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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 Office about its examination practice on inventions concerning plants and animals.

SUMMARY: Following up on CA/PL 4/20, 3/21, 20/22, 11/23, 18/24 and 12/25, the Office aims to further inform EPC contracting states about its examination practice concerning plant and animal-related inventions and the implementation of opinion G 3/19 (Pepper) of the Enlarged Board of Appeal. The present document provides an updated overview of the status of proceedings to which Rule 28(2) EPC does not apply. Up-to-date statistics concerning European patent applications relating to genetically modified plants, conventional plants and plant breeding are provided along with information on the EPO's co-operation activities with the CPVO and other EU institutions as well as recent EPO publications concerning the patentability of plants.

Table of contents

1.	**Introduction**	**2**
2.	**Arguments**	**2**
2.1	Overview	2
2.2	Practice for applications with an effective filing date on or after 1 July 2017	3
2.2.1	No European patents in respect of plants and animals exclusively obtained by means of essentially biological processes	3
2.2.2	Plants and animals obtained by technical processes; use of disclaimers	3
2.3	Status of proceedings to which Rule 28(2) EPC does not apply	4
2.4	Guidelines for Examination in the EPO	8
2.5	Statistics	9
2.6	Co-operation with the CPVO	11
2.7	EPO contribution to the public debate on the impact of NGT plant patenting	12
2.8	EPO contribution to the study supporting the evaluation of the Community plant variety rights system	13
2.9	EPO publications on plant innovation	13
3.	**Financial implications**	**14**
4.	**Documents cited**	**14**

1. Introduction

1. Under Article 53(b) of the European Patent Convention (EPC), European patents are not 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 are not 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. To ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants, the Enlarged Board further held that this patentability exception could not be applied to European patents granted before 1 July 2017, the date on which Rule 28(2) EPC entered into force, nor to pending European patent applications filed or validly claiming 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 report was noted, and delegations agreed to monitor developments to enable an evidence-based debate. In the meetings of the Committee on Patent Law in autumn 2021, 2022, 2023, 2024 and 2025, 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; CA/PL 18/24 with Add. 1; CA/PL 12/25 with Add. 1). The present report, the seventh 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 2025, 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 for conventional and genetically-modified plants, including plants produced using new genomic techniques (NGTs) (point 2.5 below), this document includes information on co-operation with the Community Plant Variety Office (CPVO) (point 2.6 below) and the EPO's contribution to evidence-based discussions as regards the patentability of plants made by NGTs and the functioning of the Community plant variety rights system (points 2.7 to 2.9 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. 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) no longer play a role in EPO practice. Where, exceptionally, claims to plants or animals exclusively obtained by means of an essentially biological process are present in a European patent application (or in a PCT application that has entered the European phase before the EPO), the patentability exception under Article 53(b) and Rule 28(2) EPC is strictly enforced by raising an objection. No patents have been granted for applications relating to plants or animals 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, meaning that plants and animals produced by technical processes which modify the genetic characteristics of the plant or animal are in principle patentable. 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.

9. To ensure that a European patent for 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 – in consultation with the EPC contracting states – developed a robust solution in 2017. Under the "disclaimer approach" described in the Guidelines (GL G-II, 5.4.2), when a technical feature of a claimed plant or animal could result from either a technical intervention or an essentially biological process, a disclaimer must be added to the patent claim to delimit the claimed subject-matter to the technically produced product and thereby to comply with the requirements of Article 53(b) and Rule 28(2) EPC. The Guidelines provide the following example of the wording of such a disclaimer: *"with the proviso that the plant/animal is not exclusively obtained by means of an essentially biological process"* (GL G-II, 5.4.2.1).

10. Without the disclaimer, a European patent application, although concerning plants or animals obtained by means of a technical process, could be considered to cover non-patentable plants/animals as well, 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 examining divisions. 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.

11. The disclaimer requirement is strictly enforced in the EPO's practice. Since publication of the last report in November 2025, seven more European patents requiring the disclaimer were proposed for grant, bringing the total number to fourteen. These cases are evidence of the strict enforcement of the disclaimer approach in the EPO's practice.

12. In addition to the disclaimer, 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 adding a disclaimer to the claims mentioned above (point 9) – 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

13. 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).

