLICY DEBATE

I. Initial situation

The requirements and limits of patenting plants, especially food and fodder plants, have been the subject of controversial debate for decades, both in civil society and between the various industry associations, as well as at the various levels of national, European and international legislation, patent offices and in case law. The adoption of the Biotechnology Directive 1998/44/EEC and its implementation in Germany required a legislative process that lasted over twenty years, from the first drafts of the Commission in 1982 to the entry into force of the amended provisions of the German Patent Act (PatG) in 2005.[1] The compromises reached at the legislative level subsequently led to a shift of the conflicts to the courtrooms and the Boards of Appeal of the European Patent Office, where the interpretation of the regulations was now fought over, sometimes accompanied by high-profile demonstrations by NGOs. The central point of contention in recent years, exemplified by patents on broccoli, tomato and bell pepper plants, has been the question of whether plants from essentially biological processes can be protected by product patents. In the "Tomato II" and "Broccoli II" decisions[2] , the European Patent Office initially considered this to be possible, but revised its opinion in the subsequent "Pepper" case following an intervention by the European Commission.[3] So while patents on plants derived from classical breeding were being fought over, since the fundamental "Transgenic Plants/Novartis II" decision[4] of the European Patent Office in 2000, it had been generally accepted - at least in the legal literature - that genetically modified plants and processes for producing such plants were eligible for patent protection, precisely because they were not produced using an essentially biological process. [5]

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1 See Godt, Eigentum an Informationen, 2007, 19 f.

2 EPO Enlarged Board of Appeal, G 2/12, GRUR 2016, 585 - Tomato II (legal issues from G 2/12 and G 2/13 - Broccoli II were dealt with in joint proceedings).

3 EPO Enlarged Board of Appeal G 3/19, OJ 2020, A 119 - Paprika.

4 EPO Enlarged Board of Appeal, G 1/98, GRUR 2000, 431 - Transgenic Plants/Novartis II.

5 Instead of all Zech/Uhrich, in: Metzger/Zech, Sortenschutzrecht, 2016, § 2a PatG; Art. 53 EPC, para. 28.

II. Commission proposal on NGT plants and demands for patent exclusion

This long-established distinction - genetically modified plants (GMOs) are patentable, conventionally bred plants are patent-free - is being called into question in the current legal policy debate with regard to new genetic engineering techniques (NGTs) such as the CRISPR/Cas 9 "gene scissors" in particular. The background to the current discussion is the "Proposal for a Regulation on plants derived from certain new genomic techniques and food and feed products derived from them" presented by the European Commission in July 2023, which aims to remove (certain) "NGT plants" from the current narrow framework of GMO regulation. [6]

This has led to initial reactions that would like to combine a liberalization of regulatory law for genetically modified plants with a simultaneous restriction of patent protection for such plants, for example from Federal Minister of Agriculture *Cem Özdemir* in August 2023 in "Der Spiegel": "*Two points are particularly important to me: coexistence and the patent issue. Organic farming and some conventional agriculture advertise that they are GMO-free. This is a functioning market worth billions. So this agriculture must not be threatened in its existence. [...] In addition, we do not want monopolists; small and medium-sized breeding companies should also continue to have a chance on the market. Therefore, there must be no patents*."[7] The German National Academy of Sciences Leopoldina and the DFG (Deutsche Forschungsgemeinschaft, German Research Foundation) also take a patent-sceptical position in a joint ad hoc statement, in which the Commission's approach is expressly supported, but at the same time it is also pointed out: "*It is not yet possible to predict whether patents on sequences in NGT-1 varieties will be a serious economic problem for plant breeders, especially small and medium-sized enterprises (SMEs), and to what extent any patent claims could realistically be enforced at all in view of the unprovability of the origin of such a mutation. Irrespective of this, the concerns expressed by plant breeders about future developments (that would block access to genetic material) must be*

6 Proposal of 5.7.2023, COM(2023) 411 final.

7 Interview in DER SPIEGEL 54/2023 (29.8.2023): "Cem Özdemir won't clean out your fridge", available at <www.spiegel.de>.

taken seriously."[8] Most recently, the European Federation of Academies of Sciences and Humanities - ALLEA - has also expressed skepticism.[9]

In Germany, the concerns raised are primarily voiced by the Federal Association of German Plant Breeders (BDP, Bundesverband Deutscher Pflanzenzüchter), whose position paper on the structure of patent protection in plant breeding from January 2023 states: "*The patentability of biological material that also occurs or could occur in nature must not be possible, regardless of how it was produced.*"[10] Fundamental concerns about the granting of patents on plants from conventional breeding, but also from genetic engineering processes, are also raised by civil society groups, in particular the "No patents on seeds" initiative, which is backed by various organizations from the fields of environmental protection and development aid.[11] The European Commission is aware of the criticisms voiced, as a study published in 2021 reveals.[12] In Germany, too, the concerns have been taken up in the Bundestag[13] and in various ministries [14]

The concerns expressed can be summarized as follows:

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8 DFG and Leopoldina, ad hoc statement of 19.10.2023: "Towards science-based regulation of plants bred using new genomic techniques in the EU", available at <www.leopoldina.org>, p. 3.

9 ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development, 8.2.2024, available at <www.allea.org>.

10 BDP position on the design of patent protection in plant breeding of 17.1.2023, available at <www.bdp-online.de>, p. 2 f.

11 See most recently Tippe/Moy et al, Patente auf Saatgut: Die große Herausforderung für die EU, , 2024.

12 Commission Staff Working Document: Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 v. 29.4.2021, SWD (2021) 92 final, p. 45 f.

13 Cf. in particular the cross-party resolution "Keine Patentierung von konventionell gezüchteten landwirtschaftlichen Nutztieren und -pflanzen" of 9.2.2012, https://dip.bundestag.de/vorgang/keine-patentierung-von-konventionell-gezüchteten-landwirtschaftlichen-nutztieren-und-pflanzen/41617 and the Parliamentary Advisory Council on Sustainable Development, 1.6.2018, Protocol No. 18/48.

14 Cf. e.g. statement by the Advisory Council on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection, May 2010 and the BMJV symposium on "Patentability of plants and animals - scope for action and need for reform?", 8.7.2021.

- Blocking access to biological material for further breeding/cultivation: Critics fear that breeders and farmers could face restrictions on access to genetic material for further breeding and seeds for cultivation.

- Excessive license fees: In addition to the ban on the use of material, there are fears of excessive license fees.

- Costs of legal examination: The growing number of patents is associated with concerns about increased costs of patent examination, so-called "freedom-to-operate analyses" (FTO analyses) and defense in legal disputes.

- Slowdown of innovation as a consequence: The obstruction of access to genetic material, excessive license fees and the costs of legal action can lead to a slowdown of innovation.

- Concentration of the industry as a result: As large companies are better able to deal with the costs caused by patents, there are fears of further concentration in the industry.

III. Proposals by the European Parliament and the Council for patent exclusions and dissenting votes

While the Commission's proposal on genetically modified plants initially only concerned regulatory law, the European Parliament responded in February 2024 with a resolution that supports the basic approach of liberalizing the use of genetically modified plants, but links this to a far-reaching exclusion of the patentability of corresponding plants.[15] According to Art. 4a of the parliamentary text, genetically modified plants, parts of plants and genetic information are to be excluded from patent protection. Somewhat hidden in a new Art. 33a para. 1 lit. a, plants derived from untageted mutagenesis are also to be excluded from patent protection in the necessary amendments to the Biotechnology Directive. In future, patents are to be disclosed in the application procedure, see Art. 6 para. 3 lit. ca. According to recital 45a, only protection as a plant variety is to be considered for corresponding plants. In addition, there are restrictions on the protective effects of patents already granted, Art. 33a para. 2 and 3.

15 Resolution of the European Parliament of 7.2.2024, P9_TA(2024)0067.

The compromise proposal of the Belgian Council Presidency from May 2024 takes a different path, but leads to similar results with regard to the exclusion from patenting.[16] According to Art. 4 para. 1 lit. b of the proposal of the Belgian Council Presidency, the classification of a plant as a "Category 1 NGT plant" is subject to the conditions that the plant is not protected by a granted patent or a patent application or that the holder undertakes not to exercise any patents. Patents must be disclosed in the application procedure, see Art. 6 para. 3 lit. d and g. If the information on patents is incorrect or if a patent is subsequently applied for, the Commission should be able to revoke the status as a "Category 1 NGT plant", Art. 11bis.

The proposals of Parliament and the Council will be examined in detail in the respective context of the report at a later point.

The far-reaching exclusion of patents in the Parliament's resolution has now, for its part, prompted critical voices to speak out in favor of maintaining the current legal situation. EuropaBio, the European biotech industry association, has criticized the Parliament's resolution in an initial statement.[17] The Institute of Professional Representatives before the European Patent Office - epi.[18] - has also expressed criticism.

Criticism of the Parliament's resolution focuses on the following points:

- Inconsistency: An exclusion from patenting would withdraw the promotion of NGT plants in the Commission proposal in the same breath.

- Weakening the competitive position of the biotech industry: The position of the European biotech industry would be weakened.

- Slowdown of innovation: An exclusion from patenting would have negative consequences for innovation activity.

16 Proposal of 14.5.2024, 9904/24.

17 See EuropaBio welcomes and warns on New Genomic Techniques European Parliament vote, 8.2.2024.

18 See epi Position Paper on New Genomic Technique (NGT) Plant Patenting Proposal of the European Parliament, 27.2.2024

- Climate protection and sustainability urgently require innovative plants, the development of which is being made more difficult.

It is not the task of this expert opinion to forecast the positive or negative effects on innovation activity associated with an exclusion from patent protection or to evaluate the other legal policy arguments. Rather, according to the mandate of the expert opinion, the sole aim is to examine whether an exclusion of NGT plants and other plants from patent protection or restrictions on the protective effects would be compatible with the legal framework under European and internatio - nal law or how this would have to be changed.

B. STATUS QUO: LEGAL BASIS, GRANTING PRACTICE, EXPERIENCE WITH THE ENFORCEMENT OF PATENTS

I. Current legal situation: TRIPS, EPC, Biotechnology Directive, UPCA, Patents Act

1. Art. 27-31 TRIPS Agreement

At the level of international law, Art. 27 TRIPS is the central provision for the question of whether certain technologies, in particular plants and animals, can be excluded from patent protection.

> Article 27 Patentable subject-matter
> (1) ubject 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. (...)
> (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. (...)
> (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.

> Article 30 Exceptions to the rights conferred
> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

> Article 31 Other use without the consent of the rightholder
> Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (...)
> (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
> (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

As part of WTO law, the TRIPS Agreement is binding for the EU and for the German legislator. Violations of WTO law can be brought before the WTO's quasi-judicial dispute settlement institutions (WTO panel) by other WTO members and sanctions can be imposed. [19]

2. EPC and EPC AO

The European Patent Convention (EPC) of 1973, revised in 2000, is also part of international law and outside EU law. The EPC applies in 38 contracting states, including all 27 EU member states as well as Switzerland, the United Kingdom, Turkey and other countries. It forms the legal basis for the examination and granting of patents by the European Patent Office. Which inventions are eligible for patent protection and which are excluded from patent protection is regulated in Articles 52 and 53 EPC.

> Article 52 Patentable inventions
> (1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. (...)

> Article 53 Exceptions to patentability
> European patents are not granted for:
> (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regu - lation in some or all of the Contracting States;
> (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 (...).

The EPC is supplemented by provisions in the Implementing Regulations to the EPC (EPC IR), which were adopted by the Administrative Council of the European Patent Organization. Rules 26-34 EPC IR are based on the EU Biotechnology Directive and implement - by way of voluntary implementation - the provisions of EU law on patenting in the field of biotechnology. Rules 27 and 28 para. 2, which supplement Art. 53 lit. b EPC, must be observed for the patent protecti - on of plants and animals:

> Rule 27 Patentable biotechnological inventions
> Biotechnological inventions are also patentable if they have a subject matter:
> a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

19 https://www.wto.org/english/tratop_e/dispu_e/dispu_body_e.htm. The legal basis is Annex 2 to the WTO Agreement ("Dispute Settlement Understanding").

(b) without prejudice to Rule 28, paragraph 2, plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety (...).

Rule 28 Exceptions to patentability
2. Under Article 53 lit. b, European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

Rule 27 adopts provisions from Art. 3 and 4 of the Biotechnology Directive almost word for word. Rule 28 para. 2 was introduced in 2017 by decision of the Administrative Council, after the European Commission had previously clarified in a communication that the Biotechnology Directive in Art. 4(1) lit. b not only excludes essentially biological processes from patent protection, but also plants produced using such processes.[20]

3. Biotechnology directive 98/44/EC

The provisions of the Biotechnology Directive are of particular importance because - as shown above - they not only form the basis for the national patent laws of the EU member states, but have also been adopted by the European Patent Organization in the EPC AO and thus determine the EPO's granting practice. An amendment to patent law at this level would therefore be particularly effective. The Directive contains provisions on patentability and the exclusion of plants and animals as well as regulations on the effects of protection:

Article 1
(1) Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

Article 2
(1) For the purposes of this Directive (...)
(2) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
(3) The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3
(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4
(1) The following shall not patentable
a) plant and animal varieties;
b) essentially biological processes for the production of plants or animals.

20 Communication from the Commission of 8.11.2016, OJ C 411/03.

(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 lit. 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.

Article 5
(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6
1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (...)
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

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.

Article 9
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 in incorporated and in which the genetic information is contained and performs its function.

Article 11
(1) By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

Article 12
(1) Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted,

the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

4. UPC Agreement

The Agreement on a Unified Patent Court (UPCA), which entered into force on June 1, 2023, forms the legal basis for the jurisdiction of the Unified Patent Court and at the same time lays down procedural and substantive rules for unitary European patents and other European patents granted by the EPO in all participating member states. With regard to patenting requirements and exclusions, the rules of the EPC apply. The protective effects, on the other hand, are regulated separately in Art. 25-30 UPCA. However, the UPCA is limited to the definition of general principles for product and process claims, which are very similar to the national provisions, such as §§ 9-11 PatG. There are no special provisions on the protective effects of biotechnological inventions. This raises the question of how the UPC will treat such inventions in the future. Like a member state court, the UPC is bound by the requirements of EU law, see Art. 24 para. 1 lit. a UPCA. Accordingly, it must also observe the provisions of Art. 8 and 9 of the Biotechnology Directive. One possible way to achieve an application of the UPCA in conformity with European law could be to interpret Art. 25, 26 UPCA in conformity with the Directive or to supplement it by way of further development of the law.

In contrast to the protective effects of patents, where there are no special provisions for biotechnological inventions, the contracting parties have taken into account the special features of plant breeding and have included provisions on the so-called breeder's exemption and the farmers' right of reproduction.

