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TITLE: EPO practice for plant- and animal-related inventions: status report

SUBJECT: Exception to patentability under Article 53(b) and Rule 28(2) EPC of plants and animals exclusively obtained by means of an essentially biological process following opinion G 3/19 of the Enlarged Board of Appeal

SUBMITTED BY: President of the European Patent Office

ADDRESSEES: Committee on Patent Law (for information)

MAJORITY: Not applicable

LEGAL BASIS: Not applicable

RECOMMENDATION: The Committee on Patent Law is requested to take note of the information provided by the EPO about its examination practice for inventions concerning plants and animals.

SUMMARY: Following on from CA/PL 4/20, 3/21, 20/22 and 11/23, the EPO aims to further inform contracting states about its examination practice in the area of plant- and animal-related inventions and the implementation of opinion G 3/19 (Pepper) of the Enlarged Board of Appeal. The present document recalls the practice of the EPO in relation to applications with an effective filing date on or after 1 July 2017 and provides an updated overview of the status of proceedings to which Rule 28(2) EPC does not apply. Up-to-date statistics on European patent applications relating to genetically modified plants, conventional plants and plant breeding are provided.

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1. Introduction

1. Under Article 53(b) of the European Patent Convention (EPC), European patents will not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals. Since 1 July 2017, Rule 28(2) EPC clarifies that under Article 53(b) EPC European patents will not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

2. In opinion G 3/19 of 14 May 2020, the Enlarged Board of Appeal of the EPO ("Enlarged Board") clarified that plants, plant material and animals are excluded from patentability under Article 53(b) EPC if the claimed product is exclusively obtained by means of an essentially biological process. In order to ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants, the Enlarged Board further decided that this patentability exception could not be applied to European patents granted before 1 July 2017, when Rule 28(2) EPC entered into force, or to pending European patent applications which were filed or validly claimed priority before that date.

3. In the meeting of the Committee on Patent Law in November 2020, the EPO informed delegations about the implementation of opinion G 3/19 in the practice of examining and opposition divisions (CA/PL 4/20 with Add. 1). The underlying document was noted, and delegations agreed to monitor developments to enable an evidence-based debate. In the meetings of the Committee on Patent Law in November 2021, 2022 and 2023, further reports on the implementation of opinion G 3/19 and the EPO's examination practice in the area of plant- and animal-related inventions were provided. These reports included statistics and information on plant-related European patents granted for applications filed before 1 July 2017 (CA/PL 3/21 with Add. 1; CA/PL 20/22 with Add. 1; CA/PL 11/23 with Add. 1). The present report, the fifth since publication of opinion G 3/19, provides up-to-date information on the situation.

2. Arguments

2.1 Overview

4. Since the report provided in November 2023, the EPO has continued to apply Article 53(b) and Rule 28(2) EPC in accordance with the decision of the Administrative Council of 2017 (CA/D 6/17) and opinion G 3/19 of the Enlarged Board. On the basis of opinion G 3/19, the law and practice are different as regards European patent applications filed on or after 1 July 2017 (point 2.2 below) and European patent applications filed before said date as well as European patents granted in respect of such applications (point 2.3 below). In addition to a report on the latest status of the Guidelines for Examination in the EPO ("Guidelines") (point 2.4 below) and the most recent statistics (point 2.5 below), this document also includes information on co-operation with the Community Plant Variety Office (CPVO) (point 2.6 below) and discussions with stakeholders as well as the EPO's contribution to the public debate (point 2.7 below).

2.2 Practice for applications with an effective filing date on or after 1 July 2017

2.2.1 No European patents in respect of plants and animals exclusively obtained by means of essentially biological processes

5. For applications filed on or after 1 July 2017 which do not validly claim a priority before that date, plants and animals exclusively obtained by means of an essentially biological process are excluded from patentability under Article 53(b) and Rule 28(2) EPC, and no European patent covering such a plant or animal is granted.

6. The patentability exception also covers parts of plants and animals exclusively obtained by means of an essentially biological process if the part in question can be used to produce whole plants or animals ("propagation" or "reproductive" material). Examples include plant seeds or, in the case of animals, fertilised ova and embryos. Plant cells or tissues are usually totipotent and capable of regenerating the full plant. Therefore, even if plant cells or cell cultures can be regarded as the product of a microbiological process, plant material which is able to propagate the full plant is excluded from patentability in accordance with the Enlarged Board's opinion G 3/19 if the plant from which the material originates has been exclusively produced by an essentially biological process.