14. 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.

15. 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. Owing to remittals from the boards of appeal and divisional applications filed, this number subsequently rose to 400. 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, and pending cases is as follows:

16. Refused European patent applications: in addition to the nine cases mentioned in earlier reports, a European patent application was refused in four further cases subject to the retroactivity prohibition of opinion G 3/19, bringing the total number to 13.

17. Withdrawn European patent applications: the European patent application was withdrawn in 108 cases in total.

18. Granted European patent applications: since the last report of November 2025, a European patent has been granted (or proposed for grant) in a further 36 examination cases, 20 relating to conventional plants and 16 to technically produced plants, with a filing or priority date before 1 July 2017:

- **Conventional plants**

  - (i) European patent application EP11807376 relates to squash leaf curl virus resistance in cucurbits.

  - (ii) European patent application EP12851010 is concerned with seedless pepper plants.

  - (iii) European patent application EP13719448 concerns thrips resistant cabbage.

  - (iv) European patent application EP13759458 relates to hairless eggplant.

  - (v) European patent application EP14809868 is concerned with fertilisation independent fruit formation in eggplant.

  - (vi) European patent application EP16725044 concerns increased yield in cucumber plants.

  - (vii) European patent application EP16782019 relates to white rust resistant chrysanthemum.

- (viii) European patent application EP17777499 is concerned with whitefly resistance in sweet melon.

- (ix) European patent application EP17783426 concerns peronospora resistance in spinach plants.

- (x) European patent application EP17194031 relates to xanthomonas resistant brassica oleracea plants.

- (xi) European patent application EP15816251 is concerned with vernalization independent lisianthus plants.

- (xii) European patent application EP12717093 concerns cucurbita plants resistant to potyvirus.

- (xiii) European patent application EP17772638 relates to red vein endivia plants.

- (xiv) European patent application EP16701482 is concerned with novel phytophthora resistant catharanthus roseus plants.

- (xv) European patent application EP11796647 concerns plasmodiophora brassicae resistant brassica plants.

- (xvi) European patent application EP17748664 relates to polyploid plants.

- (xvii) European patent application EP16753610 is concerned with multileaf lettuce plants.

- (xviii) European patent application EP23201655 concerns cucumber plants with increased fruit yield.

- (xix) European patent application EP18768516 relates to downy mildew resistant plants.

- (xx) European patent application EP15782122 is concerned with stevia plants with high rebaudioside content.

- **Technically produced plants**

  - (i) European patent application EP10797869 is concerned with soybean plants.

  - (ii) European patent application EP13709581 concerns improving drought resistance in plants.

  - (iii) European patent application EP13709583 is concerned with improving drought resistance in plants.

  - (iv) European patent application EP13817681 concerns tobacco-specific nitrosamine reduction in plants.

  - (v) European patent application EP14770963 relates to pathogen resistant potato plants.

- (vi) European patent application EP15720445 is concerned with an increase in meiotic recombination in plants.

- (vii) European patent application EP16711046 concerns increased protein content and stress resistance in plants.

- (viii) European patent application EP16804993 relates to downy mildew resistance in spinach plants.

- (ix) European patent application EP17754668 is concerned with rhizomania resistance in plants.

- (x) European patent application EP20161957 concerns parthenocarpy regulation in plants.

- (xi) European patent application EP22165166 relates to herbicide resistance in rice.

- (xii) European patent application EP22181154 is concerned with the generation of haploid plants.

- (xiii) European patent application EP22190921 concerns tomato plants allowing the establishment of mites.

- (xiv) European patent application EP23198088 relates to gluten reduction in wheat plants.

- (xv) European patent application EP15728581 is concerned with improved poppy plants.