Article 27 Limitations on the effects of the patent
The rights conferred by a patent shall not extend to any of the following (...)
(c) tthe use of biological material for the purpose of breeding, or discovering and developing other plant varieties;
(...)
(i) the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, provided that the plant propagating material was sold or otherwise commercialised to the farmer by or with the consent of the patent proprietor for agricultural use. The extent and the conditions for this use correspond to those under Article 14 of Regulation (EC) No 2100/94; (...).

5. German Patent Act

Finally, the provisions of the German Patent Act (PatG), which essentially implement the requirements of the Biotechnology Directive in the field of biotechnology, must be taken into account.

As the provisions of the PatG are virtually identical in wording to the Directive, they are not reproduced here, but only the concordance of the two texts is presented:

Biotechnology Directive	PatG
Art. 2 para. 2, 3	Section 2a para. 3 no. 3, 4
Art. 3 para. 2	Section 1 para. 2 sentence 2
Art. 4 para. 1, 2	Section 2a paras. 1, 2
Art. 5	Section 1a para. 3
Art. 8	Section 9a paras. 1, 2
Art. 9	Section 9a para. 3
Art. 11 para. 1	Section 11 no. 2a
Art. 12 para. 1	Section 24 paras. 2, 3

A significant deviation from the text of the directive can be found in Section 2a (1) No. 1:

> (1) Patents shall not be granted for
> 1. plant varieties and animal breeds and essentially biological processes for the production of plants and animals *and plants and animals obtained exclusively by such processes* (...).

The second half-sentence was added in 2013 and thus anticipated later developments at European level, namely the Commission Communication of 2016 and the amendment of Rule 28 EPC AO.

II. Which patents are granted in practice by the offices today?

1. Patents on plant breeding processes

a) General patents on methods for gene modification, in particular CRISPR/Cas

Of particular importance are the broad, generally formulated patents on methods of genome editing using CRISPR/Cas 9. Fundamental here are the patent applications by Nobel Prize winners Emmanuelle Charpentier and Jennifer Doudna and Berkeley University on the one hand (filing date: 15.3.2013) and Feng Zhang from the Broad Institute of MIT (Massachusetts Institute of Technology) (filing date: 12.12.2013) and Harvard University on the other, who are engaged in a bitter, worldwide dispute over the validity of the patents.[21] There is now a broad stream of

21 See EP 2800811 and EP 3597749 (Charpentier/Doudna/Berkeley) and EP 2771468 (Zhang/Broad) and the EPO decision T 0844/18 (CRISPR-Cas/BROAD INSTITUTE), which revoked the Broad Institute's

patent applications in which CRISPR/Cas 9 or other genome editing methods are claimed in connection with specific areas of application, particularly in plant breeding, without the method being limited to certain plant species.[22]

b) Patents on specific NGT processes for the breeding of certain plant traits

In addition to the general (and special) process patents for CRISPR/Cas 9 as a tool, there are now numerous applications in which specific processes for genome editing of individual plant species using CRISPR/Cas 9 are claimed.[23] Corresponding process claims are possible under the current legal situation, as targeted mutagenesis of plants is not an "essentially biological process" pursuant to Art. 53 lit. b or Section 2a (1) no. 1 PatG.

c) Patents on other technical processes for plant breeding (non-directed mutagenesis)

Until now, methods of untargeted mutagenesis, in which the genome of plants is altered through the use of chemicals, radiation (UV or radioactive) or other physical effects, have also been classified as technical and therefore patentable methods.[24] Today, however, such processes are likely to regularly fail to meet the requirements of novelty and inventive step.

European patent. In the USA, on the other hand, the patent of the Broad Institute with regard to eukaryotes was upheld in two "interference" proceedings by the US Patent Trial and Appeal Board, see PTAB, February 15, 2017, Interference No. 106,048 and February 28, 2022, Interference No. 106,115. 106,115. Most recently, the representatives of Charpentier/Doudna declared their intention to revoke patent EP 2800811, while patent EP 3597749 is to be maintained, see Harrison, CRISPR Nobelists surrender their own European patents, 42 Nature Biotechnology 1629 (2024).

22 Cf. Kim/Hilty/et al, CRISPR/Cas Technology and Innovation: Mapping patent law issues, Max Planck Institute for Innovation and Competition Research Paper No. 22-06, available at <papers.ssrn.com/sol3/papers.cfm?abstract_id=4106075>, 21 with further references and Kim/Kock/et al, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, Position Statement of the Max Planck Institute for Innovation and Competition, GRUR Int. 2024, 323, fn. 24 (1669 patents claiming methods based on CRISPR/Cas 9 in the field of plant breeding). An example is provided by KWS' application of 26.2.2021 (filing date) WO2021/170787A1 (EP 4110930 A1).

23 A simple patent search on "espacenet" using the search terms CRISPR and common cereal or vegetable species such as "wheat", "maize", "barley", "tomato" leads to numerous patents that claim both the method of targeted editing of certain gene sequences and the resulting plants, see for example the application of July 20, 2017 (filing date) WO2018/022410 A1 (EP 3490365 A4).

24 See EPO Guidelines for Examination G II 5.4.

d) No patents on essentially biological processes

The EPC, the Biotechnology Directive and the German Patent Act essentially exclude biological processes for the production of plants and animals from patent protection. Such processes are defined in all three texts (or in the EPC IR) as "processes for the production of plants or animals which are based entirely on natural phenomena such as crossing or selection". The regulation is logically contradictory because the attributes "entirely" and "essentially" are mutually exclusive. It is therefore considered an unsuccessful compromise.

In practice, the Boards of Appeal of the EPO find it difficult to distinguish between technical and essentially biological processes. In the "Broccoli I" decision, the Enlarged Board of Appeal ruled[25] that the use of a genetic analysis of plants classically crossed thereafter is not sufficient to add a technical step to the process and no longer classify it as essentially biological. This deserves approval on the merits, but does not prevent a patent being applied for on the genetic analysis method as such, provided it is new and inventive.[26] The so-called "whole content approach" would also not help against corresponding application strategies,[27] because the applicant can conceal in the description that the gene analysis is preferably to be used in the context of an otherwise "essentially biological method".

2. Patents on plants as products/substances

a) Patents on plants and certain characteristics of plants ("traits")

Novel plants can be described as an abstract group of plants with similar characteristics (as opposed to individual plants or plant characteristics) on the basis of biological concepts (botanical taxonomy). This is the case for plant varieties as defined in Art. 5 of the Community Plant Variety Regulation (EC) No. 2100/94 (CPVR): A grouping of plants within a single botanical taxon of the lowest known rank. Patent protection of corresponding plant groups is ruled out due to the

25 EPO Enlarged Board of Appeal, G 2/07, OJ EPO 2012, 130 - Plant Bioscience Limited/Broccoli I.

26 See, for example, EP 3560330B1 (PLANTS WITH IMPROVED DIGESTIBILITY AND MARKER HAPLOTYPES), claim 1.

27 Dolder, Die Anwendung von Patentierungsausschlüssen nach dem whole content approach, Mitt. 2017, 1-15.

exclusion of plant varieties, regardless of whether the variety is the result of classical breeding or a technical process.

In contrast, it is recognized in the case law of the EPO that certain properties of plants - so-called "traits" - can be patentable either as such or as properties of a plant group above the lowest taxon. They are not subject to the exclusion of plant varieties if they can be realized in different varieties, e.g. in different tomato or maize varieties.

However, since the amendment of Rule 28 para. 2 EPC IR and the corresponding national provisions, plants of a higher taxon or traits of plants can only be protected by patents if they have not been produced by an essentially biological process. The "trait" must therefore have been induced in the plant either by a targeted modification of the genome, for example by an NGT process, or by non-directed mutagenesis or another technical process.[28] According to the EPO's examination practice, it must be made clear by means of a disclaimer in the claim that the patent does not extend to plants in which third parties achieve the expression of the same properties using conventional breeding methods.[29] If, on the other hand, only a technical process is considered, this disclaimer is not required.

b) Patents on gene sequences of natural and technically modified plants

Through the reference in Section 2a para. 2 sentence 2 PatG to Section 1a para. 3 PatG, the Patent Act implicitly clarifies that gene sequences of plants can be the subject matter of patentable inventions. In view of Rule 29 para. 3 EPC IR, this is also undisputed for the EPC. For gene sequences of plants that are the result of a targeted modification of the genome, for example by NGT methods, or of untargeted mutagenesis, this is a sub-category of the general category of substance patents, where the technical problem to be solved lies in the provision of the substance.[30] If, on the other hand, a gene sequence occurring in nature is claimed, the additional hurdle

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28 See EPO GBK, 14.5.2020, G 3/19 - "Pepper". See also Metzger/Bartels, Wirksamkeit und Schutzumfang von Pflanzenpatenten. Auswirkungen der Regel 28 Abs. 2 EPÜ AO, ZGE/IPJ 10 (2018), 123-161. As an example from current application practice, see EP 4405377A1 (METHODS AND COMPOSITIONS FOR REDUCING POD SHATTER IN CANOLA).

29 See EPO Guidelines for Examination G II 5.4.

30 See e.g. EP 3805391B1 (Use of Yr4DS gene of aegilops tauschii in stripe rust resistance breeding of triticeae plants). In detail Krusche, DNA und ihre Verwendung als Gegenstand patentierter Erfindungen, 2019, 97 et seq.

must be overcome, according to which only substances isolated for the first time from the natural environment can be patented, see Section 1 para. 2 sentence 2 PatG or Rule 27 lit. a EPC IR. If this requirement is met, patents can also be applied for biological natural substances such as gene sequences.

However, patents on gene sequences are subject to special requirements that limit the scope of protection. Pursuant to Section 1a Para. 2 PatG, the industrial applicability of the sequence or partial sequence of a gene must be specifically described in a corresponding patent application, stating the function performed by the sequence or partial sequence. The mere sequencing as such is therefore not sufficient for the grant of a patent; rather, the function or property of the plant in which the gene sequence is expressed must be described. The question therefore does not arise as to whether mere sequencing could still be novel and inventive today.[31] It is true that Section 1a para. 3 PatG does not provide that the function must be stated in the claim itself. According to the general principles of absolute substance protection[32] , it would therefore also be conceivable that the patent proprietor could also claim possible functions of the gene sequence that are discovered later. However, such a broad interpretation was opposed by the ECJ in the "Monsanto/Cefetra" decision.[33] According to this decision, the patent proprietor's protection is limited to the function specified in the application. The principles of absolute substance protection therefore do not apply.

III. How are patents enforced in practice?

1. Hardly any court proceedings in Germany (and Europe)

So far, only a few cases have come to light in Germany and other EU Member States in which owners of patents on innovative plants have taken legal action against breeders for patent infringements.[34] In view of the high level of public awareness of patents in the plant sector and the

31 Krusche, loc. cit., 189 et seq.; Uhrich, Stoffschutz, 2010, 382-386, in each case with further references.

32 In general Mes, Patentgesetz Gebrauchsmustergesetz, 5th ed. 2020, § 3 PatG, para. 77-80.

33 ECJ, C-428/08, GRUR 2010, 989, 990 - Monsanto/Cefetra; see Zech/Uhrich, in: Metzger/Zech, Sortenschutzrecht, 2016, Section 9a PatG, para. 30 et seq.

34 One example is the Dutch case Taste of Nature v. Cresco, see Gerechtshof 's-Gravenhage , 28.5.2013, 408315/KGZA 11-1414, in which an SME breeding company took action against another SME for the cultivation of patented purple radish sprouts. The patent was later declared invalid for lack of novelty, see

very active industry associations, it is not very likely to assume a high number of unreported cases. The fact that little is made public about the judicial assertion of patent claims should not lead to the assumption that SME breeding companies in particular do not nevertheless see their business model threatened by the growing patent portfolios, particularly because they fear the costs associated with patent searches and license agreements. However, these concerns are certainly not fueled by mass patent lawsuits.

It is particularly noteworthy that so far there have been no reports of claims by patent holders against farmers. Such claims could be based on Section 9c para. 1 PatG in conjunction with Art. 14 CPVR and Implementing Regulation 1768/95/EC on Art. 14 para. 3 CPVR, particularly in the case of the reproduction of harvested material by larger agricultural enterprises. Art. 14 CPVR and the Implementing Regulation 1768/95/EC on Art. 14 para. 3 CPVR. The parallel obligation to pay compensation for the reproduction of protected varieties under Art. 14 para. 3 CPVR has long been enforced by Saatgut-Treuhandverwaltungs GmbH both in and out of court. The requirements and the amount of compensation have been disputed in numerous national court proceedings and also several times before the ECJ. [35]

2. Industry solutions: Pinto, ILP Vegetable and Agricultural Crop Licensing Platform

In the breeding industry, instead of robust enforcement of patents, the focus is on industry solutions for patent searches and licensing. Three initiatives are important here:

a) Pinto database

The PINTO ("Patent Information and Transparency On-line") database was set up by the European industry association Euroseeds in 2013.[36] The database contains information on plant varieties that may fall within the scope of protection of patents or patent applications. In this way, breeders should be able to assess which varieties they can use for further breeding without the consent of a patent holder or which varieties can only be marketed with a patent license in the case of breeding based on patent-protected older varieties. In July 2024, the PINTO database had

Rechtbank Den Haag, 18.3.2015, C/09/4 16501/HA ZA 12-452

35 Fundamental ECJ, C-305/00, GRUR 2003, 868, 872 - Schulin; ECJ, C-336/02, GRUR 2005, 236 - Brangewitz.

36 For the following, see also Kock, Neue Genomische Techniken in der Pflanzenzüchtung, 2023, 39-41.

1,171 entries of varieties that may fall within the scope of protection of patents or patent applications.[37] With a total number of currently approx. 15,000 registered varieties from the areas of agricultural fruits and vegetables,[38] the 1,171 entries contained in the database seem manageable. However, this should not lead to the conclusion that the other varieties do not fall within the scope of patent protection. PINTO does not provide a complete record of all varieties and patents in question. The database is based on a voluntary commitment by the members of the industry association Euroseeds, which only represents breeders of agricultural fruit and vegetables. Ornamental plants and fruit varieties are not included. Nevertheless, the PINTO database contributes to the transparency of the patent landscape in the areas covered. For example, the varieties and patents registered in the database show that the proportion of varieties that could be protected by two or more patents has increased significantly in the period 2021-2023. [39]

b) ILP Vegetable

A second noteworthy industry initiative is the "ILP Vegetable" license clearinghouse[40] , founded in 2014, in which 16 large and medium-sized breeding companies from Europe, the USA and Japan have joined forces to grant each other licenses to the 350 patents currently registered on reasonable terms.[41] The amount of the license fees is determined by an arbitration board by way of "baseball arbitration". The licenses granted are based on a standard license agreement with worldwide validity. ILP Vegetable does not publish annual reports showing how many license agreements have been brokered by the organization and under what conditions. To date, no licenses have been issued for NGT plants in the EU because, under current law, they fall under the regulation for GMO plants and can therefore only be cultivated in the EU under certain conditions.[42]

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37 See https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/pinto-database.