7. A very small number of pending European patent applications relating to plants or animals exclusively obtained by means of an essentially biological process (or to propagation material of such plants/animals) have been identified with an effective filing date after 1 July 2017 and are being closely monitored and objected to during examination. In view of the applicable patentability exception under Rule 28(2) EPC, applicants appear to have adapted their filing behaviour and no longer claim plants or animals exclusively obtained by means of an essentially biological process or, in the case of international applications filed under the Patent Cooperation Treaty, drop such claims early during prosecution before the EPO as regional Office. Where such claims are present in a European patent application, the patentability exception is strictly enforced by raising an objection and pointing towards the refusal of the application or requiring the introduction of a disclaimer to explicitly exclude conventional plants/plant material from the scope of the patent (see points 13 *et seq.* below). Thus, no patents have been granted for applications relating to plants exclusively obtained by means of an essentially biological breeding process with a filing or priority date on or after 1 July 2017.

2.2.2 Plants and animals obtained by technical processes; use of disclaimers

8. In accordance with Rule 27(b) and (c) EPC, plants and animals (other than a plant or animal variety) obtained by means of a technical process are in principle patentable. This is in line with the corresponding provision of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("EU Biotech Directive") and the Commission Notice of November 2016 on certain articles of that directive. The trigger point for the patentability of either a plant or an animal is the technical process used, so that plants and animals produced by technical processes which modify the genetic characteristics of the plant or animal are in principle patentable.

9. Technical processes for the production of plants and animals include, for example, genetic engineering techniques as well as technically induced mutagenesis. This covers, *inter alia*, targeted molecular methods such as CRISPR-Cas. As explained in the Guidelines (GL G-II, 5.4.2), the abbreviation "NBT" (new breeding technique) is not a technical term but a general one which is used for a variety of methods, some clearly technical but others either comprising or consisting of essentially biological processes. Therefore, it is not relevant in EPO practice to differentiate between patentable and non-patentable breeding processes and resulting plants. The same applies with regard to the term "new genomic technique" (NGT).

10. To ensure that a European patent concerning a plant or an animal obtained by means of a technical process does not cover the same plant or animal exclusively obtained by means of an essentially biological process, the EPO follows the disclaimer solution described in the Guidelines (GL G-II, 5.4.2). Under this approach, if a technical feature of a claimed plant or animal might be the result of either a technical intervention or an essentially biological process, it is necessary to insert a disclaimer in the patent claim to delimit the claimed subject-matter to the technically produced product to comply with the requirements of Article 53(b) and Rule 28(2) EPC. According to an example provided in the Guidelines (GL G-II, 5.4.2.1), the disclaimer may be worded as follows: *"with the proviso that the plant/animal is not exclusively obtained by means of an essentially biological process"*.

11. Without the disclaimer, a European patent application, although concerning plants or animals obtained by means of a technical process, could be considered to cover also non-patentable plants/animals, and is therefore refused under Article 53(b) and Rule 28(2) EPC. As it is based on Rule 28(2) EPC, the disclaimer requirement is binding and strictly enforced by examiners. A disclaimer is required in all cases and even if the description only mentions a technical method of production and is silent on the use of an essentially biological process. If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a transgene, no disclaimer is necessary.

12. Since publication of the last report in November 2023, a third European patent requiring the disclaimer was proposed for grant. European patent application EP18855603 was filed on 14 September 2020 (priority date 15 September 2017) and relates to low-fibre pennycress meal. The intention to grant the patent was published in June 2024. Subject to steps to be performed by the applicant, the European patent will be granted in late 2024.

13. In addition, if a technical characteristic of a plant or animal resulting from a technical step is claimed, the description must not contain any references to essentially biological methods (such as screening wild populations or conventional breeding) as alternative methods for obtaining the claimed plant or animal. If such references are made, they must be deleted because they are not commensurate with the scope of the claim which, to be allowable, must be limited to the technically produced plant or animal. Adapting the description in this way is necessary – in addition to inserting the disclaimer in the claims mentioned above (point 10 above) – to bring the description into line with the claims (see GL G-II, 5.4).