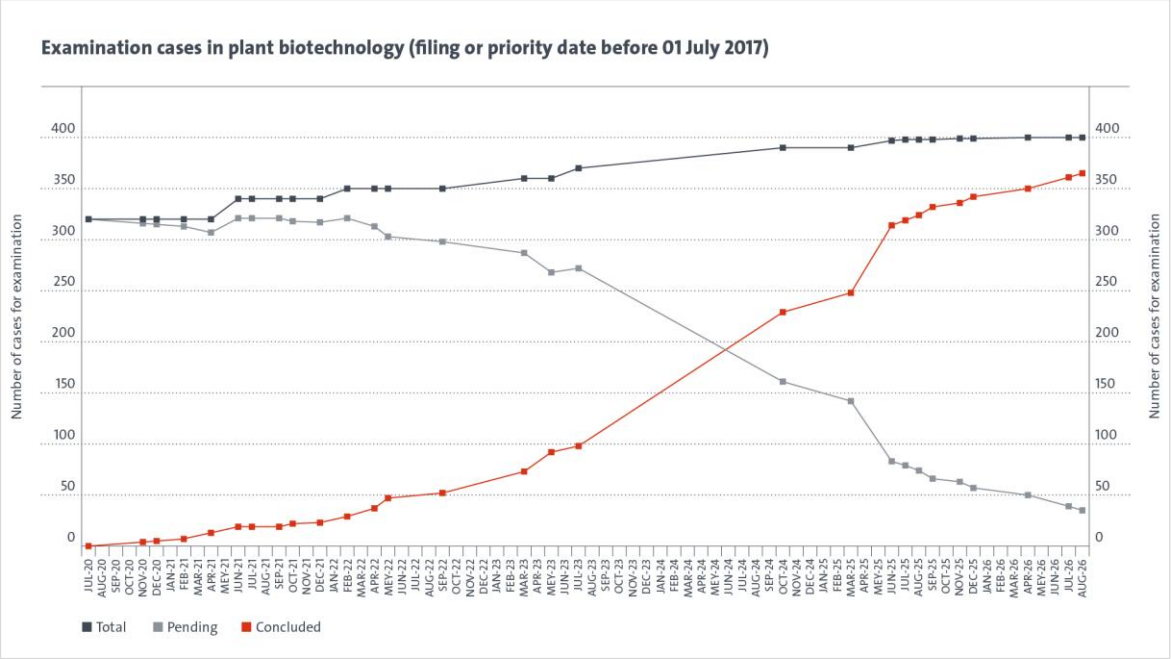
- (xvi) European patent application EP24213677 concerns herbicide resistant plants.

19. The first 20 cases listed above with a filing or priority date before 1 July 2017 relate to plants exclusively obtained by means of an essentially biological process which would not be patentable under EPO practice if filed on or after 1 July 2017. The subsequent 16 cases with a filing or priority date before 1 July 2017 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 16 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 36 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.

20. Since 2020, the total number of European patents granted or proposed for grant in cases subject to opinion G 3/19 amounts to 244, 125 concerning technically produced plants and 119 relating to conventional plants. In a limited number of cases, an opposition against the grant of the patent has been filed with the EPO and is still pending. There are no relevant cases concerning animals exclusively obtained by means of an essentially biological process.

21. 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 EPC contracting states, including CH/LI, DE, FR, GB and NL. For some of the above-mentioned European patents granted in 2026, no reliable information on the legal status is available, since periods for validation are still running. The EPO is not aware of 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 other competent authority of a contracting state or before the Unified Patent Court.

22. Pending cases: Approximately 35 affected examination cases are still pending, about 23 concerning conventional plants and roughly 12 relating to technical mutant plants. About 365 cases have been concluded since the resumption of proceedings in 2020. The number of pending examination cases has steadily and significantly declined since then, as shown in the graph below, and has now reached a "technical zero". The number of still-pending examination cases contains divisionals, which can be filed as long as the parent application is pending and can only be concluded after completion of the search and examination stage, potentially including oral proceedings. This explains why a very small number of cases will still remain pending, albeit for a limited period of time.