38 See https://cpvo.europa.eu/en/about-us/what-we-do/statistics.

39 Cf. in detail Kock, loc. cit., 40.

40 See <ilp-vegetable.org>.

41 According to Kock, op. cit., ILP Vegetable represents 60 % of the global commercial market for vegetable seeds.

42 https://ilp-vegetable.org/q-and-a/q14.html.

c) Agricultural Crop Licensing Platform - ACLP

A platform based on similar principles for the agricultural sector is currently being set up ("Agricultural Crop Licensing Platform - ACLP").[43] ACLP is supported by ten member companies of various sizes. Information on the patents covered by the platform is not available on the website. In contrast to ILP Vegetable, ACLP only offers licenses for Europe.

IV. In addition: Plant variety protection law

In addition to patent law, plant variety protection law must be observed with regard to individual plant varieties. Varieties can also be registered for genome-edited plants, provided they meet the requirements of distinctness, homogeneity, stability and novelty in accordance with Art. 5-10 CPVR and Section 1 German Plant Variety Act (SortG). Since plant variety protection is based on the phenotypic characteristics of the plant and does not refer to genetics or the breeding method in the variety description, it is irrelevant for eligibility for protection how the breeder arri - ved at the plant with these characteristics. Nevertheless, information on genetically modified traits must be provided when applying for a Community variety pursuant to Art. 50 para. 2 CPVR in conjunction with Art. 19 para. 2 lit. b indent 2 of Regulation 874/2009. [44] It should also be noted that in the case of genome editing of protected plant varieties, the resulting new variety may be classified as an "essentially derived variety" (EDV) and thus as dependent on the pre-existing variety,[45] with the further consequence that this new variety is then in turn not protected against further derivations (Art. 13 para. 5 in conjunction with Art. 15 lit. d CPVR or Section 10 para. 2 in conjunction with Section 10a para. 1 no. 3 SortG). One may complain about this discrimination of genome-edited plants in plant variety protection.[46] However, breeders are not unprotected under the current legal situation as long as patent protection for genome-edited plants remains possible.[47] In the ongoing legal policy debate on the liberalization of NGT plants, howe-

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43 https://aclp.eu.

44 On the information required in the variety application, see Köller, in: Metzger/Zech (eds.), Sortenschutzrecht (2016), GSortV Art. 49-Art. 65, para. 10 f.

45 UPOV's Explanatory Note on the concept of EDV, UPOV/EXN/EDV/3 of 27.10.2023, 6.

46 Kim/Kock/et al, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 336-338. Similarly, Kock, Essentially Derived Varieties in View of New Breeding Technologies - Plant Breeders' Rights at a Crossroads, GRUR Int. 2021, 11.

ver, it must be borne in mind that if these plants are excluded from patent law, only limited plant variety protection exists.

V. Interim conclusion

The overall picture shows that anyone who wants to breed plants today is faced with a confusing landscape of numerous, overlapping patents and plant variety rights, which makes freedom-to-operate analyses complex and costly. The same applies to obtaining any necessary licenses. The measures taken by the industry itself do not yet offer comprehensive solutions. Developments in the coming years will show what role clearing houses will play in the future. It is already clear that, even if they are successful, they will not be able to offer a satisfactory solution for all patent and plant variety rights in question. This is already true because vegetables and field crops only represent a fraction of all the patents that could be considered.

47 The classification of genome-edited plants as EDV strengthens the position of those breeders who continue to breed new varieties conventionally and over a long period of time. These breeders are solely dependent on plant variety protection due to Art. 53 lit. b EPC and Rule 28 (2) EPC AO. See also Krieger/De Keyser/De Riek, Do New Breeding Techniques in Ornamentals and Fruits Lead to Essentially Derived Varieties?, Front. Plant Sci, 04 March 2020.

C. EXCLUSION OF PLANTS FROM PATENT PROTECTION, RAISING THE PROTECTION REQUIREMENTS

I. Exclusion of patentability, raising the requirements for protection : Alternative approaches

In the following, various alternatives for excluding plants, plant varieties, their seeds and their genetic resources from patent protection and raising the protection requirements are examined in more detail. The examination is carried out at the level of international law (TRIPS, EPC), the Biotechnology Directive and German Patent Act (PatG). In order to avoid repetition, the conceivable restrictions are presented in advance. In the following, the study uses the terms presented here:

A1 "Full exclusion": The legislator could completely exclude plants, plant varieties, their seeds, their genetic resources and all processes for breeding plants from patent protection and rely solely on protection through plant variety rights.

A2 "Exclusion of natural plants and gene sequences": The legislator could exclude naturally occurring plants, plant characteristics and gene sequences of plants from patent protection.

A3 "Exclusion of NGT plants from patent protection": The legislator could exclude plants, plant material, parts thereof, genetic information and the process characteristics contained therein from NGT processes from patent protection. This corresponds to the European Parliament's proposal:

Art. 4a Draft Biotechnology Directive (EP resolution of 7.2.2024)
NGT plants, plant material, parts thereof, genetic information and the process characteristics contained therein are not patentable.[48]

A4 "Exclusion of plants from untargeted mutagenesis from patent protection": The legislator could exclude plants, plant material, parts thereof, genetic information and the process characteristics contained therein from patent protection that originate from untargeted mutagenesis and cell fusion. This corresponds to the proposal of the European Parliament (EP resolution of 7.2.2024), which refers in Art. 33a para. 1 lit. a (at the end) to Annex I B of Directive 2001/17/EC, where non-directed mutagenesis and cell fusion are listed.[49]

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48 The exclusion of plants from technical processes that resemble natural breeding proposed by the European Parliament as a new Article 9(2) of the Biotechnology Directive, see Article 33a para. 3 of the EP resolution of 7 February 2024, is covered by the proposal for a new Article 4a and is therefore not examined separately below.

49 The EP proposal goes on to say "which *may be obtained* by techniques excluded from the scope of Directive 2001/18/EC in accordance with Annex IB thereto".

A5 "Exclusion of patented plants from NGT liberalization": The legislator could exclude patented plants from NGT liberalization (proposal by the Belgian Council Presidency).[50]

A6 "Strengthening the public policy proviso": The legislator could specify and sharpen the public policy proviso with regard to ethical concerns about the patenting of plants.

A7 "Raising the standards of novelty and inventive step": The legislator could tighten the examination standards for assessing novelty and inventive step in order to ensure that patents are not granted for plants or genetic resources that are identical or similar to naturally occurring plants.

II. Requirements of WTO law (TRIPS)

1. Compatibility with the TRIPS Agreement

a) Full exclusion of plants and breeding methods

According to its wording, Article 27 para. 3 lit. b sentence 1 TRIPS not only permits the exclusion of plant varieties from patentability, but also of plants at higher levels of the taxonomy. The broad wording was not chosen by chance, but corresponds to the intention of the contracting parties.[51] This means that it is possible to exclude plants from patent protection in any abstract or concrete form, regardless of whether they are the result of essentially biological crossing and selection, technically induced untargeted mutagenesis or targeted intervention in the genome. It is also not clear from the provision that corresponding exclusions in Member State patent laws must be limited to whole plants. Accordingly, parts of plants can also be covered, whereby this is considered permissible at least if these materials are suitable for producing complete plants.[52] Correspondingly broad exclusions can also cover derivative process products in accordance with Art. 28 para. 1 lit. b TRIPS.[53] Whether individual gene sequences can be excluded from patent

50 Art. 4 para. 1 lit. b: (the plant) "is not protected by one or more patents or published patent applications in one or more Member States of the European Union, or the holders of such patents or patent applications commit not to exercise their rights on the NGT plant in the European Union as long as it is declared category 1 NGT plant status (...)."

51 See also Gervais, The TRIPS Agreement: Drafting History and Analysis, 2021, 443.

52 Correa, in: Correa (ed.), Research Handbook on the Protection of Intellectual Property under WTO Rules, 2010, 584.

53 Goebel, Pflanzenpatente und Sortenschutzrechte im Weltmarkt, 2001, 212 f.

protection as parts of plants is unclear, but the literature tends to deny this, meaning that member states must grant patents in this respect. [54]

However, according to Art. 27 para. 3 lit. b sentence 2 TRIPS, a patent exclusion for plants requires that the Member States provide for the protection of plant varieties by an effective system "sui generis", whereby it is generally recognized that a plant variety protection right which is in accordance with the UPOV Convention of 1991 constitutes an effective system in this sense. [55] In this respect, this condition is fulfilled in the EU by the establishment of the protection of Community varieties on the basis of Regulation 2100/94.

For the exclusion of breeding processes, Art. 27 para. 3 lit. b sentence 1 TRIPS distinguishes between the possibility of excluding essentially biological processes from patent protection and the obligation of member states to protect all other processes - provided they meet the other require - ments - by patents. To date, there has been no decision by a WTO panel on the distinction. The literature on the TRIPS Agreement focuses on whether a process for plant breeding also contains at least technical steps.[56]

b) Exclusion of natural plants and gene sequences

In accordance with the above, plants occurring in nature can also be excluded from patent protection under the TRIPS Agreement as long as plant varieties are eligible for protection as a variety. This is possible in principle under the Community Plant Variety Regulation 2100/94, provided it is a new variety, for example if it is found for the first time in the breeder's garden.

In the case of gene sequences, however, the question arises as to whether it is a new invention in a field of technology within the meaning of Art. 27 para. 1 TRIPS. This question has not yet been clarified by the case law of the WTO panels. In this context, it is of interest that numerous WTO member states exclude gene sequences of naturally occurring plants from patent protecti-

54 Bender/Michaelis, in: Hilf/Oeter, WTO-Recht, 2nd ed., 2010, 500; Goebel, loc. cit., 185-192; v. Saint-André/Taşdelen, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed., 2013, Art. 27, para. 88; see also Correa, loc. cit., 584.

55 Gervais, The TRIPS Agreement: Drafting History and Analysis, 2021, 445; Saint-André/Taşdelen, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed. 2013, Art. 27, para. 96.

56 Correa, in: Correa (ed.), Research Handbook on the Protection of Intellectual Property under WTO Rules, 2010, 580.

on.[57] Of particular note here is the 2013 decision of the US Supreme Court in the "Myriad Genetics" case, in which the court found that a naturally occurring DNA sequence does not constitute an invention simply because it has been isolated from its natural environment for the first time. [58]

c) Exclusion of NGT plants from patent protection

Since plants can generally be excluded from patent protection in accordance with Art. 27 para. 3 lit. b sentence 1 TRIPS, this also applies to plants produced using NGT processes. However, such plants must be protectable as varieties if they meet the requirements for plant variety protection.

d) Exclusion of plants from untargeted mutagenesis from patent protection

For the exclusion of plants from untargeted mutagenesis, the same applies to NGT plants: They can be excluded from patent protection according to Art. 27 para. 3 lit. b sentence 1 TRIPS as long as plant variety protection is available.

e) Exclusion of patented plants from NGT liberalization

The exclusion of patented plants from the application of the possible new, liberal provisions for NGT plants of category 1 (A5) proposed by the Belgian Council Presidency does not directly affect patenting or the exclusions from patent protection for plants. Since, according to the above, the plants concerned could be directly excluded from patent protection in accordance with Art. 27 para. 3 lit. b sentence 1 TRIPS, there is also no contradiction with the provisions of the TRIPS Agreement if patenting is linked to disadvantages in regulatory law.

f) Clarification of the reservation of public policy

According to Art. 27 para. 2 TRIPS, member states can exclude inventions from patenting if their commercial exploitation is contrary to public policy or morality. In principle, the provision is open to legislation by the Member States that specifies the standards for individual groups of cases (A6), although it should be noted that the mention of the exemplary protected interests of "human, animal or plant life or health or to prevent serious harm to the environment" makes it

57 See generally Kock, Neue Genomische Techniken in der Pflanzenzüchtung, 2023, 28.

58 Association for Molecular Pathology v. Myriad Genetics, Inc, 569 U.S. 576 (2013).

clear that the hurdle should not be set too low.[59] It should also be noted that a Member State ban on the exploitation of the patented technology is not in itself sufficient to constitute an infringement. Against this background, the direct route via Art. 27 para. 3 lit. b TRIPS ultimately appears preferable for Member States that wish to exclude plants from patent protection.

g) Raising the standards of novelty and inventive step

Art. 27 para. 1 TRIPS only contains the patentability requirements of novelty and inventive step in a very general form. In this respect, footnote 5 to the TRIPS Agreement merely explains that "inventive step" can also be implemented as "non-obvious". In view of this very broad framework, there is considerable scope for clarification at the level of Member State law, for example to ensure that patents are not granted for plants or genetic resources that are identical or similar to naturally occurring plants (A7).

In future, the transparency requirements for patent applications with regard to genetic material and traditional knowledge will also result from the WIPO Treaty of May 24, 2024, which obliges its member states to require patent applicants to indicate the country of origin of genetic resources.[60] Although this will not lead to a change in the examination standard for novelty or inventive step, it is likely to increase the number and quality of citations to be examined by the patent offices for corresponding applications.

2. Reform perspectives

Amendments to WTO law, including the TRIPS Agreement, are subject to high hurdles. According to Art. X para. 3 of the WTO Agreement, the votes of 2/3 of the WTO members are required in principle to achieve a change in the rights and obligations of the member states. The long time from the proposal of a new Art. 31bis TRIPS in 2001, to the official decision of the WTO General Council in 2005, to the entry into force of this - so far the only amendment to the text - in 2017 illustrates how rocky the road to amending the TRIPS Agreement is. [61]

59 v. Saint-André/Taşdelen, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed. 2013, Art. 27, para. 62.

60 Art. 3 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge of 24.5.2024, not yet in force. The wording in Art. 3 ("shall") is to be understood as a mandatory legal obligation, cf. the WIPO declaration at https://www.wipo.int/edocs/mdocs/mdocs/en/gratk_dc/gratk_dc_exsum.pdf ("mandatory patent disclosure requirement").

61 See https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

III Requirements of the European Patent Convention

1. Compatibility with the EPC, prospects for reform

a) Full exclusion of plants and breeding methods

The European Patent Convention is based on a concept of invention open to all fields of technology, which is also expressed by the wording in Art. 52 EPC: "European patents shall be granted for any inventions, *in all fields of technology*,(...)". According to the established case law of the Boards of Appeal and the - as far as can be seen unanimous - commentary literature, this covers inventions in the field of biology, including plants.[62] The openness for inventions in the field of biology is also expressed in Rules 26, 27 EPC IR. Art. 53 EPC formulates exceptions to this principle, whereby Art. 53 lit. b EPC is particularly important here, which excludes "plant varieties or animal breeds and essentially biological processes for the production of plants or animals" from patent protection. In accordance with the system of the provisions, exceptions to patent protection in the field of biology must be measured against whether they are covered by the elements of Art. 53 EPC. When interpreting the provisions, the Boards of Appeal of the EPO apply a rather cautious method which is closely aligned with the wording, system and purpose of the provisions.[63] Since Art. 53 lit. b EPC is a provision of an exceptional nature, this applies in a more stringent form: It is true that the Enlarged Board of Appeal of the EPO has expressly spoken out against the application of the maxim "exceptions are to be interpreted narrowly".[64] However, this does not change the fundamental tendency of the EPO's case law to be rather cautious towards legal policy reform ideas. Decisions that deviate from the wording of the regulations and develop the law are rare. Against this background, it is inconceivable that the Boards of Appeal of the EPO could classify a general full exclusion (A1) of all plants, plant varieties, their seeds and their genetic resources as compatible with Art. 52, 53 EPC on the basis of the current law. Such an exclusion would clearly go beyond the wording and purpose of Art. 53 lit. b EPC and

62 EPO Enlarged Board of Appeal, G 2/07, OJ EPO 2012, 130, 194 - Plant Bioscience Limited/Broccoli I; Melullis/Koch, in: Benkard, Europäisches Patentübereinkommen, 4th ed. 2023, Art. 52, para. 78-80 with further references.