2.3 Status of proceedings to which Rule 28(2) EPC does not apply

14. On the basis of the considerations of the Enlarged Board in opinion G 3/19 about protecting the legitimate interests of patent proprietors and applicants, Rule 28(2) EPC cannot be applied by the EPO to pending European patent applications filed or validly claiming a priority date before 1 July 2017 or to European patents granted in respect of such applications (prohibition on retroactivity).

15. The non-applicability of Rule 28(2) EPC means that a refusal of a European patent application on the ground that it relates to plants or animals exclusively obtained by means of an essentially biological process is not legally sound and that in the case of plants or animals obtained by means of a technical process the introduction of a disclaimer cannot be made a requirement (see points 13 *et seq.* above). The same applies *mutatis mutandis* in opposition proceedings. The prohibition on retroactivity laid down by the Enlarged Board is *de facto* binding for EPO practice, as confirmed by numerous decisions of the EPO's technical boards of appeal.

16. At the time of publication of opinion G 3/19 in May 2020, there were about 310 affected European patent applications pending in examination and about 10 European patents in opposition with a filing or priority date before 1 July 2017, all relating to plants. No animal-related cases affected by opinion G 3/19 existed before or have arisen since publication of that ruling. Following the gradual resumption of proceedings since May 2020, the situation regarding refusals, withdrawals, granted patents, opposition decisions and pending cases is as follows:

17. Refused European patent applications: in addition to the three cases previously mentioned, a European patent application was refused in two further cases subject to the retroactivity prohibition of opinion G 3/19.

18. Withdrawn European patent applications: the European patent application was withdrawn in 77 cases.

19. Granted European patent applications: since the last report of November 2023, a European patent has been granted (or proposed for grant) in a further 55 examination cases, 29 relating to conventional plants and 26 to technically produced plants:

- **Conventional plants**

  - (i) European patent application EP10250790 relates to soybean plants with high germination rates and ultra-low raffinose and stachyose content.

  - (ii) European patent application EP12177635 concerns improved pepper plants.

  - (iii) European patent application EP13819037 is concerned with cabbage plants resistant to clubroot.

  - (iv) European patent application EP14761579 relates to plants such as maize resistant to Helminthosporium turcicum (responsible for corn leaf blight).

  - (v) European patent application EP17739942 concerns melon plants resistant to the tomato leaf curl New Delhi virus.

- (vi) European patent application EP17838222 is concerned with specific endophytes residing in the tissues of plants and responsible for their increased fitness such as higher resistance.

- (vii) European patent application EP18174549 relates to herbicide-tolerant plants.

- (viii) European patent application EP19175414 concerns melon plants with resistance to a yellowing virus.

- (ix) European patent application EP19177524 is concerned with the generation of haploid plants (i.e. that carry only a single set of chromosomes rather than two sets, one from each parent) and improved plant breeding.

- (x) European patent application EP19187124 relates to plants resistant to Bremia.

- (xi) European patent application EP12728330 concerns pest-resistant plants.

- (xii) European patent application EP15856545 is concerned with improved flower breeding.

- (xiii) European patent application EP16733449 relates to cucumber fruit with small seed cavity.

- (xiv) European patent application EP16753578 concerns spinach plants resistant to downy mildew.

- (xv) European patent application EP18727798 is concerned with tomato plants resistant to tomato brown rugose fruit virus (which causes major problems in tomato breeding).

- (xvi) European patent application EP20156547 relates to improved seed vigour in plants.

- (xvii) European patent application EP07718255 relates to a novel Cucurbita plant.

- (xviii) European patent application EP07728037 concerns brassica oleracea plants with resistance to mycosphaerella brassicola, a plant pathogen that causes the ring spot disease of brassicas.

- (xiv) European patent application EP09716576 is concerned with agronomically elite lettuce resistant to downy mildew.

- (xx) European patent application EP10708946 relates to brassica plants resistant to campestris, a disease infecting all cultivated varieties of brassicas worldwide.

- (xxi) European patent application EP11799422 is concerned with a new broccoli plant.

- (xxii) European patent application EP13784196 concerns methods and compositions for producing plants with high sugar content.

- (xxiii) European patent application EP14741337 relates to downy mildew-resistant sunflower plants.