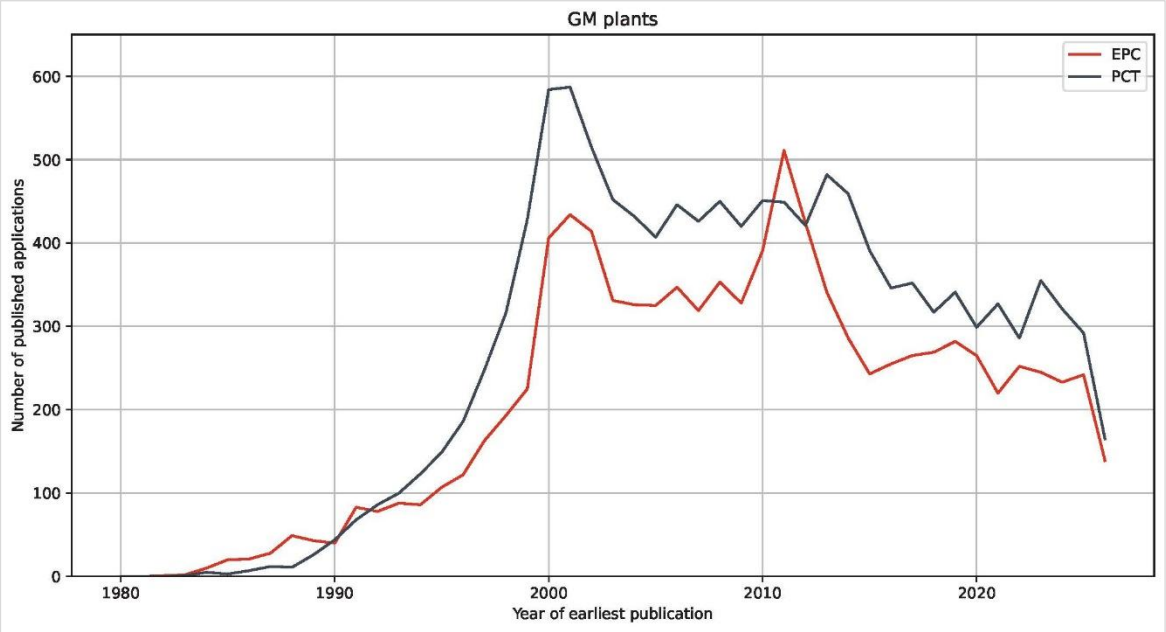
2.4 Guidelines for Examination in the EPO

23. 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 12 above).

24. In the same way as in 2024 and 2025, following discussions with the users in the Working Party on Guidelines of the Standing Advisory Committee before the EPO (SACEPO) and an open online consultation, no need was identified for further clarification of the EPO's examination practice in the area of plant- and animal-related inventions in 2026, primarily because of the comprehensive revisions made between 2021 and 2023. The Guidelines will continue to be updated annually on the basis of an online user consultation and further consultations with the user delegations via the SACEPO Working Party on Guidelines, including a review of sections G-II, 5.4 and 5.5.