63 In detail Metzger, Interpretation of IP Treaties in Accordance with Art 31-33 VCLT: A Case Study on the Practice of the European Patent Office, in: Grosse Ruse-Khan/Metzger (eds.), Intellectual Property Beyond Borders, Cambridge 2022, 157, 168-173.

64 EPO Enlarged Board of Appeal, G 2/12, GRUR 2016, 585 - Tomate II, under VI. 2.

would exclude an entire field of technology from patent protection. If you want to enforce such a broad exclusion, the only option is to revise the legal basis.

b) Exclusion of natural plants and gene sequences

An exclusion of natural plants and gene sequences (A2), on the other hand, could be compatible with the EPC. The exception in Art. 53 lit. b EPC would not be the starting point for this, because A2 would also involve more than plant varieties, especially if "traits" from naturally occurring plants are in question, which are not limited to individual varieties. It would therefore be more promising to start with the term "technical invention" itself in Art. 52 para. 1 EPC. The term invention is not defined in more detail in the EPC. Following the earlier decision of the German Federal Court of Justice in the "Rote Taube" case,[65] the Enlarged Board of Appeal of the EPO defines an invention as a teaching for planned action using controllable natural forces to achieve a causally foreseeable result.[66] If, in accordance with the traditional doctrine of the protectability of natural substances, the technical problem solved by the invention is understood to be the isolation and provision of the substance as such for the first time, this can be understood as the use of controllable natural forces,[67] whereby the further requirement of specifying the function of the gene sequence in the patent claim must then be observed.[68] However, the assumption of patentability of gene sequences occurring in nature is by no means mandatory, as a look at foreign legal systems, in particular US law, shows. In this respect, reference can be made to the comments on A2 in connection with the TRIPS Agreement. If one follows this approach, plants occurring in nature and their gene sequences would not be inventions within the meaning of Art. 52 EPC, but mere discoveries which are excluded from patent protection under Art. 52 para. 2lit. a EPC. [69] In any case, such an interpretation would be compatible with the wording and the system of the provision.

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65 BGH GRUR 1969, 672 - Rote Taube.

66 EPO Enlarged Board of Appeal, G 2/07, OJ EPO 2012, 130, 193 - Plant Bioscience Limited/Broccoli I.

67 EPO Opposition Division, EPO OJ EPO 1995, 338 - Relaxin, at 5.1 and 5.4.

68 Supra B II 2 b. The decision ECJ, C-428/08, GRUR 2010, 989, 990 - Monsanto/Cefetra must also be observed when applying the EPC on the basis of Rule 26 (1) EPC AO. See also Rules 27 lit. a, 29 para. 3 EPC AO.

69 In detail Godt, Eigentum an Information, 2007, 37 ff., 315 f.; Uhrich, Stoffschutz, 2010, 240 ff., 272 ff.

c) Exclusion of NGT plants from patent protection

An exclusion of NGT plants, plant parts, process features and gene sequences of these plants is contrary to the provisions of Art. 52, 53 EPC. It is undisputed in the case law of the EPO and also in the patent law literature that methods for modifying the genome of a plant are to be classified as technical and, accordingly, that the resulting plants and gene sequences are of a technical nature.[70] Such processes are the paradigmatic example of technical processes. They are therefore also expressly treated by the Enlarged Board of Appeal as non-essentially biological processes and are therefore patentable to date. This applies both to the older methods of gene modification, for example with agrobacteria, and to NGT methods, such as CRISPR/Cas 9 technology. It would hardly be promising to assign these methods to non-technical, essentially biological methods because the properties of plants achieved by NGT methods could also occur in nature. This does not affect the exclusion of plant varieties that have been produced using NGT processes or that have used NGT plant material for breeding. For these, the exclusion according to Art. 53 lit. b EPC remains.[71]

The fact that exclusions for plants from NGT procedures are not compatible with the current rules of the EPC does not mean that they cannot nevertheless be achieved. However, this would require an amendment to the EPC in the form of an addition to Art. 53 lit. b EPC. Such an amendment could be achieved either by a revision of the EPC pursuant to Art. 172 EPC within the framework of a diplomatic conference or by a unanimous decision of the Administrative Council pursuant to Art. 33 para. 1 lit. b, Art. 35 para. 3 EPC, provided that (1.) the EU would first amend Union law - i.e. the Biotechnology Directive - accordingly and (2.) no contracting state would declare within twelve months of such a decision that the decision should not be binding. The hurdles to be overcome are therefore high.

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70 EPO Enlarged Board of Appeal, G 2/07, OJ EPO 2012, 130, 205. EPO 2012, 130, 205 - Plant Bioscience Limited/Broccoli I, headnote 3: "However, if such a process contains, within the steps of sexual crossing and selection, an additional technical process step which itself *introduces a trait into the genome of the bred plant or modifies a trait in its genome*, so that the introduction or modification of that trait is not achieved by mixing the genes of the plants selected for sexual crossing, the process is not excluded from patentability under Article 53 lit. b EPC." Cf. from the literature Zech/Uhrich, in: Metzger/Zech, Sortenschutzrecht, 2016, Section 2a PatG; Art. 53 EPC, para. 28.

71 EPO Enlarged Board of Appeal, G 1/98, GRUR 2000, 431 - Transgenic Plants/Novartis II.

d) Exclusion of plants from untargeted mutagenesis from patent protection

According to the prevailing opinion, the assessment of an exclusion of mutagenesis processes and the resulting plants follows the same lines. Corresponding processes are classified as technical in the case law of the EPO; accordingly, an assessment as essentially biological processes is ruled out.[72] However, there is also an opposing view in the literature, according to which mutagenesis induced by irradiation, chemicals or other means should be classified as an essentially biological process.[73] Although this view can be accepted in that the technical processes of non-directed mutagenesis are often not new themselves, this does not change the fact that they are initially to be classified as technical and therefore not essentially biological.[74] For the examination of novelty, only the product, the plant obtained, is relevant.

In view of the current case law of the EPO, the legislative materials and the prevailing view in the literature, it would appear problematic to arrive at a different interpretation of the provision on the basis of a corresponding amendment to Rule 28 EPC IR without amending the text of the EPC itself. Rather, an amendment to the Convention itself would be necessary.

e) Exclusion of patented plants from NGT liberalization

The exclusion of patented plants from the application of the possible new, liberal provisions for NGT plants of category 1 (A5) proposed by the Belgian Council Presidency does not directly affect patenting or the exclusions from patent protection for plants. Inventors and companies remain free to apply for patents on plants, gene sequences or processes or to use patented materi-

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72 EPO Enlarged Board of Appeal, G 1/98, GRUR 2000, 431 - Transgenic Plants/Novartis II, under 3.7 on irradiation. Cf. from the literature Melullis/Koch in: Benkard, Europäisches Patentübereinkommen, 4th ed. 2023, Art. 53, para. 108 with further references; Metzger/Bartels, Wirksamkeit und Schutzumfang von Pflanzenpatenten. Auswirkungen der Regel 28 Abs. 2 EPÜAO, ZGE/IPJ 10 (2018), 123, 138; Pihlajamaa, Patentability of plant-related inventions: Die Praxis nach der Stellungnahme G 3/19, GRUR 2022, 949, 950; in detail Kahrmann, Patentierbarkeit von mittels Zufallsmutagenese erzeugten Pflanzen, 2024, D III; see also Travaux préparatoires zum EPÜ, Doc. IV/2071/61, cited in EPO, Technical Board of Appeal 3.3.4, 22.5.2007, T 83/05, OJ EPO 2007, 644, 653 ff - Broccoli/PLANT BIOSCIENCE.

73 See in particular Godt, Technology, Patents and Markets: The Implied Lessons of the EU Commission's Intervention in the Broccoli/Tomatoes Case of 2016 for Modern (Plant) Genome Editing, IIC 2018, 512, 522 f. Cf. also from the legal policy discussion No Patents on Seeds, Correct legal interpretation of Article 53 lit. b, EPC, within the context of the EU patent directive 98/44: Legal analysis provided by No Patents on Seeds!, March 2023.

74 Mes, Patentgesetz, 6th ed. 2024, § 2a, para. 38.

al or patented processes of third parties in the production of plants. However, their plants will then continue to be subject to the previous, stricter regulations on GMOs (unless the patent holder declares that it will not exercise its patents in the EU with regard to the plants in question). However, this would only affect NGT plants, but not those derived from untargeted mutagenesis, which means that the proposal goes less far than the EP proposal in this respect. It is not apparent that such a legal situation and practice of the EU Member States would entail a direct violation of the EPC. According to Art. 53 lit. a of the EPC, they are free to prohibit or restrict the use of patented technologies through national regulatory law - and this would be precisely the effect of the proposed regulation. Nevertheless, the proposal is disturbing insofar as the restriction of the use of NGT technology is linked to the patent protection granted by the EPO. This may be seen as a contradiction to the aim of strengthening cooperation between European states in the field of protection of inventions, as stated in the preamble to the EPC. In addition, the principle of good faith (also) applicable in international law can be recalled,[75] because the EU Member States would indirectly prevent the objectives of the EPC from being achieved through their national law if the proposal of the Belgian Council Presidency were implemented, whereby regulatory law would only be used as a pretext to make provisions in patent law - which would be irrelevant in this respect. However, since the protective effects of patents lie outside the regulatory scope of the EPC and the competence of the EPO and its Boards of Appeal, this cannot be seen as a legal - ly tangible, justiciable infringement of the EPC.

f) Clarification of the reservation of public policy

Finally, it would also be conceivable to specify the public policy proviso in Art. 53 lit. a EPC with regard to ethical objections to the patenting of plants. So far, the Boards of Appeal of the EPO have assumed a narrow understanding of the provision. A patent can only be refused on the basis of Art. 53 lit. a EPC if the exploitation of the invention (not the application as such) would be contrary to public policy or morality. According to case law, this is only the case if every conceivable type of exploitation is affected. If individual, unproblematic uses are also conceivable, the provision cannot be applied.[76] Furthermore, the possible use must violate elementary principles which are uniformly valid for the entire EPC treaty area. In principle, a patent must be gran-

75 See Art. 26 Vienna Convention on the Law of Treaties: "Once in force, a treaty is binding on the parties and must be performed by them in good faith."

76 See EPO Test Guidelines G II 4.1.2.

ted for inventions which are only regarded as objectionable in individual contracting states.[77] The EPO's Guidelines for Examination state that the standard to be applied is "whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."[78] In view of these strict standards, it is obvious that the public policy exception is only used "in very rare and extreme cases".[79] Previous attempts by NGOs to have innovations in the field of plants that are perceived as offensive declared null and void as contrary to public policy have therefore failed.[80] In this context, particular reference should be made to the Plant Cells/PLANTGENETIC SYSTEMS decision from 1995,[81] in which Greenpeace opposed a patent on a transgenic, herbicide-resistant plant because plants are the "common heritage of mankind" and opinion polls in Sweden and Switzerland show that patents on herbicide-resistant plants are rejected. The Board of Appeal did not follow the above-mentioned strict standards. The attempt to have the patenting of DNA as a natural product declared contrary to public policy and the patent therefore invalid was also unsuccessful.[82] A change to this restrictive handling of the general clause in Art. 53 lit. a EPC would require an amendment or clarification of the provision. Such an approach is not without precedent, as examples of inventions contrary to public policy can already be found in Rule 28 para. 1 EPC IR.[83] In this respect, however, careful consideration should be given to whether the reservations against NGT plants or other plant innovations are actually of ethical and moral origin and are therefore correctly located here, or whether it is also - or even primarily - a matter of a need for freedom to operate in the interests of

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77 EPO Technical Board of Appeal 3.3.4, 21.2.1995, T 356/93, OJ EPO 1995, 545 - Plant cells/PLANTGENETIC SYSTEMS.

78 See EPO Guidelines for Examination G II 4.1 Critically Metzger, Patentrecht, 5th ed. 2022, para. 160.

79 This is expressly stated in EPO Guidelines for Examination G II 4.1. Likewise and in detail in Bartels, Ethik und Patentrecht, 2020, 63-76.

80 An evaluation of opposition and nullity proceedings brought by NGOs can be found in Metzger, Das Einspruchsverfahren als politische Arena: Zur Rolle von NGOs im Patentrecht, in: Metzger (ed.), Methodenfragen des Patentrechts, Theo Bodewig zum 70. Geburtstag, Tübingen 2018, 111-135.

81 EPO Technical Board of Appeal 3.3.4, 21.2.1995, T 356/93, OJ EPO 1995, 545 - Plant cells/PLANTGENETIC SYSTEMS.

82 EPO Opposition Division, 8.12.1994 GRUR Int. 1995, 708 - Relaxin.

83 Against regulatory technology: Bartels, Ethics and Patent Law, 2020, 327 f.

breeders, farmers and biodiversity. If so, a separate exclusion in Art. 53 EPC would be more appropriate.

g) Raising the standards of novelty and inventive step

Art. 54, 56 EPC provide detailed provisions on the standards of novelty and inventive step, which also apply to the examination of applications in the field of plants. Significant in the present context is the definition of prior art in Art. 54 para. 2 EPC, according to which written or oral descriptions and mere use in public are also expressly to be regarded as prejudicial to novelty, even if the description or use takes place abroad. This means that, for example, already known properties of plants that are used in traditional healing methods abroad can no longer be applied for a patent in Europe. If the EPO overlooks the prior use abroad during the examination, this can later be held against the patent in opposition or nullity proceedings.[84] However, the prerequisite for this is that the relevant property or gene sequence of the plant was known at the time the patent application was filed. If it was isolated from its natural environment for the first time after the filing date, it does not stand in the way of novelty.[85] The substantive requirements of the novelty test are therefore perfectly suitable for preventing the mere incorporation of alrea - dy known plants or properties into patents.

Prior use abroad is also relevant for the examination of inventive step pursuant to Art. 56 EPC. In this respect, the invention applied for must not be obvious from the prior art, otherwise there is no inventive step. Therefore, if the application is for a plant that has only been slightly modified and is based on a previously known plant that occurs in nature, inventive step may be denied. The hurdle of "non-obviousness" is often considered too low in the general patent law dis - cussion, which has been discussed for many years under the heading of "raising the bar".[86] An isolated solution for the field of plant innovations alone is unlikely to be achievable.