- (xxiv) European patent application EP15706016 is concerned with Gemini virus-resistant watermelon plants.

- (xxv) European patent application EP15719411 concerns Bremia lactucae-resistant plants.

- (xxvi) European patent application EP08741653 relates to brassica plants resistant to white dust.

- (xxvii) European patent application EP11807988 is concerned with sweet peppers resistant to water moulds.

- (xxviii) European patent application EP13707002 concerns capsicum plants resistant to tomato spotted wilt orthotospovirus.

- (xxix) European patent application EP21151638 relates to melon plants resistant to melon yellowing-associated virus.

▪ **Technically produced plants**

- (i) European patent application EP06814159 relates to soybean plants with a high beta-conglycinin content.

- (ii) European patent application EP10702906 concerns plants with improved breeding capabilities.

- (iii) European patent application EP11802063 is concerned with cabbage plants where the seeds have improved breeding capability.

- (iv) European patent application EP17726583 relates to seedless fruit plants.

- (v) European patent application EP18184232 concerns gene and protein mutations in plants.

- (vi) European patent application EP18728734 is concerned with alfalfa plants with reduced lignin content for better digestibility (lignin being an indigestible component of the plants' cell walls).

- (vii) European patent application EP10760791 relates to transgenic potato plants resistant to late blight, one of the most serious diseases in worldwide potato production.

- (viii) European patent application EP11821819 concerns tomato plants that do not produce a glycoalkaloid that is toxic to humans at high levels.

- (ix) European patent application EP12741906 is concerned with herbicide-resistant plants.

- (x) European patent application EP12846192 relates to high-amylose wheat.
- (xi) European patent application EP14198330 is concerned with herbicide-resistant plants.
- (xii) European patent application EP15722078 concerns virus-resistant plants.
- (xiii) European patent application EP15738904 relates to cucumber plants with improved shelf life.
- (xiv) European patent application EP17702591 is concerned with reduced cadmium accumulation in tobacco plants.
- (xv) European patent application EP08761211 concerns resistant melon plants.
- (xvi) European patent application EP08782920 relates to barley with low levels of gluten.
- (xvii) European patent application EP11701711 is concerned with compositions and methods for minimising nornicotine synthesis in tobacco.
- (xviii) European patent application EP15797045 concerns haploid inducers, reducing the chromosome number in the progeny of plants after fertilisation.
- (xix) European patent application EP18708396 relates to haploidisation in sorghum plants.
- (xx) European patent application EP11722368 is concerned with cucumber resistance to post-harvest deterioration.
- (xxi) European patent application EP16865304 concerns rice grains with thickened wall tissue.
- (xxii) European patent application EP17701911 relates to Papaver plants
- (xxiii) European patent application EP17719469 is concerned with high alkaloid content.
- (xxiv) European patent application EP17739712 concerns plants resistant to roundworms.
- (xxv) European patent application EP18172142 relates to herbicide-tolerant soybean plants.
- (xxvi) European patent application EP19201376 is concerned with a reversible genic male sterility trait in Asteraceae plants.

20. The former 29 cases listed above relate to plants exclusively obtained by means of an essentially biological process which are not patentable under EPO practice for applications filed on or after 1 July 2017. The latter 26 cases concern plants obtained by technical processes which, as outlined above, are patentable under current EPO practice based on Article 53(b) and Rule 28(2) EPC. However, in accordance with the prohibition on retroactivity resulting from opinion G 3/19, these 26 European patents granted or proposed for grant do not contain the disclaimer required since 1 July 2017 under Article 53(b) and Rule 28(2) EPC for the same plants exclusively obtained by means of an essentially biological process. In all 55 cases, compliance with the requirements for the grant of a European patent (including clarity, sufficient disclosure, novelty and inventive step) was thoroughly examined by the examining division consisting of three expert examiners.

21. Since 2020, the total number of European patents granted or proposed for grant in cases subject to opinion G 3/19 thus amounts to 135, 74 concerning technically produced plants and 61 relating to conventional plants. In eight cases, an opposition against the grant of the patent has been filed with the EPO (see also point 26 below). In several reported cases, the due date for filing an opposition has not yet expired. There are no relevant cases concerning animals exclusively obtained by means of an essentially biological process.