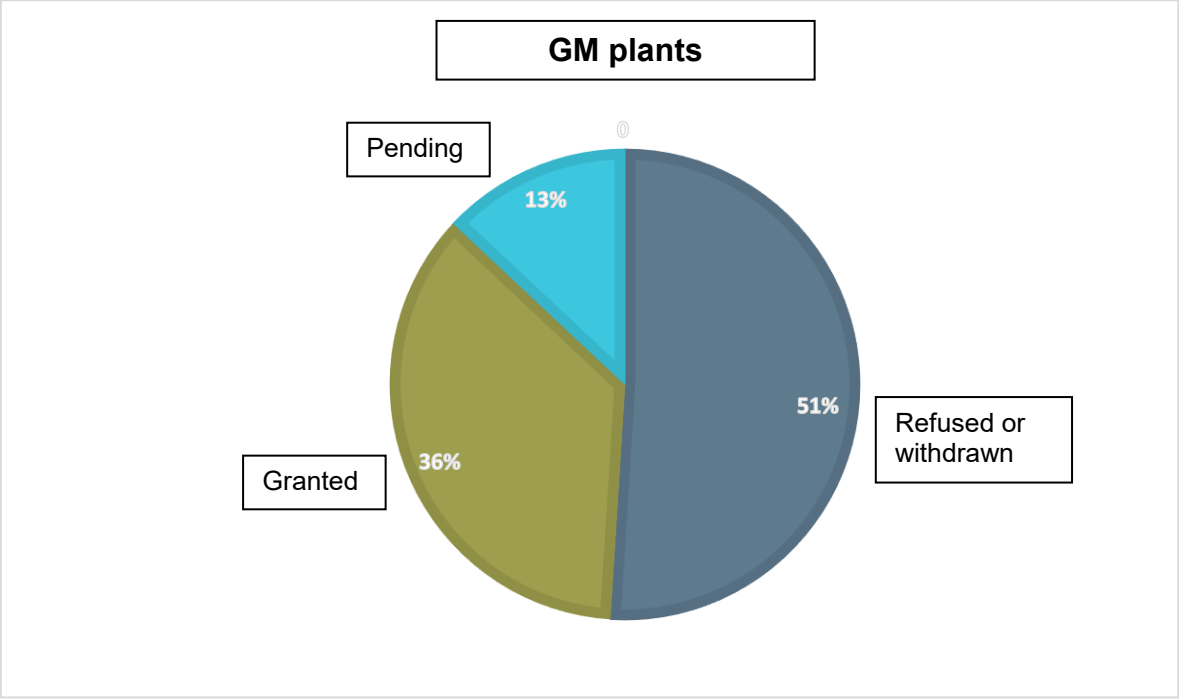
2.5 Statistics

25. By the end of August 2026, the absolute number of published European patent applications relating to genetically modified plants (both processes and products)[1] published since 1982 amounted to around 9 805.

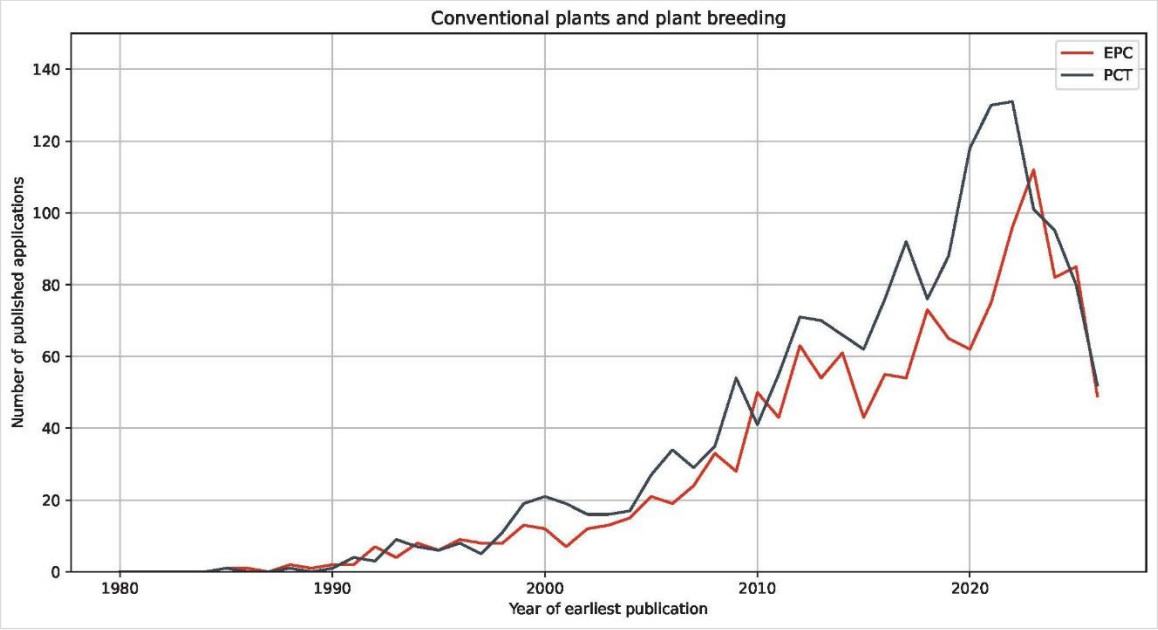


[1] Classes C12N15/82/LOW/CCI – Introduction of foreign genetic material into plant cells.

26. Of these, about 5 048 cases had been withdrawn or refused, about 3 567 European patents had been granted and roughly 1 190 cases were still pending before the EPO.