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84 See, for example, the opposition proceedings against the application of Dr. Willmar Schwabe GmbH for a process for the preparation of an extract of Pelargonium (EP 1429795A1), in which, among others, a South African NGO invoked prior use in South Africa. The proceedings ended with a withdrawal of the application.

85 See also Kock, Neue Genomische Techniken in der Pflanzenzüchtung, 2023, 27.

86 Einsele, in: BeckOK Patentrecht, 33rd edition, 2024, § 4 PatG, para. 14.

Unlike the WIPO Treaty on Genetic Resources and Traditional Knowledge and German law, the EPC and EPC IR do not yet require applicants to provide information on the geographical origin of biological material when filing an application. Such a provision could be included in the EPC IR. In any case, it would not contradict the provisions of the EPC.

2. Possible adoption of an amendment to the Biotechnology Directive in the EPC IR

Insofar as a patent exclusion - or another of the above-mentioned additions - is compatible with the provisions of Art. 52, 53 EPC, this could be clarified by a more detailed explanation in the EPC IR. With regard to the exclusion of natural plants and gene sequences (A2) discussed above, it would be imperative to amend Rule 27, the current version of which expressly declares biological material to be patentable "which is isolated or produced from its natural environment by means of a technical process, even if it was already present in nature". The regulation would have to be deleted or amended in such a way that natural plants, parts and gene sequences of such plants are excluded. This would require a decision of the Administrative Council adopted by a three-quarters majority of the contracting states represented, Art. 33 para. 1 lit. c, Art. 35 para. 2 EPC.[87] However, since Rules 26-34 EPC IR are based on the Biotechnology Directive and Rule 26 para. 1 sentence 2 EPC IR refers to the supplementary application of the Directive, this would only be advisable if the Biotechnology Directive itself were also amended beforehand. Without a prior amendment of the Directive, it is also hardly conceivable that a decision in the Administrative Council would achieve the required majority. The same applies to a possible addition to Rule 28 para. 1 EPC IR of an example rule relating to plant innovations (A6). In contrast, an obligation to indicate the geographical origin of biological material (A7) could already be introduced today by a decision of the Administrative Council, as there is a basis for this in Recital 27 of the Biotechnology Directive.

In contrast, the other exclusions of plant innovations from patent protection discussed above, which would be in conflict with Art. 52, 53 EPC (A1, A3 and A4), cannot be implemented by amending or supplementing the EPC IR, since in the event of a conflict the provisions of the EPC take precedence pursuant to Art. 164 para. 2 EPC.

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87 In decision G 3/19, OJ EPO 2020, A 119 - Paprika, under XXV, the Enlarged Board of Appeal dealt in detail with the question of whether the Administrative Council can take a decision by a three-quarters majority to amend the EPC AO, which provides for an interpretation of the EPC that deviates from the previous case law of the EPO Boards of Appeal, and expressly answered this question in the affirmative.

III. Requirements of the Biotechnology Directive

1. Compatibility with the Directive, prospects for reform

a) Full exclusion of plants and breeding methods

A far-reaching exclusion of plants, plant varieties, their seeds, their genetic resources and all processes for the breeding of plants from patent protection (A1) would not be compatible with the Biotechnology Directive in its current form. According to Article 1 para. 1 of the Directive, it is precisely aimed at protecting biotechnological inventions and stipulates in Article 4 para. 1 lit. a and lit. b that only plant varieties and essentially biological processes are excluded from patent protection. According to a communication from the Commission in 2016, it can be assumed that this also covers plants from essentially biological processes that are not specific varieties.[88] A full exclusion of plants would go well beyond the current exclusions and could only be achieved by the European legislator amending Art. 4.

b) Exclusion of natural plants and gene sequences

The exclusion of naturally occurring plants, plant characteristics and gene sequences of plants (A2) is precluded by the provision in Art. 3 para. 2 of the Directive, which expressly assumes the patentability of biological material that is isolated or produced from its natural environment by means of a technical process. In this respect, too, the legislator would be called upon to achieve a corresponding exclusion.

c) Exclusion of NGT plants from patent protection

The legislator could exclude plants, plant material, parts thereof, genetic information and the process characteristics contained therein from NGT processes from patent protection, as proposed by the European Parliament in its resolution (A3). However, such an exclusion would require an amendment to the Directive. Methods of targeted genetic modification[89] are currently classified as technical and therefore not essentially biological methods.

88 Communication from the Commission of 8.11.2016, OJ C 411/03.

89 Communication from the Commission of 8.11.2016, OJ C 411/03, 6.

d) Exclusion of plants from untargeted mutagenesis from patent protection

According to the prevailing opinion, the same applies to methods of untargeted mutagenesis (A4).[90] According to the prevailing opinion, the Austrian proposal to also classify methods of non-directed mutagenesis as essentially biological processes and to exclude them from patent protection violates the Directive in its current form.[91] Consequently, the Directive would have to be amended if plants derived from untargeted mutagenesis are to be excluded from patent protection in the EU with legal certainty.

e) Exclusion of patented plants from NGT liberalization

The EU legislator could exempt patented plants from the liberalization of genetically modified plants (proposal of the Belgian Council Presidency) (A5) without contradicting specific rules of (higher-ranking) European law. This would leave the current legal situation unchanged, according to which NGT plants can be patented and utilized under the regulatory requirements of GMO regulation. However, compatibility with European law could be challenged with regard to the general principle of proportionality (Art. 5 (4) TEU) if the legislator ultimately refers to extraneous considerations – from patent law – as the basis for regulations in the area of regulatory law that are not supported by a risk assessment.

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90 This is controversial in the patent law literature, cf. for the h.M. Metzger/Zech, A Comprehensive Approach to Plant Variety Rights and Patents in the Field of Innovative Plants, in: Godt/Lamping (eds.), A Critical Mind - Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property, 2023, 619, at 3.1.2; Moufang, in: Schulte, Patentgesetz, 11th ed. 2022, § 2a, para. 41; Pihlajamaa, Patentability of Plant-Related Inventions: Die Praxis nach der Stellungnahme G 3/19, GRUR 2022, 949, 950. Dissenting Godt, Technology, Patents and Markets: The Implied Lessons of the EU Commission's Intervention in the Broccoli/Tomatoes Case of 2016 for Modern (Plant) Genome Editing, IIC 2018, 512, 522 f. (on Art. 53 lit. b EPC).

91 The explanatory notes to the government bill on the revised Sec. 2 para. 2 sentence 3 Austrian Patent Act (1955 of the Supplements XXVII. GP - government bill - explanatory notes, p. 6) are content with the justification that the exclusion "clarifies" that untargeted mutagenesis is an essentially biological process. This conceals the fact that the Austrian legislator has created an exclusion that goes beyond Art. 4 para. 1 of the Biotechnology Directive, which, according to the prevailing opinion, has no support in the Directive.

f) Clarification of the reservation of public policy

Finally, it would also be conceivable to specify the public policy proviso in Art. 6 of the Biotechnology Directive with regard to ethical objections to the patenting of plants (A6). For this, reference can be made to the comments on Art. 53 lit. a EPC.[92] Starting with the public policy reservation would have the advantage that it would be possible to work towards an adoption in the EPC IR without having to amend the text of Art. 53 lit. a EPC. However, it is questionable whether the objections to patents on NGT and other plants are actually based on ethical considerations. In addition, any flexibility to react to a possible change in the social classification of plant innovations would be lost if the examples in Art. 6 para. 2 of the Directive were to be supplemented. [93]

g) Raising the standards of novelty and inventive step

To date, the Biotechnology Directive has not laid down any specific requirements for the examination of novelty and inventive step, but refers in Art. 3 para. 1 to the general patentability requirements. As explained above with regard to the EPC, this approach should be retained. The introduction of special standards for plant innovations (A7) is neither sensible nor promising.

On the other hand, in a possible reform of the Biotechnology Directive, the soft target requirement on indications of source for biological material in recital 27 should be converted into a binding regulation. The new regulation should comply with the requirements of the WIPO Treaty and implement the obligations and sanctions specified therein.[94] Increasing transparency with regard to the origin of the material used would also make it easier for patent offices to examine novelty and inventive step.

2. Prospects for reform: amendment of the Biotechnology Directive

Not only because of the lengthy legislative process leading up to the adoption and implementation of the Biotechnology Directive, but also because of the diverse, sometimes diametrically opposed interests of the various stakeholders from industry and civil society, the Directive has long

92 Supra C. III. 1. f.

93 Bartels, Ethik und Patentrecht, 2020, 327 f.

94 Cf. the opinion of GRUR (author Dornis) on the draft treaty, GRUR 2023, 1602.

been described as a Pandora's box that should rather not be opened because it is not possible to predict what will come out at the end of a reform.[95] Initiated by the European Parliament's resolution of February 7, 2024, there could now be movement in the discussion about a reform of the directive. By linking the EPC IR with developments in EU law, changes to the provisions on patentable inventions or exclusions could also have an impact on the European Patent Office's granting practice.

IV. Options for action at national level

The scope for action for national legislators is very limited by the Biotechnology Directive. As outlined above, the Directive regulates in detail in its Articles 1-6 which inventions in the field of plants are patentable and which innovations are excluded from patent protection. As the European Court of Justice clarified in the Monsanto/Cefetra decision, the Biotechnology Directive is a fully harmonizing directive that leaves no scope for deviating regulations by the member states with regard to the conditions or scope of protection. [96]

A full exclusion of plants (A1) would be contrary to Art. 3 para. 1 of the Directive, an exclusion of natural plants and gene sequences (A2) would be contrary to Art. 3 para. 2. An exclusion of NGT plants from patent protection (A3) would not be compatible with Art. 3 para. 1 in conjunction with Art. 4 para. 1 and 2. Art. 4 para. 1 and 2, which assume a fundamental patentability of biological inventions in the plant kingdom and only exclude certain plants. According to the prevailing opinion, the same applies to plants derived from untargeted mutagenesis (A4); the Austrian legislator's attempt to classify methods of untargeted mutagenesis as essentially biological processes by definition and thus also exclude plants produced accordingly can only be based on a minority opinion in the literature and the demands of NGOs.[97]

Although the exclusion of patented plants from NGT liberalization (A5) would not contradict the Biotechnology Directive, it would be problematic with regard to European genetic engineering

95 ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development, 8.2.2024, available at <www.allea.org>, 9.

96 ECJ, C-428/08, GRUR 2010, 989, 990 - Monsanto/Cefetra, Ls. 2 and para. 51-63 with regard to Art. 9 of the Directive; general opinion of Advocate General Mengozzi on the Directive, para. 42-56.

97 § Section 2 para. 2 sentence 3 Eastern Patent Act, see supra C. III 1.d.

law, which defines a uniform European legal framework for the approval of genetically modified plants in Regulation 1829/2003 on genetically modified food and feed.

Any tightening of the public policy proviso (A6) would have to be measured against Art. 6 para. 1 of the Biotechnology Directive; in this respect, there could be scope for observing the public policy ideas in individual Member States.[98] However, the effects would be limited because the grant of patents by the EPO would not be affected, but at most the grant of patents by the DPMA could be influenced. Finally, the scope for the national legislator to define the standards of novelty and inventive step (A7) in more detail is also limited, as the concepts are Europeanized by Art. 3 para. 1 of the Biotechnology Directive.

In contrast, the transparency requirements for patent applications with regard to genetic material and traditional knowledge (A7) are not yet prescribed by European law, but are left to the Member States, see Recital 27 of the Biotechnology Directive. The German Patent Act has made use of the possibility of a corresponding national provision in Section 34a PatG, albeit only in the weak form of a target provision. In practice, corresponding indications of source have only rarely been made to date. If the Biotechnology Directive is not amended to include an obligation to indicate origin, the national legislator would be called upon to adapt it to the requirements of the WIPO Treaty of 24.5.2024 as soon as Germany accedes to the treaty. [99]

98 Cf. recital 39 Biotechnology Directive.

99 Art. 3 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge of 24.5.2024, not yet in force.

D. RESTRICTIONS ON THE SCOPE OF PROTECTION

I. Restrictions on the scope of protection: Alternative approaches

B1 "Patent exemption of biological offspring, evidence": The legislator could clarify that biological offspring that have the same properties or the same gene sequence as a patented plant are excluded from the scope of protection of the patent. The regulation could be additionally safeguarded by rules on providing evidence.

B2 "Limited product protection for NGT process patents": The legislator could clarify (1.) that general NGT process patents are to be classified as working processes and not as manufacturing processes, so that plants bred using the processes do not constitute derivative process products and (2.) specify when the breeder has the burden of proof to have used a different process in the case of an identical product.

B3 "Extension of the breeder's privilege": Based on the regulations in plant variety protection law, the legislator could not only permit the use of biological material for the purpose of breeding, discovering and developing a new plant variety, but also the dissemination of the resulting new plant variety.

B4 "Compulsory licenses for the breeding of new varieties": The legislator could follow the example of Switzerland (see Section 36a of the Swiss Patent Act)[100] and specify the requirement of "important technical advance of considerable economic significance" for the granting of a compulsory license to the effect that the breeding of a new variety that is eligible for approval under seed law constitutes such progress.

B5 "Limitation of the patent proprietor's claims in the event of refusal to cooperate in FTO analysis": The legislator could limit the patent proprietor's claims if the latter does not respond to requests in the context of a freedom-to-operate analysis or provides incorrect information on the patent status of biological material.[101]

B6 "Transparency register for plant patents": Legislation could require entry in a transparency register for all patents on plants, plant varieties, gene sequences and breeding techniques used.[102]

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100 Art. 36a para. 1 of the Swiss Patent Act: "If a plant variety right cannot be claimed or used without infringing a previously granted patent, the plant breeder or the holder of the plant variety right shall be entitled to a non-exclusive license to the extent necessary to obtain and use his plant variety right, provided that the plant variety represents a notable advance of considerable economic importance over the patented invention. In the case of varieties for agriculture and food, the criteria of the Seed Ordinance of December 7, 1998 are to be taken into account as reference points."

101 Cf. Kock, Intellectual Property Protection for Plant Related Innovation Fit for Future?, 2023, 286

102 This is called for in the ALLEA Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development, 8.2.2024, available at <www.allea.org>, 7. See also Kim/Kock/et al, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 335.

II International law requirements: TRIPS Agreement and EPC

1. Patentability of biological offspring, evidence

Article 28 of the TRIPS Agreement only contains a very general provision on the scope of protection of patents. In the case of product claims, the patent proprietor can prohibit the manufacture, use or sale if the infringing object in question is the protected product. This also means that no claims can be asserted with regard to plants, plant material or gene sequences that do not fall within the scope of protection of the patent claims. Assuming that the member states of the TRIPS Agreement can exclude all plants derived from essentially biological breeding processes from patent protection, it also follows that the member states are permitted to clarify at the level of the scope of protection that offspring derived from essentially biological processes which have the same characteristics or the same gene sequence as claimed in the patent are not covered by the scope of protection of the patent (B1). Ultimately, a corresponding provision in the context of the scope of protection is a mere clarification.