22. According to the information published in the Federated Register, European patents granted in the cases falling under the retroactivity prohibition of opinion G 3/19 are on average validated and in force in eight contracting states, including CH/LI, DE, FR, GB, NL. For some of the above-mentioned European patents granted in 2024, no reliable information on the legal status is available, since time limits for validation are still running. The EPO has no information about any invalidity or infringement actions relating either to the above-mentioned or to other plant-related patents (with or without disclaimer) pending before the court or authority of a contracting state or before the Unified Patent Court.

23. Opposition cases: in all eleven cases affected by opinion G 3/19, opposition proceedings have been concluded with the following outcome: four European patents were revoked; in five cases, the opposition was rejected and the patent maintained as granted; and in the remaining two cases, the patent was maintained in amended, more limited form. In three cases, the opposition division's decision was appealed and the appeal is still pending before the Boards of Appeal (T 2546/22; T 2178/22; T 791/24). In addition, eight new opposition cases have arisen in relation with European patents granted for plant-related applications filed before 1 July 2017 (see point 23 *ad finem* above). In five cases, the opposition proceedings were concluded by revoking the patent (one case), by rejecting the opposition (one case), because the opposition was deemed not filed (one case) or withdrawn (two cases); in one case, the decision has been appealed (T 2049/23 relating to bushy watermelons). Overall, the total number of pending opposition or opposition-appeal proceedings against European patents granted in the non-retroactivity cases amounts to eleven.

24. Pending cases: in addition to the aforementioned pending opposition cases, approximately 160 affected examination cases are still pending, about 100 concerning conventional plants and roughly 60 relating to technical mutant plants. About 220 cases have been concluded since the resumption of proceedings in 2020 (refusals, withdrawals and grants, see points 20-23 above). The number of still-pending examination cases can be explained by the fact that divisional applications are being filed. A divisional application benefits from the filing and priority date of its parent application with the consequence that, if the relevant date is before 1 July 2017, it falls under the retroactivity prohibition of opinion G 3/19. Another reason for the number of pending cases is the time factor: applications and the underlying inventions have to be strictly examined for compliance with all requirements of the EPC. Proceedings can only be concluded under Article 97(1) or (2) EPC once it has been examined if the general patentability requirements such as novelty, inventive step, sufficient disclosure and clarity are fulfilled, and the applicant has been given the right to be heard in this regard.

2.4 Guidelines for Examination in the EPO

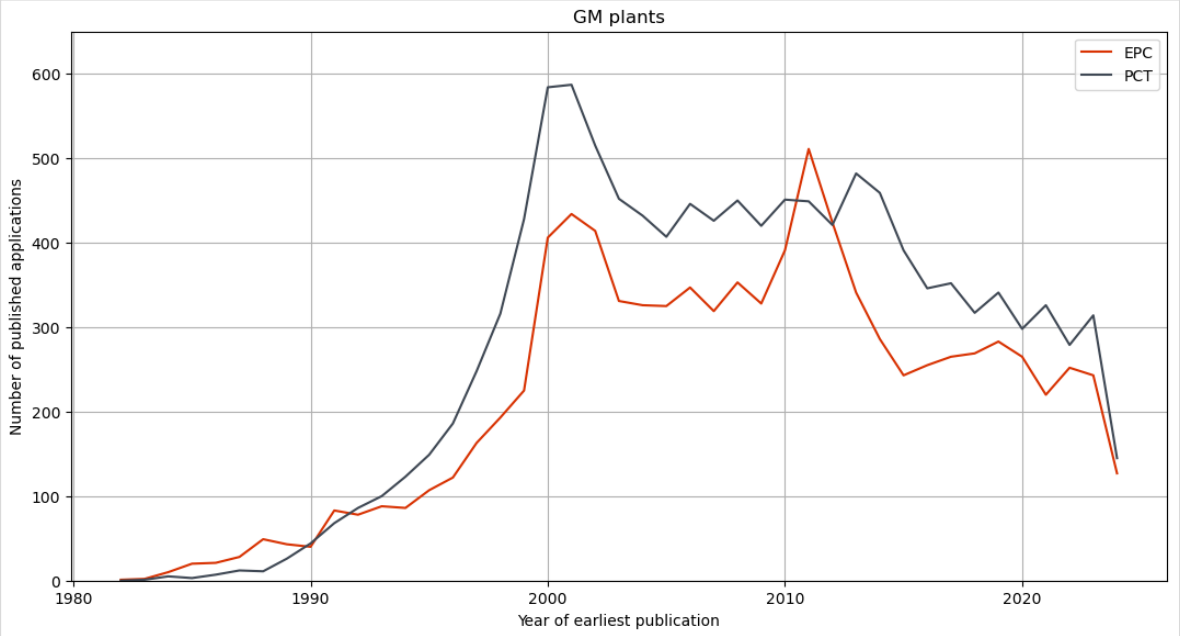
25. In 2021, 2022 and 2023, the EPO updated the relevant sections of the Guidelines to provide further clarification on its examination practice for plant- and animal-related inventions. Notably, more information on the disclaimer requirement was included, together with an example (GL G-II, 5.4 and 5.4.2.1). Another important amendment concerned the clarification that, irrespective of their microbiological character, totipotent plant cells or tissues originating from a plant exclusively obtained by an essentially biological process are excluded from patentability under Article 53(b) and Rule 28(2) EPC (GL G-II, 5.5.1). In the 2023 edition of the Guidelines, the EPO clarified the need to delete from the description any references to essentially biological methods (such as screening wild populations or conventional breeding) (see GL G-II, 5.4 and point 16 above).

