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DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING FARMERS’ AND/OR BREEDERS’ USE OF PATENTED INVENTIONS

Document prepared by the Secretariat

INTRODUCTION

1. At its thirty-sixth session, held in Geneva from October 14 to 18, 2024, the Standing Committee on the Law of Patents (SCP) agreed, *inter alia*, that, in accordance with the agreement reached at its twenty-sixth session and following its decision at the thirty-fifth session, the Secretariat would prepare a draft reference document on the exception regarding farmers’ and/or breeders’ use of patented inventions, to be submitted to the thirty-seventh session of the SCP (see document SCP/36/12, paragraph 33(a), under “Exceptions and Limitations to Patent Rights”).
2. In accordance with the above decision of the SCP, the Annex to this document contains the said draft reference document for the Committee’s discussion at its thirty-seventh session, to be held in Geneva from November 3 to 7, 2025. In the preparation of the draft reference document, the Secretariat made use of information provided by the Member States¹, as well as other information made available through various SCP activities. In addition, the Secretariat consulted other sources of information to obtain supplementary material on the topic.
3. As mandated by the Committee, the document primarily focuses on the exception regarding farmers’ and/or breeders’ use of patented inventions. It does not aim to address

¹ Member States and Regional Patent Offices were invited, through its Note C. 9260, dated January 31, 2025, to submit to the International Bureau any inputs for the preparation of the draft reference document on the exception regarding farmers’ and/or breeders’ use of patented inventions. The inputs received are published on the website of the SCP electronic forum at: https://www.wipo.int/en/web/scp/electronic-forum/meetings/session_37/comments_received. It should be noted, however, that only a limited number of responses were received from Member States in connection with this document.

issues relating to the patentability of biotechnological inventions or the scope of protection conferred upon such inventions under applicable national or regional laws.

4. While other exceptions and limitations to patent rights, including those relating to private and non-commercial use, experimental or research use, and compulsory licensing, may also be relevant to certain agricultural or breeding activities, the present document confines its analysis to exceptions that are specifically applicable to patented biotechnological inventions and that are uniquely available to farmers and breeders. For information on other exceptions and limitations to patent rights, reference is made to relevant documents prepared within the framework of the Committee's work.²

5. Likewise, the document does not address the interface between patent systems and plant variety protection regimes. Nor does it examine exceptions and limitations available to breeders and farmers under plant variety protection regimes, except where such provisions are expressly applicable to patent rights.

6. The document contains the following sections: (i) Overview of the exceptions regarding farmers' and/or breeders' use of patented inventions; (ii) Types of exceptions regarding farmers' and/or breeders' use of patented inventions and their policy objectives ; (iii) International legal framework of the exceptions; (iv) Regional instruments relating to the exceptions; (v) National implementation of the exceptions; (vi) Challenges faced by Member States in implementing the exceptions; and (vii) Results of national/regional implementation of the exceptions. In addition, the document contains an Appendix that compiles legal provisions from various national/regional laws on the exceptions regarding farmers' and/or breeders' use of patented inventions.

[Annex follows]

² For documents relating to other exceptions and limitations to patent rights, please consult the SCP website at: https://www.wipo.int/en/web/patents/topics/exceptions_limitations.

**DRAFT REFERENCE DOCUMENT ON THE
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APPENDIX

1. Overview of the Exceptions Regarding Farmers' and/or Breeders' Use of Patented Inventions

7. As of August 2025, fifty-four countries have been identified to provide exceptions and/or limitations related to farmers' and/or breeders' use of patented inventions in their applicable laws. An analysis of national and regional laws reveals that, in general, there are four main types of exceptions and limitations that are particularly relevant to farmers and breeders with respect to the use of patented biological material: (i) use for the purpose of breeding new plant varieties; (ii) use by farmers on their own holdings; (iii) use of propagated material for its marketed purpose (exhaustion of rights); and (iv) compulsory cross-licensing.