With regard to the allocation of the burden of presentation and proof, the TRIPS Agreement only contains a provision for the special case of derivative process products in Art. 34, see below under 2. For product claims and other process claims, the Agreement does not contain any provision on the burden of proof. Art. 43 TRIPS is relevant for the preservation of evidence in court proceedings. According to this provision, patent proprietors who have submitted all reasonably available evidence to sufficiently substantiate their claims may apply to the court for the submission of legally relevant evidence that is in the opposing party's possession, if necessary under conditions that ensure the protection of confidential information. Art. 43 TRIPS provides the basis for member state regulations according to which a patent holder who can demonstrate and prove that the alleged infringer's plant has exactly the same characteristics or gene sequences as the patented plant can apply to the court for the alleged infringer to produce its documentation of the breeding, such as studbooks. Such a request must specifically identify the evidence to be handed over; a "discovery of evidence" is not admissible.[103] A request for the submission of breeding documentation should be sufficiently specific.

103 See in detail Vander/Steigüber, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed., 2013, Art. 43 para. 4-9.

2. Limited derivative product protection for NGT process patents

According to Art. 28 para. 1 lit. b TRIPS, patent protection for processes also extends "to the product obtained directly by that process" (so-called derivative product protection). Art. 34 TRIPS places the burden of proof on the (alleged) infringer in the case of an identical product that this was produced by a different process. However, it should be noted that the provisions only concern process claims directed to the manufacture of products.[104] In contrast, the TRIPS Agreement does not force its member states to introduce corresponding provisions on the scope of protection and burden of proof for mere working processes which are not directed to the manufacture of a specific product (B2). The above-mentioned general NGT process patents are classified in the literature with good reason as working processes,[105] so that Art. 28 para. 1 lit. b, Art. 34 TRIPS do not apply in this respect. Patents on special NGT processes for breeding certain plant characteristics are to be classified as manufacturing processes, so that the provisions on derivative product protection apply. However, if the process products are plants, the broad exclusion in Art. 27 para. 3 lit. b TRIPS allows Member States to also exclude derivative process products from patent protection,[106] which then also excludes the application of the provisions in Art. 28 para. 1 lit. b , Art. 34 TRIPS. [107]

3. Extension of the breeder's privilege

The introduction of an extended or full breeder's privilege (B3) has been discussed for many years under the heading "full breeder's exemption". Compatibility with the TRIPS Agreement would have to be checked against the so-called three-step test in Art. 30 TRIPS, according to which patent right barriers (1.) must be restricted to limited exceptions, (2.) must not unreasonably conflict with the normal exploitation of the patent and (3.) must not unreasonably prejudice the legitimate interests of the patent proprietor, whereby the legitimate interests of third parties must also be taken into account. The openly formulated elements of the provision leave conside-

104 Neef, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed. 2013, Art. 34 para. 1.

105 This is the tendency in Kim/Kock/et al, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 328-330, who, however, would like to see clarification from the legislator.

106 Supra C. II. 1. a.

107 See Goebel, Pflanzenpatente und Sortenschutzrechte im Weltmarkt, 2001, 212 f.

rable room for interpretation. Accordingly, it is uncertain how a WTO panel would interpret the provision in the event of a conflict with regard to a possible full breeder's privilege. The only comprehensive scientific analysis of the issue is skeptical with regard to the compatibility of a full breeders' privilege with Art. 30 TRIPS.[108] Even the "limited" nature of such an exception is doubtful. In addition, a "contradiction to the normal exploitation of a patent" must certainly be assumed if patentees are denied the possibility of granting licenses to competing breeders, although this restriction does not automatically have to be classified as "unreasonable" in view of the objective of the breeder's privilege - the promotion of innovation. If the first two hurdles in Art. 30 are seen as surmountable, it would ultimately depend on a balancing of interests, which can be different for TRIPS member states. For example, the interests of the patent holder must be subordinated to the interests of the general public if the food supply is impeded due to conflicting patents.[109] If, on the other hand, as in the European Union, there is a struggle for the right innovation model in a situation of great security of supply and a very innovative technology sector such as plant breeding, it is more than questionable whether a WTO panel would ultimately subordinate the interests of the patent holder. In view of the general exception for plants in Article 27(3)(b) of the TRIPS Agreement, it could, however, also be argued that a full breeder's exemption would have a less drastic effect than the full exclusion of plants permitted under Art. 27(3)(b) TRIPS and, accordingly, does not have to meet the strict requirements of Art. 30 TRIPS. Such an approach has not yet been examined by WTO panels and, as far as can be seen, is not addressed in the literature on the TRIPS Agreement either.

4. Compulsory licenses for breeding new varieties

If the European (or German) legislator were to enact a regulation on compulsory licenses for patents along the lines of Art. 36a of the Swiss Patent Act (B4), Art. 31 lit. l TRIPS would have to be used as a standard of review, as it formulates special requirements for compulsory licenses in the case of dependent patents, which are to be applied analogously to the case of dependent plant

108 See also Prifti, The Breeder's Exception to Patent Rights: Analysis of Compliance with Article 30 of the TRIPS Agreement, 2015, 134-145. Also Goebel, Pflanzenpatente und Sortenschutzrechte im Weltmarkt, 2001, 231-232.

109 This is ultimately the only situation for which Prifti clearly assumes that the general interest prevails, loc. cit. 146.

variety rights.[110] The main question here is whether the "important technical advance of considerable economic importance" required in Art. 31 lit. l i) TRIPS for dependent plant variety rights can be replaced by the criteria that seed marketing law imposes on the authorization of varieties. According to the European directives on seed approval, in order to be approved as seed, a variety must, in addition to the requirements of plant variety protection law, demonstrate a "cultural value", which presupposes that, according to the totality of its characteristics, it can be expected to present "a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived therefrom" compared to other varieties.[111] In view of the fact that the requirements of Art. 31 lit. l TRIPS are applied analogously to dependent plant variety rights, the linguistic differences between "important technical advance" and "clear improvement" or between "considerable economic importance" and the fact that the approval as seed means the direct market access of a variety appear to be negligible. They result from the wording of the wording of the seed marketing law, which is specifically tailored to varieties. The advantage of an adaptation to the nomenclature of plant variety protection law is that it makes it easier for breeders to prove the requirements for obtaining a compulsory license: Anyone who obtains an authorization for a variety under seed marketing law and is prepared to meet the other requirements for the grant of a compulsory license - in particular the prior effort to obtain a voluntarily granted license, the territorial limitation to the territory of the granting state, the remuneration set by the court - can successfully apply for the grant of a compulsory license or use this option as a "bargaining chip" in negotiations with patent holders.

5. Limitation of the patent proprietor's claims in the absence of cooperation

The provisions on civil law sanctions in the event of an infringement in Art. 41-48 TRIPS regulate the claims of the right holder, but do not provide for any defenses from general civil law that a defendant can also invoke in the event of infringements of intellectual property rights, such as the statute of limitations, forfeiture or good faith. In this respect, the national regulations remain

110 See Höhne, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed., 2013, Art. 31 para. 38. The provision in Art. 27 para. 3 lit. b speaks for an analogous application.

111 See, for example, Art. 4 para. 1 and Art. 5 para. 4 of Directive 2002/53/EC on the common catalog of varieties of agricultural plant species. According to the European Commission's proposal for a reform of European seed marketing law, the criterion of agricultural value is to be replaced in future for all varieties subject to authorization by the criterion of value for "sustainable cultivation and use", see Art. 52 Proposal for a Regulation on the production and marketing of plant reproductive material in the Union of 5.7.2023, COM(2023) 414 final.

applicable. However, Art. 8 para. 1 in general and Art. 41 TRIPS in particular for sanctions stipulate that Member States may take appropriate measures to prevent the abuse of intellectual property rights and procedures. The provisions open up the possibility for Member States to apply general civil law defenses - or special legal provisions - that prevent the patent holder from using a patent contrary to its purpose to prevent technical progress.[112] This should allow Member States to refuse to issue an injunction to a patent proprietor who refuses to provide information on his property rights in response to a prior, substantive and timely request from a breeder in the context of an FTO analysis (B5).[113] In addition, it should be possible to assume that the requesting breeder has complied with due diligence obligations when examining claims for damages and to deny fault for patent infringement.

6. Transparency register for plant patents

The TRIPS Agreement does not contain any provisions for possible obligations of patent owners to provide information to public authorities, such as a register to improve patent transparency.

7. EPC

The EPC does not contain any provisions on the scope of protection of patents or their enforcement, but refers in this respect to the law of the respective contracting states for which the patent has been granted, Art. 64 para. 1 EPC. The legal measures dealt with in this section, which are based on scope of protection, are in principle outside the scope of the EPC and do not require any further coordination with the European Patent Organization. However, insofar as the provisions on scope of protection amount to a complete exclusion of any protection for patents granted by the EPO, this can be seen as a breach of the principle of good faith in the application of international treaties.[114]

112 This presupposes that the definition of abuse in Art. 41 TRIPs is not narrowed down to cases of abuse of a dominant market position under competition law, see Brand, in: Busche/Stoll/Wiebe, TRIPs, 2nd ed., 2013, Art. 8 para. 34; Temmerman, The Legal Notion of Abuse of Patent Rights, NCCR Working Paper No 2011/23, May 2011, 12.

113 Most recently in detail on the assessment under the TRIPS Agreement Leistner, Unterlassungsverfügung im Einheitspatentsystem, GRUR 2022, 1633-1635.

114 Art. 26 VCLT, supra fn. 75.

III. Provisions of the UPC Agreement

1. Patentability of biological offspring, evidence

In Art. 25 and Art. 26, the UPCA only contains very general provisions on the sole right of the patent proprietor to the direct and indirect use of the invention. Although the UPC, as a member state court, is bound by Union law, there are no specific provisions transposing Art. 8 and 9 of the Biotechnology Directive into the UPCA. The UPC must already now - and would also have to do so in the event of a possible amendment of Art. 8, 9 Biotechnology Directive - either interpret Art. 25 UPCA in conformity with the Directive or, pursuant to Art. 24 para. 1 lit. e UPCA, use national patent law to fill gaps which was enacted in implementation of Art. 8, 9 Biotechnology Directive. An amendment of the UPCA is unlikely with this regulatory structure.

The provisions of Art. 54 and 59 UPCA are decisive for the question of who has to prove that a challenged plant is a natural descendant which is not covered by the scope of protection of the patent. Art. 54 UPCA contains the general rule of the allocation of the burden of proof, according to which each party bears the burden of proof for the facts on which it relies. Accordingly, the patent proprietor bears the burden of proving that the defendant has produced a plant using a non-essentially biological process, for example by adopting the patent proprietor's biological material or using an NGT process itself. In contrast, the defendant has no burden of proof that the allegedly infringing plant originates from natural breeding, as this does not involve any other fact favoring the defendant, but merely represents the reverse side of the fact to be proven by the patent proprietor.[115] The UPCA does not provide for a reversal of the burden of proof in this constellation. [116]

At best, it would be conceivable to impose on the defendant, in accordance with the principles of the secondary burden of proof, to present facts which take place within his business and which are therefore beyond the patent proprietor's knowledge.[117] Whether the UPC will apply these

115 Metzger/Bartels, Effectiveness and scope of protection of plant patents. Effects of Rule 28 para. 2 EPÜAO, ZGE/IPJ 10 (2018), 123, 151 f.

116 Such a provision can only be found in Art. 55 UPCA for derivative process products, see below under 2.

117 Metzger/Bartels, Effectiveness and scope of protection of plant patents. Effects of Rule 28 para. 2 EPÜAO, ZGE/IPJ 10 (2018), 123, 151 f.

principles known from German civil procedure law is not yet foreseeable.[118] In any case, Art. 59 para. 1 UPCA provides as a procedural means that, at the request of the patent proprietor, the court may order the production of evidence by the opposing party, provided that the patent proprietor has submitted all reasonably available evidence to sufficiently substantiate his claims. In particular, the obligation to produce evidence may also include the documentation of the breeding.[119] However, the court must ensure the protection of confidential information, which is also generally expressed in Art. 58 UPCA. The court has discretion in the choice of confidentiality protection measures; in particular, the number of persons to whom the evidence is made accessible can be limited.[120] If the party obliged to produce the evidence fails to comply with the order, the court must take this failure into account when deciding on the matter in question. [121]

A restriction of the submission of evidence pursuant to Art. 59 para. 1 UPCA for breeders (B1) would require an amendment to the UPCA and also to the underlying Enforcement Directive 2004/48/EC,[122] which is unlikely to be achieved in the short term. On the other hand, possible clarifications of the protection of breeders' secrets, if these were included in the Biotechnology Directive, would have to be taken into account by the UPC within the scope of its discretionary powers when applying Art. 58 UPCA. [123]

2. Limited derivative product protection for NGT process patents

The UPCA contains a general provision on derivative product protection for process patents in Art. 25 lit. c UPCA and a general rule on the reversal of the burden of proof in Art. 55 UPCA. Specific provisions for the implementation of Art. 8, 9 of the Biotechnology Directive in the UPCA are already missing today and would not be achievable in the short term even if the Bio-

118 For German law, see Grabinski/Zülch/Tochtermann, in: Benkard, Patentgesetz, 12th ed. 2023, § 139, para. 115.

119 Cf. the comments on Art. 43 TRIPS, supra D. II. 1.

120 According to Rule 262A para. 6 UPC Rules of procedure, however, at least one natural person and one legal representative must be granted access.

121 Rule 190 para. 7 UPC Rules of procedure

122 See there Art. 6.

123 Cf. Augenstein, in: BeckOK Patentrecht, 33rd edition, 2024, Art. 58 UPCA, para. 15. The obligation to take such clarifications into account would arise from Art. 24(1) lit. a UPCA.

technology Directive were amended due to the nature of the agreement under international law. Therefore, the only way to implement any amendments would be either to interpret Art. 25, 55 UPCA in conformity with the Directive or to use harmonized national patent law to fill gaps in accordance with Art. 24 para. 1 lit. e UPCA.

3. Extension of the breeder's privilege

Art. 27 lit. c UPCA contains a limited breeder's privilege, which permits the use of biological material for the purpose of breeding, discovering or developing other plant varieties, but does not provide for any restriction of the patent right for subsequent propagation and distribution. In this respect, the subsequent breeder is dependent on obtaining a license from the owner of the patent for the material used.[124] An extension of the breeder's privilege to commercialization (B3) would require an amendment to the UPCA, which, in view of the treaty nature of the UPCA and the very lengthy negotiations on the way to the agreement, is unlikely to be achieved in the short term.

4. Compulsory licenses for breeding new varieties

The UPCA does not contain any provisions on compulsory licenses, so that the regulations of the member states and the provisions of the Biotechnology Directive remain applicable in this respect.