26. Discussions with the users took place in the SACEPO (Standing Advisory Committee before the EPO) Working Party on Guidelines and an open online consultation was conducted on comments and change proposals relating to the Guidelines. This time, no need was identified for further clarification on the EPO's examination practice in the area of plant- and animal-related inventions, primarily because of the comprehensive revisions made between 2021 and 2023 (see point 27 above). The updated version of the Guidelines entered into force on 1 March 2024.

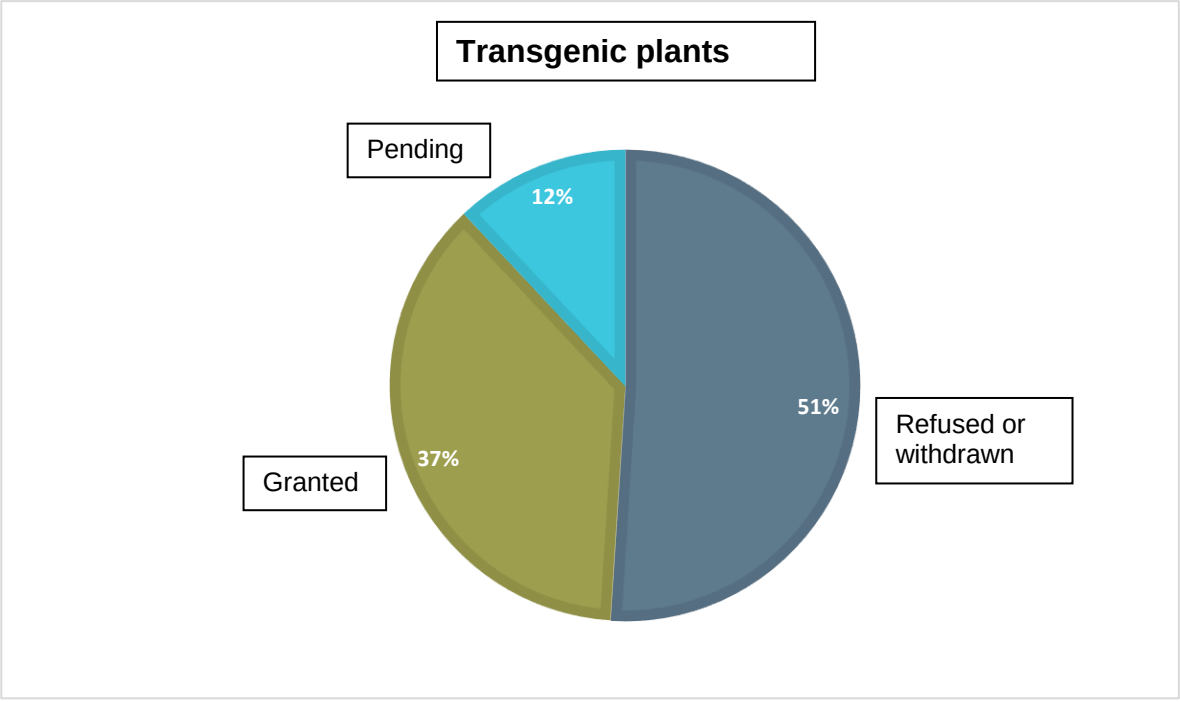
27. The next revised edition of the Guidelines will enter into force on 1 April 2025. The Guidelines will continue to be updated annually on the basis of an online user consultation each spring and further consultations with the user delegations via the SACEPO Working Party on Guidelines.