8. While no international instrument expressly regulates the four types of exceptions listed above, exceptions (i) to (iii) must comply with Article 30 of the TRIPS Agreement, which permits WTO Members to provide limited exceptions to patent rights under specific conditions, whereas exception (iv) falls under Article 31 concerning "other use without authorization of the right holder" insofar as it relates to the use of a patent without the consent of the right holder.

9. As regards regional instruments, two instruments in Europe include provisions governing exceptions for farmers' and/or breeders' use of patented inventions: the European Union (EU) Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (the Biotech Directive), and the Agreement on a Unified Patent Court (UPCA).³ In the European context, the farmers' use exception under the EU Biotech Directive is closely linked to the framework of the Community Plant Variety Rights (CPVR) Regulation.⁴ Accordingly, developments and interpretations under the CPVR system, as well as guidance from the International Convention for the Protection of New Varieties of Plants (UPOV Convention), particularly Article 15(2) of the 1991 Act, may inform the interpretation of the farmers' use exception under patent law. In addition, provisions relating to farmers' and/or breeders' use of patented inventions are found in Decision № 486 of September 14, 2000 of the Commission of the Andean Community.

10. While each of the exceptions may be based on distinct policy considerations, they collectively contribute to balancing the interests of the patentee with those of farmers and breeders. Specifically, these exceptions are designed to safeguard agricultural production, support food security, promote agricultural and livestock innovation, and preserve traditional farming practices. They help ensure that farmers can reuse biological material for agricultural purposes, while breeders can access patented material to develop new varieties.

11. With respect to the scope of the relevant provisions in national laws, most countries have not developed any judicial interpretation concerning the four types of exceptions related to breeders' and farmers' use of patented inventions. In a few other countries, a small number of court cases have addressed one or more of these exceptions.

³ The Agreement on a Unified Patent Court of June 1, 2023. The Agreement applies to European patent applications, European patents with unitary effect as well as those European patents and supplementary protection certificates that take effect in Contracting Member States of the Agreement (See Art. 3 of the UPCA). As of August 2025, the UPCA is effective in 18 EU Member States.

⁴ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.

2. Types of Exceptions Regarding Farmers' and/or Breeders' Use of Patented Inventions and their Policy Objectives

12. The policy goals underlying exceptions for farmers' and breeders' use of patented inventions vary depending on the type of exception. However, their overarching aim is to balance the interests of the patentee with those of farmers and breeders. In general, national and regional laws provide for four types of exceptions that are particularly relevant to the use of patented biological material by farmers and breeders:

- (i) the patent right does not extend to propagated/multiplied biological material obtained from the biological material placed on the market by the patent holder or with his consent, if the propagation/multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation/multiplication (hereinafter referred to as "exhaustion of rights");
- (ii) where plant propagating material is sold or otherwise commercialized by the patent holder or with his consent to a farmer for agricultural use, the farmer is authorized to use the product of his harvest for further propagation/multiplication on his own farm; similarly, the sale or any other form of commercialization of animal reproductive material by the patent holder or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose (hereinafter referred to as "farmers' use");
- (iii) the patent right does not extend to acts for creating or developing a new plant variety (hereinafter referred to as "breeders' use");
- (iv) where a breeder cannot exploit a plant variety right without infringing a prior patent, a compulsory license may be issued. In such a case, the holder of the patent is entitled to a cross-license on reasonable terms to use the protected plant variety (hereinafter referred to as "compulsory cross-licensing").

Policy Rationales for the Exhaustion Doctrine

13. The exhaustion doctrine, also known as the first sale doctrine, limits the patent holder's control over a patented product after its authorized sale. The key policy rationale is to prevent the extension of patent rights beyond the point of first sale, thereby promoting market efficiency and legal certainty.