5. Limitation of the patent proprietor's claims in the absence of cooperation

The UPCA does contain detailed provisions on the powers of the court in the event of patent infringements, which also provide the basis for the individual claims of the patent proprietor, namely the injunction in Art. 63 UPCA and damages in Art. 68 UPCA. However, corresponding provisions on the possible objections of the actual or alleged patent infringer are largely missing. The requirement of "fair and balanced" application of the legal remedies in Art. 42 para. 2 UPCA and the consideration of the interests of both parties in Art. 56 para. 2 UPCA relate to the proceedings and do not provide a basis for restricting the claims in substantive terms with a view to an abuse of rights by the patent proprietor or an exercise of rights in bad faith. However, this cannot mean that alleged or actual patent infringers cannot raise any objections to the patent proprietor's claims. Parallel to the lively discussion in recent years on the question of whether the UPC may

124 Kiefer, in: BeckOK Patentrecht, 33rd edition, 2024, Art. 27 UPCA, para. 18.

or must examine proportionality when issuing injunctions,[125] it is well justifiable to consider the UPC obliged to interpret the remedies of the UPCA in conformity with Union law in the light of the general legal principles of good faith or the refusal of an abusive assertion of rights, see Art. 3 para. 2 Enforcement Directive.[126] If interpreted accordingly, the UPCA already provides the legal basis to refuse a patent proprietor an injunction or, in the case of claims for damages, to deny a breach of the duty of care if a breeder has previously requested information about patents in a reasonable manner and with sufficient notice and the patent proprietor refuses to provide the relevant information. A clarification (B5) in the Biotechnology Directive would also have to be taken into account by the UPC.

6. Transparency register for plant patents

The UPCA does not contain any provisions on patent information and would not be affected by a corresponding obligation for patent proprietors.

IV. Compatibility with the Biotechnology Directive 98/44/EC, possible amendments

1. Patentability of biological offspring, evidence

The legislator could clarify by amending Art. 8 of the Biotechnology Directive that biological offspring which have the same properties or the same gene sequence as the patented plant are excluded from the scope of protection of the patent (B1). The wording, system and legislative history already permit such an interpretation of Art. 8 today, as the provision states that only biological material from breeders which has been produced from the material of the patent proprietor ("from that biological material") and has the same characteristics falls within the scope of protection of a patent.[127] However, this narrow interpretation of Art. 8 is controversial, making it diffi-

125 See Dijkman, Unterlassungsverfügung im Einheitspatentsystem, GRUR 2023, 1737, 1738; Leistner, Unterlassungsverfügung im Einheitspatentsystem, GRUR 2022, 1633; Ohly, Injunctions in the UPC and the principle of proportionality Stockholm Intellectual Property Law Review Vol. 5 (2022), 58.

126 "Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a way as to avoid the creation of barriers to legitimate trade and to ensure that they are not abused."

127 Metzger, Der Schutzumfang von Patenten auf Pflanzen nach den EPA-Entscheidungen "Brokkoli II"/"Tomate II", GRUR 2016, 549, 552 f.; see also Metzger/Bartels, Wirksamkeit und Schutzumfang von Pflanzenpatenten. Auswirkungen der Regel 28 Abs. 2 EPÜAO, ZGE/IPJ 10 (2018), 123, 142-144.

cult to predict how a court and ultimately the ECJ would position themselves on this issue.[128] In order to eliminate this uncertainty, the European Parliament proposes in its resolution of 7.2.2024 to add a paragraph to Art. 8 clarifying that biological material with the same properties but obtained independently of the patented biological material and by an essentially biological process should not be covered:

> *Art. 8 Draft Biotechnology Directive (EP resolution of 7.2.2024)*
> *(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.*[129]

The French Patent Act already contains a corresponding clarification.[130] The regulation would have a limited impact, as the EPO has already ensured that plants derived from classical breeding are excluded from the patent claims when granting patents since Rule 28 para. 2 EPC IR came into force. In this respect, the addition to Art. 8 of the Biotechnology Directive would be of particular importance for patents granted before July 1, 2017, which may cover plants derived from essentially biological processes.

Due to the open wording of the current version of Art. 8 of the Biotechnology Directive, it would also be conceivable to leave the text of the directive unchanged and work towards an interpretation that excludes plants from classical breeding from the scope of protection by means of a corresponding communication from the Commission. [131]

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128 In contrast, Kock/Zech, Pflanzenbezogene Erfindungen in der EU – aktueller Stand, GRUR 2017, 1004, 1010 f.

129 If one understands the exclusion of plants from technical processes that resemble natural breeding proposed by the European Parliament as a new Art. 9 para. 2 Biotechnology Directive, see Art. 33a para. 3 of the EP resolution of 7.2.2024, as a regulation on the scope of protection - which is supported by its systematic position - then its regulatory content would be covered by the proposed Art. 8 para. 3.

130 Article L613-2-3 Code de la propriété intellectuelle: "La protection conférée par un brevet relatif à une matière biologique dotée, du fait de l'invention, de propriétés déterminées ne s'étend pas aux matières biologiques dotées de ces propriétés déterminées, obtenues indépendamment de la matière biologique brevetée et par procédé essentiellement biologique, ni aux matières biologiques obtenues à partir de ces dernières, par reproduction ou multiplication."

131 The Commission Communication of November 8, 2016, OJ C 411/03 could serve as a model in this respect.

However, the European Parliament does not want to leave it at the clarification in Art. 8 of the Biotechnology Directive, but would like to go much further by amending Art. 9:

> *Art. 9 para. 3 Draft Biotechnology Directive (EP resolution of 7.2.2024)*
> *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..*

Such a provision would lead to the de facto exclusion of NGT plants from patent protection, because the scope of protection of the patent claim would not only be restricted with regard to products in which the genetic information is contained as a result of an essentially biological process, but direct transfers of the patent-protected gene sequence would also be excluded as soon as a plant with the same gene sequence has been or can be produced by the defendant (or a third party) by conventional means. The extent of this limitation can be seen from the more detailed definition of NGT plants in category 1 in the Commission proposal. These are only to be exempted from strict GMO regulation if they are "equivalent to naturally occurring plants", which according to recital 14 means that they "could also occur naturally or be produced by conventional breeding techniques". If this statement is taken literally, the criteria for classification as an NGT plant category 1 set out in Annex I to the Commission proposal are equivalent to classification as a plant that could be obtained by an essentially biological process. This would indirectly lead to the scope of protection for gene sequences from category 1 genetically modified plants being reduced to zero.[132] In view of Union law alone, such an indirect exclusion seems conceivable. However, the question then arises as to whether the EPC and the principle of good faith would be violated if 27 Member States were to deny a patent of the EPO any protection under patent law.

The Biotechnology Directive does not contain any provisions on the burden of proof or the presentation of evidence - apart from the provision on derivative process products discussed below. In this respect, reference can be made to what has been said about the UPCA with regard to the submission of evidence pursuant to Art. 6 of the Enforcement Directive 2004/48/EC. Beyond this, the application of the national procedural law of the Member States remains applicable.

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132 Critical also Kock, EU Parliament on Patents for NGT-Derived Plants: Pawn Sacrifice or Sacrificed to the Pawns?, Bio-Science Law Review 19 (2004), 127, 136.

2. Limited derivative product protection for NGT process patents

Art. 8 para. 2 of the Biotechnology Directive stipulates for the protection of derivative process products in the field of biology that a patent for a process which "makes it possible to obtain biological material endowed with certain properties by virtue of the invention" also covers the biological material "directly obtained by that process and any other biological material endowed with the same properties which is obtained by generative or vegetative propagation in an identical or different form from the directly obtained biological material". The provision thus specifies for the field of biology that only those manufacturing processes which enable the production of biological material "with certain characteristics" are covered by the products obtained by them. This provides a starting point for excluding general NGT processes, which are not aimed at producing certain properties in certain plants, from derivative product protection. A clarification in the directive or a communication from the Commission (B2) could provide legal certainty here.[133]

For patent claims on special NGT processes for breeding certain plant characteristics, on the other hand, a derivative product claim could be considered if the modified gene sequence resulting from the NGT process is found in the plant produced. If, on the other hand, the gene sequence or property is contained in the defendant's plant, but this originates from essentially biological breeding, then patent infringement is already ruled out under current law. The plant has then not been obtained directly by the patented process. In its resolution of February 7, 2024, the European Parliament proposed adding a paragraph 4 to Art. 9 to restrict the scope of derivative product protection:

> *Art. 9 para. 4 Draft Biotechnology Directive (EP resolution of 7.2.2024)*
> *(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.*

The proposal goes beyond the current legal situation because it would not only restrict the patent claim with regard to products in which the genetic information is contained as a result of an essentially biological process, but would also exempt direct transfers of the gene sequence as soon

133 See also Kim/Kock/et al, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector, GRUR Int. 2024, 323, 330.

as a plant with the same gene sequence has been or can be produced by the defendant or a third party by conventional means. With regard to processes used for the production of NGT plants of category 1, derivative product protection would thus be de facto excluded, as already explained in more detail in connection with Art. 9 para. 3 of the draft Biotechnology Directive as amended by the European Parliament.[134]

The Biotechnology Directive does not contain a separate provision on the allocation of the burden of proof for derivative process products, but refers in recital 54 to the provision in Art. 34 TRIPS. Art. 34 TRIPS places the burden of proof on the alleged infringer in the case of an identical product that it was produced by a different process. The Biotechnology Directive would have to be supplemented by a suitable burden of proof provision if the regulations on derivative product protection were to be amended. According to the new Art. 9 para. 4 Biotechnology Directive (draft) proposed by the EP, it would no longer depend on whether the alleged infringer has used another process, but whether an essentially biological production of the genetic information has already been achieved or is possible. According to the general principle of the burden of proof, according to which each party bears the burden of proof for the facts on which it relies, see Art. 54 UPCA, the alleged infringer would have to prove this.

3. Extension of the breeder's privilege

The Biotechnology Directive does not yet contain any provisions on exceptions to patent law for breeders. The various regulations in the member states - in Section 11 No. 2a of the German Patent Act, Art. L. 613-5-3 of the French Code de la Propriété Intellectuelle, Art. 54c lit. c of the Dutch Rijksoctrooiwet, Section 22 para. 1a Austrian PatG - and in Art. 27 lit. c UPCA have been introduced "alongside" the Directive, which is certainly problematic in view of the fully harmonizing nature of the Directive, but has not yet been critically addressed.

If the Biotechnology Directive is reformed, the widely undisputed limited breeder's privilege should be included in the text of the Directive in order to create a corresponding legal basis for the above-mentioned Member State regulations and the UPCA. The introduction of an unrestricted breeder's privilege (B3), which also permits the commercialization of derived varieties,

134 Supra D. IV. 1.

would be not without doubt with regard to its compatibility with Art. 30 TRIPS and, if nevertheless adopted in the Biotechnology Directive, would have to be implemented in the UPCA.[135]

4. Compulsory licenses for breeding new varieties

With regard to a possible adaptation of the requirements for the granting of a compulsory license to the model of Art. 36a of the Swiss Patent Act (B4), reference can be made to the comments on Art. 31 lit. l TRIPS.[136] Replacing the criterion of "significant technical advance of considerable economic importance" in Art. 12 para. 3 lit. b of the Biotechnology Directive with the criterion of "terrestrial value" from European seed marketing law would be compatible with the TRIPS Agreement and would make the regulation of compulsory licenses easier to handle for breeders because it would draw on concepts from plant variety protection law.

If the Biotechnology Directive is amended, the provision in Art. 12 para. 3 lit. b should be adapted accordingly. Alternatively, it would also be conceivable to leave the text of the directive unchanged and work towards such an interpretation by means of a corresponding communication from the Commission. [137]

5. Limitation of the patent proprietor's claims in the absence of cooperation

The Biotechnology Directive does not contain any provisions on the enforcement of claims by the patent proprietor or on objections by actual or alleged patent infringers. In this respect, the Enforcement Directive 2004/48/EC is authoritative at European level, which, however, does not contain any specific provisions on the question of whether the patent proprietor's claims can be restricted in the event of refusal to cooperate in an FTO analysis. In this respect, only Art. 3 para. 2 of the Enforcement Directive, which stipulates that sanctions for infringements of intellectual

135 The introduction of such an unrestricted breeders' privilege is, as far as can be seen, no longer demanded by the industry associations, see in particular BDP position on the design of patent protection in plant breeding of 17.1.2023, available at <www.bdp-online.de>, p. 2; CIOPORA Position on Breeders' Exemption v. 2.4.2014, <www.ciopora.org/_files/ugd/53e3d5_ea7d8e9e0384497eaa7d7bfb73d57b92.pdf>; Euroseeds View on Intellectual Property v. 4.6.2024, available at <https://euroseeds.eu/app/uploads/2024/06/24.0386.3-Euroseeds-view-on-IP.pdf>. The Dutch plant breeders' association Plantum, Plantum NL position on patent- and plant breeders' rights v. 6.5.2009, available at <cucurbitbreeding.wordpress.ncsu.edu/files/2016/04/plantum-nl-position-on-patent-and-plant-breeders-rights.pdf>.

136 Supra D. II. 4.

137 The Commission Communication of 8.11.2016, OJ C 411/03 could serve as a model in this respect.

property rights must be proportionate and abusive assertion must be avoided, can currently be used as a basis. Precise regulations in the Biotechnology Directive (B5) could strengthen the position of defendants who have asked the patent holder in vain for information about patents to be observed and are later sued on the basis of precisely these rights.[138] On the one hand, such a regulation should restrict the right to injunctive relief and instead provide for appropriate compensation in the form of damages,[139] on the other hand, it should make it clear that the defendant cannot be at fault in the context of claims for damages if information on patents has previously been refused. However, the restrictions should be linked to the condition that the patent proprietor is requested to provide information in an appropriate manner - in particular by specifying the exact biological material of the patent proprietor that is to be used for further breeding - and by setting appropriate deadlines.

6. Transparency register for plant patents

The European legislator could introduce an obligation for patent holders to enter patents on varieties or other biological material in a register. Such information could be required when registering varieties for approval under seed marketing law. In this way, the variety owners' own patents would in any case be covered, but not third-party patents.[140] Nevertheless, such an obligation could achieve a significant improvement in transparency compared to the current approach of merely voluntary disclosure in the PINTO database. If a corresponding transparency obligation were introduced, a violation could be sanctioned with the restrictions of the patent holder's claims discussed under 5.[141] A combination of the two approaches would also be conceivable,

138 In Switzerland, a review request entitled "More transparency in patent rights in the field of plant breeding" was submitted to the Federal Council, see Motion 22.3014 of 1.2.2022, Official Bulletin of the Federal Assembly, Spring Session 2022, Supplements, p. 365, available at <www.parlament.ch/centers/documents/de/SR_5113_Annex_D.pdf>.