2.5 Statistics

28. By the end of July 2024, the absolute number of published European patent applications relating to genetically modified plants (both processes and products)[1] published since 1982 amounted to around 9 300.

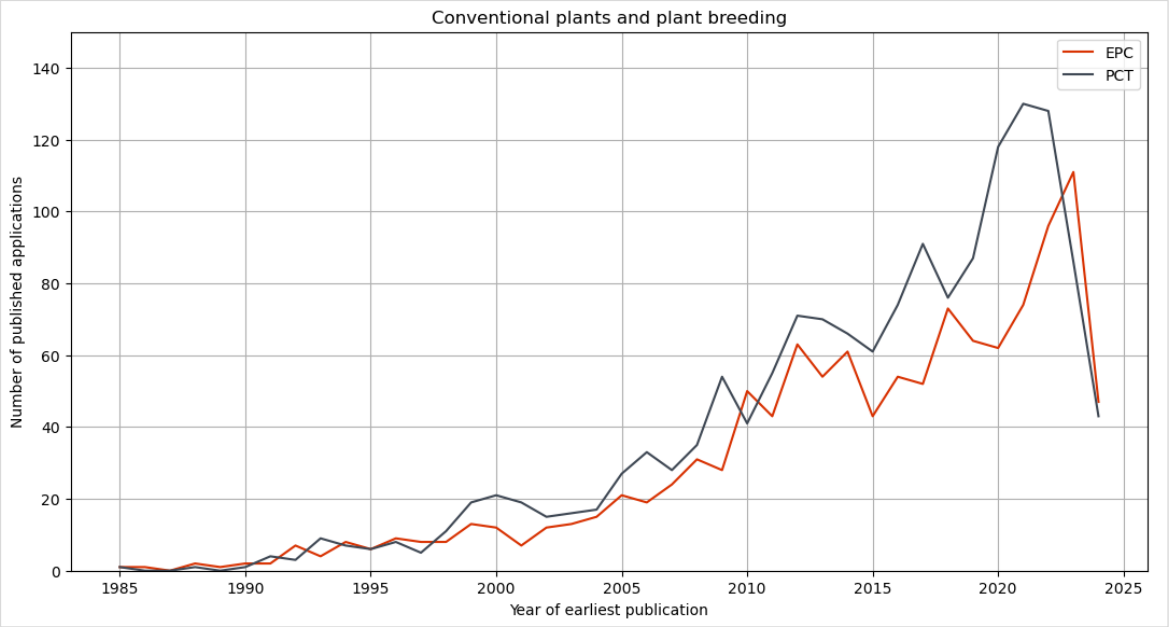


29. Of these, about 4 760 cases had been withdrawn or refused, about 3 400 European patents had been granted and roughly 1 100 cases were still pending before the EPO.