14. As noted in the SCP reference document⁵ dedicated to the subject of exhaustion of patent rights, in many countries, it is considered that such limitation on the rights of the patentee would achieve a balance among various private and public interests in the patent system, promote free movement/circulation of goods, and protect the interest of consumers. In addition, the exhaustion is noted to serve the purpose of maintaining the "normal economic order", and that the restriction on the further alienation of goods legitimately sold on the market would run counter the goals of patent and property laws. Moreover, it is often stated that the patentee should be prevented from receiving further compensation for the same product once it has sold it and thus been rewarded.⁶

⁵ See document SCP/34/3 "Draft Reference Document on the Exception Regarding the Exhaustion of Patent Rights", p.8.

⁶ *Ibid.*

15. In the context of self-replicating biological material, such as seeds or breeding animals, courts and commentators have recognized that applying the exhaustion doctrine raises particular challenges. If purchasers are allowed to reproduce patented material indefinitely, it may undermine the patent holder's ability to recoup R&D investments, effectively creating new competitors with each sale.⁷ Conversely, if exhaustion is narrowly interpreted, the utility of biological inventions may be significantly impaired, particularly in agriculture, where replication is integral to use.

16. Therefore, the need to establish a specific exhaustion rule tailored to the unique characteristics of biological material has been recognized in some jurisdictions. In general, such a rule seeks to balance the patentee's exclusive rights with the practical realities of biological propagation and the needs of users, including farmers and breeders. It ensures that once the patented material has been lawfully placed on the market, certain acts of propagation or multiplication that necessarily result from its intended use fall outside the scope of patent protection.

Policy Rationales for the Farmers' Use Exception

17. According to submissions from some Member States and legal commentators, the primary objective of the farmers' use exception is to safeguard agricultural production. Thus, e.g., in its submission, Spain explained:

“Case-law considers that the underlying purpose of this exception is to promote and protect agricultural production, so that the seeds obtained from the plant material covered by the patent can be used freely by the farmer.

This exception could be understood as a solution to the existing conflict between the interests of the holders of exclusive rights over plants (plant variety rights or patents) and those of farmers. Patent holders want royalties for each sowing, while farmers want to be able to save seeds for the next growing season without having to pay royalties or seek permission from the patent holder.

Consequently, with this exception, farmers are recognized the right to use the product of their harvest for further reproduction or multiplication carried out by themselves on their own farms, provided that the farmer has previously obtained the seed from the patent holder or with their consent.”⁸

18. In response to the Questionnaire on Exceptions and Limitations to Patent Rights, some Member States noted that the policy rationale behind the farmers' use exception is that farmers should be permitted to use propagated or reproduced biological material protected by a patent, provided it is used for the purposes for which it was sold, namely, agricultural use. For example, Austria and Germany stated that the

“objective is to allow the farmer to use a part of his harvest product again for planting even if the propagating material is patented, since the seeds are intended for agricultural

⁷ See, e.g., *Bowman v. Monsanto Co.*, 569 U.S. 278 (2013).

⁸ See a response from Spain to C.9260, dated January 31, 2025, published on the SCP Electronic Forum website at: https://www.wipo.int/en/web/scp/electronic-forum/meetings/session_37/comments_received. See also commentary by Winfried Tilmann and Clemens Plassmann on Article 27(i) and (j) of the UPCA cited in paragraph 60 of this document.

*use and were sold for this purpose” and that this “applies mutatis mutandis to the reproduction of animals”.*⁹

19. Legal commentators have also emphasized broader policy objectives. In the book “Intellectual Property and International Trade: The TRIPS Agreement”, the justification for adopting the farmers’ use exception in patent law is linked to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Specifically, it is noted:

*“Allowing farmers to save, exchange and use seed is instrumental to the realization of the goals stated in the ITPGRFA provisions. In particular, it might strengthen the ability of farmers to develop varieties adapted to social and ecological conditions as stated in Article 6.2(c). Given the important role of PGRFA in food security, the society as a whole has an interest in a farmers’ exemption to patent rights that supports the implementation of the ITPGRFA treaty. This may be a sufficient condition to justify its adoption.”*¹⁰

Policy Rationales for the Breeders’ Use Exception

20. With respect to the rationale behind the breeders’ use exception,¹¹ in France, the *Rapport Assemblée Nationale* n°1936, explains that

“Article L. 613-5-3 of the French Intellectual Property Code establishes a breeders’ exception to patent rights, allowing the use of patented plant varieties for the purpose of creating, discovering, or developing new varieties. This provision aims to harmonize patent law with plant variety protection law, where a broader breeders’ exemption already exists.