139 Cf. art. 12 Enforcement Directive: "Member States may provide that the competent courts may, in appropriate cases and at the request of the person on whom the measures provided for in this Section could be imposed, order that compensation be paid to the injured party instead of the application of the said measures, provided that the person concerned has not acted intentionally or negligently, that he would suffer disproportionate damage from the application of the measures in question and that the payment of compensation to the injured party appears to be adequate reparation."

140 Kock, Intellectual Property Protection for Plant Related Innovation: Fit for Future?, 2022, 287 .

141 The Commission's proposal for a Regulation on standard-essential patents of 27 April 2023, COM(2023) 232 final, goes further in Art. 24 (1) and para. 2: If a patent proprietor fails to have a standard-essential patent entered in the register, claims for injunctive relief and damages are excluded completely and wi-

establishing an obligation to cooperate in FTO analyses as a principle and an exemption from the obligation with regard to information in the transparency register as an exception. As a further alternative approach, an obligation for patent holders to provide their plants or products with a reference to patents relating to the product and to assume restrictions on claims in the event of infringement in the absence of a reference would also be conceivable.[142]

V. Options for action at national level

In view of the fully harmonizing nature of the Biotechnology Directive, the scope for the national legislator to restrict the scope of protection is very limited, whereby this scope arises from the interpretation of the individual articles of the Directive, which have not yet been confirmed by the European Court of Justice or the German courts as being in conformity with EU law. In the interests of legal certainty, clarification at European level would therefore be preferable.

The national legislator could clarify the patent exemption of biological offspring (B1) by making a corresponding addition to Section 9a para. 1 PatG. As explained above, such a restriction of the scope of protection is compatible with Art. 8 para. 1 of the Biotechnology Directive according to the controversial view expressed here. The French legislator has included such a clarification in the Code de la Propriété Intellectuelle.[143] It would also be up to the national legislator to introduce special regulations on the burden of presentation and proof with regard to natural descendants, since apart from the special case of derivative process products, no European or international requirements have to be observed. However, this would not change the European requirement to provide evidence under Section 140c PatG, which is based on Article 7 of the Enforcement Directive.

With regard to NGT processes, the legislator could clarify that general NGT process patents are to be classified as working processes and not as manufacturing processes, so that plants cultiva - ted with the aid of the processes do not constitute derivative process products (B2). Such a clarification could be included in Section 9a para. 2 PatG. However, changes to the allocation of the

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thout compensation.

142 Thus Section 287 US Patent Act.di

143 Article L613-2-3 Code de la propriété intellectuelle, supra footnote 130.

burden of proof for direct products from specific NGT processes would contradict Art. 34 of the TRIPS Agreement, to which the Biotechnology Directive refers in recital 54.

An extension of the breeder's privilege (B3) would not conflict with European law, but could be challenged with regard to Art. 30 TRIPS, as explained in detail above. On the other hand, specifying the requirements for compulsory licenses for the breeding of new varieties (B4) along the lines of the Swiss model (Section 36a of the Swiss Patent Act) would be compatible with Art. 12 para. 3 of the Biotechnology Directive if interpreted accordingly.

If the patent proprietor refuses to cooperate in an FTO analysis of a breeder, the limitations of the claims (B5) discussed above already result from the applicable law. Since 18 August 2021, injunctive relief in patent law has been subject to the proviso of proportionality pursuant to Section 139 para. 1 sentence 3 PatG, whereby the prior conduct of the patent proprietor is recognized as a criterion when weighing up the interests of the parties.[144] A patent proprietor who does not respond to a precise inquiry about the patent status of certain plant varieties of the patent proprietor within a reasonable period of time or provides incorrect information cannot later claim injunctive relief against the breeder making the inquiry if the breeder uses the variety in question in his breeding program and has relied on the patent exemption. In this case, however, the breeder remains obliged to pay reasonable compensation in accordance with Section 139 para. 1 sentence 4 PatG. In this case, claims for damages pursuant to Section 139 para. 2 fail due to the lack of fault on the part of the breeder: Anyone who locates and contacts the owner of potentially affected patents may rely on the lack of patent protection if no information is provided or may invoke contributory negligence on the part of the patent owner pursuant to Section 254 para. 2 sentence 1 BGB.[145] An explanation in the explanatory memorandum of the next amendment to the Patent Act should be sufficient to clarify this and would be preferable to a small-scale amend - ment to the generally formulated provision of Section 139 PatG.

The introduction of a mandatory transparency register for plant patents (B6) would be possible at national level. There are no European or international requirements in this respect. For example, it would be conceivable to link entry in such a register to the application for certification of a va - riety under the Seed Marketing Act. However, the details would then have to be examined more

144 Explanatory memorandum to the government draft of the Second Act on the Simplification and Modernization of Patent Law, printed matter 19/25821, 54.

145 See OLG Düsseldorf GRUR-RR 2002, 121, 125 (on copyright).

closely with regard to the various European seed directives,[146] especially if the information in the transparency register is to be declared a prerequisite for certification as seed. It should also be noted here that certification can also take place in another EU Member State, so that an EU-wide regulation would have clear advantages.[147] However, an otherwise regulated and sanctioned obligation to provide information to a transparency register, for example with fines or restrictions on the subsequent enforcement of corresponding patents, would be legally possible.

146 See, for example, Regulation 2002/55 of 13.6.2002 on the marketing of vegetable seed.

147 The current reform of European seed marketing law, supra footnote 111, would provide a suitable framework for this.

E. RESULTS AND OPTIONS FOR ACTION

The study has shown that, despite the dense network of regulations at international, European and national level, there is certainly scope for restricting patent protection for plants. This scope lies less in patent exclusions than in the restriction of their scope of protection. In the following, various options for restricting patent protection are presented, whereby, in accordance with the mandate of the expert opinion, only the possibilities of legally secure implementation are considered and no recommendations are made:

A1: A "full exclusion" of plants, plant varieties and their seeds would be possible under the TRIPS Agreement insofar as protection of plant varieties is granted under plant variety protection law, which is the case in Europe. However, the TRIPS Agreement obliges WTO member states to protect gene sequences and technical processes for plant breeding, i.e. not "essentially biological processes", through patents. The scope within the European patent system is narrower. According to the EPC, only plant varieties, essentially biological breeding processes and plants resulting therefrom can be excluded, but not technical processes and plants derived from technical processes, in particular NGT or mutagenesis processes and plants resulting therefrom. The Biotechnology Directive formulates the same requirements. Anyone wishing to exclude plants derived from technical breeding processes from patent protection would therefore have to amend the EPC and the Biotechnology Directive. Only then would there be scope for national legislators.

A2: An exclusion of natural plants and gene sequences from technical inventions would be compatible with the TRIPS Agreement, in particular because other WTO member states also assume such an interpretation of the agreement. According to its wording, the EPC would also allow plants and gene sequences occurring in nature to be excluded from the term "invention". In this respect, however, the EPC IR and the case law of the EPO have so far stood in the way. Unlike the TRIPS Agreement and the EPC, the Biotechnology Directive explicitly states in its wording that biological materials occurring in nature and isolated for the first time, including gene sequences, are eligible for protection. The Directive would have to be amended in order to achieve a corresponding exclusion. Until then, there are no options for action for the national legislator.

A3: The European Parliament has proposed to exclude NGT plants from patent protection. Such an exclusion would be compatible with the TRIPS Agreement as long as at least plant variety protection is granted for these plants. On the other hand, the exclusion would be contrary to the EPC in its current form because the plants in question are not varieties or plants derived from essentially biological processes. As long as the Biotechnology Directive has not been amended, such exclusions would also be incompatible with Union law, so that there is no leeway for national legislators in this respect.

A4: The exclusion of plants derived from non-directed mutagenesis, also proposed by the European Parliament, would be compatible with the TRIPS Agreement as long as at least plant variety protection is granted. However, according to the prevailing but controversial view, such an exclusion would not be compatible with the EPC because it does not concern plants derived from essentially biological processes. The same applies to the Biotechnology Directive, unless one follows the view of the Austrian legislator, which considers an exclusion to be compatible with the Directive. In the interests of

legal certainty, such an exclusion should be expressly enshrined in the Directive if this proposal is to be implemented. Without an amendment to the Directive, national regulations based on the Austrian model are - at least according to the prevailing opinion in patent law literature - contrary to European law.

A5: An exclusion of patented plants from NGT liberalization, as proposed by the Belgian Council Presidency, would be compatible with the TRIPS Agreement, the EPC and the Biotechnology Directive. However, doubts arise with regard to the general principle of proportionality under EU law..There is no leeway for national legislators in view of the harmonization of European genetic engineering law.

A6: A tightening of the public policy reservation with regard to ethical objections to the patenting of plants would in principle be compatible with the TRIPS Agreement and the EPC, for example if this clarification were made by supplementing the EPC IR. The advantage of such an approach would be that the EPC would not have to be amended. However, the case law of the Boards of Appeal on public policy has so far been very restrictive. If the legislator is more concerned with the need for freedom to operate in the interests of breeders, farmers and biodiversity, a separate exclusion in Art. 53 EPC would be more appropriate. Any tightening of the public policy proviso at national level would have to be measured against Art. 6 para. 1 of the Biotechnology Directive. The effects of such an approach would be limited because the EPO would not cover the granting of patents.

A7: The TRIPS Agreement only contains the patenting requirements of novelty and inventive step in a very general form and leaves considerable scope for clarification at the level of Member State law, for example to ensure that patents are not granted for plants or genetic resources that are identical or similar to naturally occurring, already known plants. The EPC contains corresponding provisions, but could be supplemented by an amendment to the EPC IR to include provisions on the disclosure of the origin of biological material. These could also implement the provisions of the WIPO Treaty on genetic resources and traditional knowledge. The Biotechnology Directive does not yet contain an obligation to disclose. In contrast, the German legislator has already included such an obligation in the Patent Act.

The overall view of the patent exclusions and patentability requirements shows that the following measures would be possible by amending the Biotechnology Directive without violating the TRIPS Agreement or the EPC: an exclusion of natural plants and gene sequences (A2), an exclusion of patented plants from NGT liberalization (A5), a tightening of the public policy proviso (A6) and an obligation to disclose the origin of biological material (A7). On the other hand, an exclusion of NGT plants from patent protection would not be compatible with the EPC (A3). According to the prevailing opinion, this also applies to plants derived from non-directed mutagenesis (A4). The same applies to an even more far-reaching full exclusion of all plants, plant parts, gene sequences and processes (A1).

At the level of national law, no changes with significant effects would be possible without amending the Biotechnology Directive or European genetic engineering law.

The following picture emerges for the scope of protection:

B1: A clarification by the legislator that biological offspring with the same properties or the same gene sequence as a patented plant are excluded from patent protection would be compatible with the TRIPS Agreement. The EPC does not contain any provisions on the enforcement of patents and would not be affected by this. If the European legislator were to add such a clarification to the Biotechnology Directive, as proposed by the European Parliament, this would only have an impact on old cases (applications filed before July 1, 2017) due to Rule 28 para. 2 EPC IR, according to which plants derived from essentially biological processes are excluded from patent protection. According to the view expressed here, the national legislator could also include such a clarification in the Patent Act, as the Biotechnology Directive already permits this today. A more far-reaching exclusion of plants that have the same properties as plants that have been or can be produced in the traditional way, as also proposed by the European Parliament, would, on the other hand, reduce the scope of protecti - on for gene sequences from NGT plants of category 1 to zero. This can be seen as a violation of the EPC and the principle of good faith, because 27 member states would then deny any patent protection to an EPO patent.

The TRIPS Agreement, the EPC and the Biotechnology Directive do not contain any provisions regarding the burden of proof of a natural descendant. The burden of proof under the UPCA and natio - nal law therefore lies in principle with the patent proprietor, who must prove that the (alleged) infringer's plant originates from a technical process. Irrespective of the burden of proof, however, the patent proprietor can request the submission of evidence under TRIPS, the UPCA, the Enforcement Directive and the Patent Act, which may also include the breeding books. There would be scope here at the level of the Biotechnology Directive to provide for special regulations on the protection of secrets.

B2: The legislator could clarify at all levels that general NGT process patents are to be classified as working processes and not as manufacturing processes, so that plants bred using the processes do not constitute derivative process products. For other NGT processes that teach the production of certain traits in plants and are therefore subject to the rules on derivative product protection, changes to the burden of proof rules would be possible, according to which the breeder has the burden of proof to have used a different process for an identical product. In this respect, the TRIPS Agreement would al - low an exception for plants, so that the European legislator would not have to observe any require - ments from international law. However, the UPCA would have to be amended or, if only the Biotechnology Directive were to be amended, the UPCA would have to be interpreted accordingly.

B3: An extension of the breeder's privilege with regard to the dissemination of the resulting new plant variety would be doubtful in light of the provision of the TRIPS Agreement on limitations in Art. 30. and, if nevertheless adopted in the Biotechnology Directive, would have to be implemented in the UPCA as well.

B4: The legislator could follow the example of Switzerland (see Section 36a of the Swiss Patent Act) and specify the requirement of "important technical advance of considerable economic importance" for the granting of a compulsory license to the effect that the breeding of a new variety that is eligible for approval under seed law constitutes such progress. Such a specification would be conceivable both at the level of European law, specifically the Biotechnology Directive, as well as national law.

B5: The European legislator could restrict the patent proprietor's claims if they do not respond to requests as part of a freedom-to-operate analysis or provide incorrect information on the patent status of biological material. Such a regulation would not be precluded by any provisions of international law (TRIPS Agreement). German law already regulates patent claims and the infringer's objections so flexibly that no amendment to the Patent Act would be necessary.

B6: The introduction of a mandatory transparency register for plant patents for all patents on plants, plant varieties, gene sequences and the breeding techniques used would be possible at both European and national level. The international treaties do not stand in the way of this.

Overall, this means that the following measures would be possible for the scope of protection by amending the Biotechnology Directive without violating the TRIPS Agreement or the EPC: A clarification that biological offspring are not covered by product patents (B1), a clarification that general NGT process patents are to be classified as working processes and not as manufacturing processes (B2), a change to the burden of proof rule for derivative process products from specific NGT processes (B2), a clarification of the provisions on compulsory licenses to the effect that the breeding of a new variety that can be licensed under seed law constitutes an "important technical advance of considerable economic significance" (B4), a provision that sanctions the refusal of the patent holder to cooperate in an FTO analysis with a restriction of his claims (B5) and the introduction of a mandatory transparency register (B6). On the other hand, a restriction of the scope of protection with regard to plants that have the same properties as plants that have been or can be produced by conventional means would not be compatible with the EPC (B1). A broad breeders' privilege (B3) would be doubtful with regard to Art. 30 TRIPS and, if nevertheless adopted in the Biotechnology Directive, would have to be implemented in the UPCA as well.

At the level of national law, it would be possible to exclude natural progeny (B1), clarify general NGT working methods (B2), adapt the compulsory licensing system along the lines of the Swiss model (B4) and introduce a mandatory transparency register (B6) without amending the Biotechnology Directive.