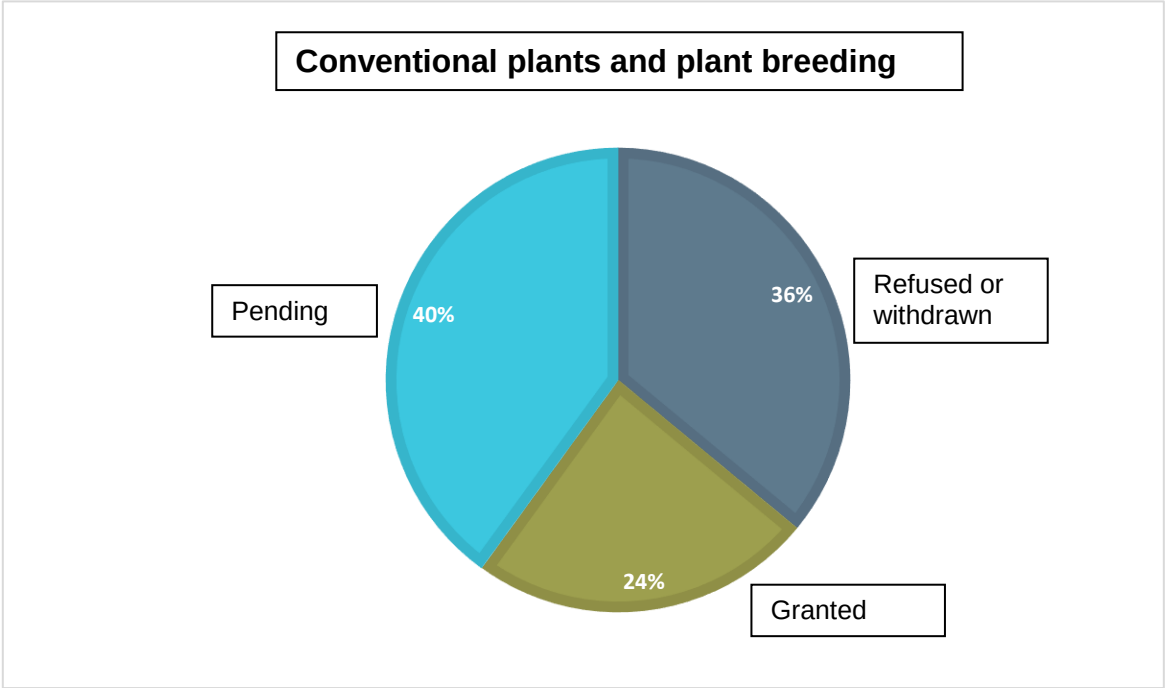


[1] Classes C12N15/82/LOW/CCI – Introduction of foreign genetic material into plant cells.

30. By the end of July 2024, the absolute number of European patent applications relating to conventional plants and plant breeding (including tools used for breeding)[2] published since 1985 amounted to approximately 1 200:



31. Of these, about 430 cases had been refused or withdrawn, about 280 European patents had been granted and roughly 490 cases were still pending before the EPO.



[2] Classifications A01H5+ and A01H7+/CCI.

2.6 Co-operation with the CPVO

32. In accordance with Article 53(b) EPC, no European patents are granted in respect of plant varieties. Pursuant to Rule 27(b) EPC biotechnological inventions concerning plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety. In decision G 1/98, the Enlarged Board ruled that a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties.

33. The EPO is working together with the CPVO to further clarify the intersection between inventions related to plants that are patentable and inventions related to plant varieties that are not. This co-operation seeks to promote innovation in the plant sector through the exchange of knowledge and information as well as through joint training activities, helping to maintain high quality decisions in both institutions. One important element of this co-operation is that CPVO records are made available to the EPO in electronic searchable format (in an XPCPVO database), making it easy for EPO examiners to take them into account when examining plant-related European patent applications. The CPVO data has been cited in search reports and opinions drawn up in respect of European patent applications. The database is also available to EPO contracting states.

34. The current administrative arrangement (2022/01373) with the CPVO entered into force on 31 March 2022 and calls for regular technical meetings between the two organisations to consider and discuss topical issues in the field of plant-related intellectual property rights.

35. A technical meeting took place on 16 April 2024. It dealt with the EPO's practice in the field of plants, the latest on EPO case law on plant-related patents and statistics on plant-related applications and patents on plant-related matter. The next meeting will take place on 20 November 2024.

2.7 Stakeholder exchanges

36. The EPO recognises the societal and economic implications related to the patentability of plants and animals. It remains committed to continuing exchanges with various stakeholder groups, including NGOs, industry and EU institutions with the aim of bringing expertise and evidence to the discussions.

37. In this context, mention is also made of the EPO's Observatory. Supported by the IP Lab, the Observatory has become a dedicated forum for important debates, including on sensitive topics with diverse societal views.

3. Financial implications

38. Not applicable.

4. Documents cited

39. CA/PL 11/23 with Add. 1; CA/PL 20/22 with Add. 1; CA/PL 3/21 with Add. 1; CA/PL 4/20 with Add. 1; CA/D 6/17.