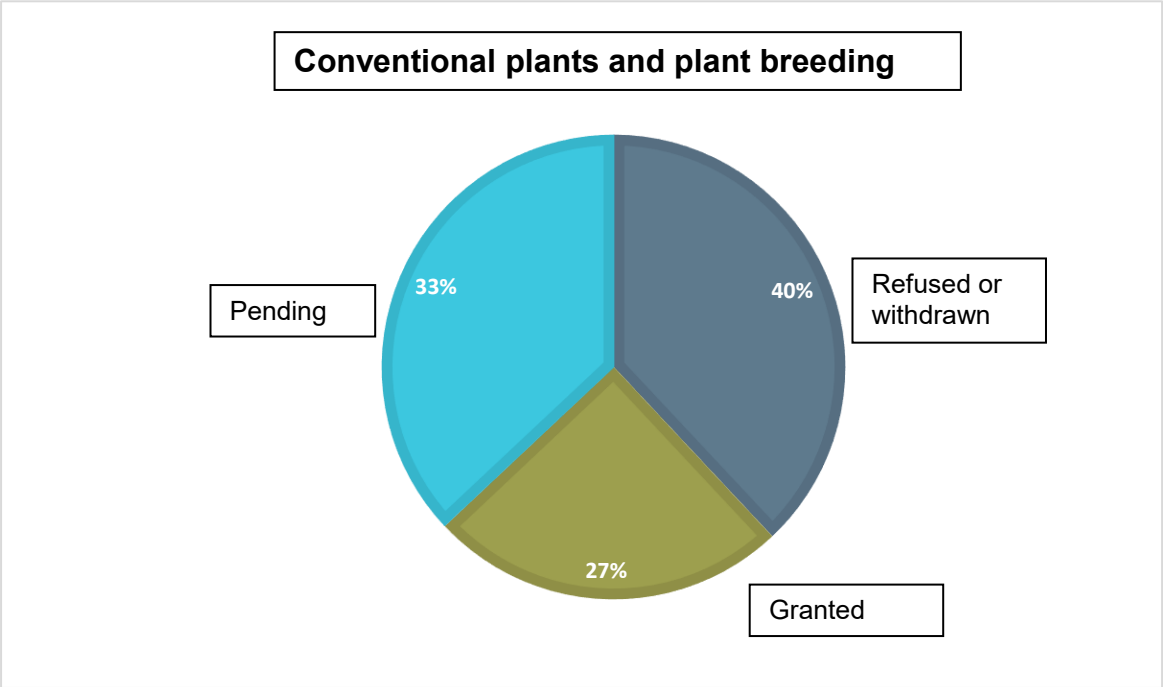


27. By the end of August 2026, the absolute number of European patent applications relating to conventional plants and plant breeding (including tools used for breeding)[2] published since 1985 amounted to approximately 1 378.



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

28. Of these, about 545 cases had been refused or withdrawn, about 376 European patents had been granted and roughly 457 cases were still pending before the EPO.



In view of the ongoing discussions related to NGTs and plant patenting (point 2.7 below), the EPO has continued to gather statistical information about relevant filings. There is no separate class for NGTs under the International Patent Classification system. Patent applications concerning genome editing techniques and related products, considered to fall under the definition of NGT1 and/or NGT2, can be classified in both classes A01H+ and C12N15/82+ (typically in the case of technical mutant plants), or only in class C12N15/82+ (typically in the case of transgenic plants). Out of roughly 950 published European patent applications classified in both classes A01H+ and C12N15/82+, about 12% refer to genome edited products in the claims or description. As regards relevant European patent applications classified in C12N15/82+ only, about 4% mention genome edited products in the claims or description.

2.6 Co-operation with the CPVO

29. 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.

30. The EPO is working together with the CPVO to further clarify the dividing line between inventions related to plants that are patentable and inventions related to plants that are not patentable. This co-operation seeks to promote innovation in the plant sector through the exchange of 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 EPC contracting states.

31. Under the current administrative arrangement, the two organisations hold regular technical meetings to consider and discuss topical issues in the field of plant-related intellectual property rights. Since the last report was issued, one technical meeting with the CPVO took place via videoconference. Held on 27 May 2026, it covered three topics: the patentability of new compounds found in genetic resources (presented by the EPO), essentially derived varieties (presented by the CPVO) and a bilateral discussion analysing the impacts of the EU's new regulation on plants obtained by new genomic techniques (Regulation (EU) 2026/1388).

32. The current administrative arrangement (2022/01373) with the CPVO entered into force on 31 March 2022 and is due to expire in March 2027. Considering the highly positive results achieved so far, the EPO and the CPVO have agreed to extend the current arrangement for a period of ten years. This extension will be finalised shortly.

2.7 EPO contribution to the public debate on the impact of NGT plant patenting

33. On 16 July 2026, Regulation (EU) 2026/1388 on plants obtained by certain new genomic techniques and their products and amending Regulation (EU) 2017/625 (the NGT Regulation) entered into force. The NGT Regulation establishes a framework to support a more competitive, innovative and sustainable European agri-food sector. It also recognises that innovations in plant breeding, including NGT plants, may benefit from protection through plant variety rights and/or patents, where the applicable legal requirements are met.

34. The EPO contributed to the public debate that led to the adoption of the NGT Regulation by providing policymakers and stakeholders with data and expertise to support evidence-based discussions. EPO contributions included hosting an expert workshop for delegations on biopatents in September 2025, developing a widely distributed and well-received biotech information kit and participating in numerous expert meetings with, for example, EU institutions and key players in the innovation ecosystem.

35. Under the NGT Regulation, an expert group has been established to assess the impact of patent protection on NGT plants. As a member of this group, the EPO is committed to contributing its expertise and supporting informed, evidence-based discussions on the role of intellectual property in promoting innovation while ensuring transparency and access to genetic resources. In the group's first meeting, the EPO provided comprehensive information in the form of a presentation on its practice for examining plant-related inventions.

36. The EPO also supports the other measures provided for under the NGT Regulation to increase IP awareness among small breeders and farmers, in particular, and to enhance the transparency of information relating to plant patents, i.e. by drawing up a code of conduct as well as guidance for operators on matters relating to plant intellectual property.

2.8 EPO contribution to the study supporting the evaluation of the Community plant variety rights system

37. The European Commission's Directorate-General for Health and Food Safety (DG SANTE) has launched a study to support the evaluation of Council Regulation (EC) No 2100/94 of 27 July 1994 on the Community plant variety rights and the Community Plant Variety Office. The EPO contributed to this study via a targeted user consultation and an interview as well as by participating in a validation workshop and a focus group dedicated to the intersection between plant variety rights and other IP instruments such as patents.

38. As part of its contribution, messages were delivered on the successful co-operation between the EPO and the CPVO and the complementarity of the two IP systems, which benefits plant innovation and sustainability. Other messages emphasised the importance of patents in promoting innovation in plant breeding techniques that cannot be protected by plant variety rights, the fact that plant varieties are excluded from patentability and that the EPO does not grant patents on plant varieties, as well as the EPO's efforts to increase legal certainty, transparency and awareness about plant patents, especially for SMEs, through measures such as the disclaimer solution.

39. Finalisation of the study has been announced for the last quarter of 2026. The EPO will continue to follow this important matter as far as it relates to the intersection between plant variety rights and plant patents, and keep delegations informed.

2.9 EPO publications on plant innovation

40. In September 2025, the EPO's Observatory on Patents and Technology published a new technology insight report entitled "Digital agriculture – towards sustainable food security". This report highlights the potential of digital technologies to help meet the challenge of producing enough food while using fewer resources and was created in co-operation with European and Latin American national patent offices. Its findings consider information from some 270 000 patent families covering 400 000 different patent applications. A related podcast entitled "Digital and data-driven: the new age of agriculture" is also available.

41. As part of its 2025 Technology Dashboard, the EPO published an "Insight into plant biotechnology: How new genomic techniques can provide food security". providing information on the number and origin of European patent filings in a technical field that is of the utmost importance for achieving a more sustainable future.

42. Finally, in September 2026, the EPO released a new podcast on "Green biotechnology: growing resilience for tomorrow's food security". In this episode, EPO experts discuss how plant biotechnology help crops withstand drought, flooding and disease, clean polluted soil and even produce medicines. They explore the groundbreaking research behind gene editing, biotechnology's role in supporting food security and climate resilience and the patents and plant variety rights that reward inventors.

3. Financial implications

43. Not applicable

4. Documents cited

44. CA/PL 12/25 with Add. 1; CA/PL 18/24 with Add. 1; 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