Without such a privilege, breeders would be required to obtain a license even when the resulting variety contains no trace of the patented gene. This could significantly hinder plant innovation, especially given past practices where patented varieties were developed from freely accessible European plant varieties.

The inclusion of the breeders’ privilege helps prevent the systematic appropriation of plant genetic resources and removes obstacles to plant breeding creativity. While the exception allows for the development of new varieties, commercial exploitation of the resulting variety still requires authorization from the holder of the original patent or plant variety right and is subject to royalty payment.

*Ultimately, this provision is intended to rebalance negotiating power between European breeders and large multinational patent holders, enabling breeders to develop complete varieties before entering into licensing negotiations.”*¹² [non-official translation]

21. As regards legal commentary, a volume edited by Winfried Tilmann and Clemens Plassmann notes that the purpose of the breeders’ use exception in the UPCA is “to prevent

⁹ See the responses to the Questionnaire at: <https://www.wipo.int/scp/en/exceptions/>.

¹⁰ The authors also stated: “This exemption will increase agricultural produce and promote a more sustainable life for poor farmers. Since the reduction of poverty is in the interest of society as a whole, this exemption will bring about beneficial outcomes.” Carlos M. Correa and Abdulqawi A. Yusuf, “Intellectual Property and International Trade. The TRIPS Agreement,” Third edition, 2016 Kluwer Law International BV, The Netherlands, pp.318-9.

¹¹ The exception is provided in Article L613-5-3 of the Intellectual Property Code of France.

¹² See the *Rapport Assemblée Nationale* n°1936, which can be found at: <https://www.assemblee-nationale.fr/12/rapports/r1936.asp>.

plant research from being excessively hampered by the effect of patents for biological material".¹³

22. Another legal commentary on the breeders' use exception in the EU Biotech Directive explains:

"One of the most claimed and objectively speaking appealing rationales for introducing a breeders' exemption in the patent system is that such an exemption would guarantee access to genetic material with a view to develop new varieties. The access to genetic material for breeding is important for quick innovation in plant breeding. In the absence of the availability of a breeders' exemption [...] all this material is locked up in patents and not accessible to third parties without obtaining a licence, which in turn will go at the expense of further technological development and in the long run a loss of biodiversity. In the same vein, the argument concludes that this would in the end also be beneficial to farmers, growers and consumers, as it would lead to a higher diversity of varieties on the market."¹⁴[...]

The breeders' exemption is regarded by breeders as a prerequisite for further innovation in plant breeding. New varieties are based on the use of biological material such as plants and cannot be developed out of information on paper. [...] In favour of the introduction of a breeders' exemption in patent law, it is sometimes argued that never before has the patent system overlapped to such an extent with the work of breeders. Technological developments outside of the area of transgenic plants are being increasingly used by breeders to develop new varieties. That is a new development, and might in the absence of a breeders' exemption affect breeders in their businesses more than was the case in a situation where only transgenic plants were being made by genetic engineering methods. As access to biological material is essential for further innovation in breeding, a model without a breeders' exemption might hamper their viability and innovative capabilities."¹⁵

Policy Rationales for Compulsory Cross-licensing

23. The policy rationale for the compulsory cross-licensing mechanism is clearly articulated in the EU Biotech Directive, which provides such a provision in Article 12. This Article establishes a reciprocal framework allowing a breeder to request a compulsory license to use a patented invention, and *vice versa*, when such use is necessary for the exploitation of a plant variety or biotechnological invention, respectively:

"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 [...] and

"Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right [...]"

¹³ Chapter V, Sources of Law and Substantive Law in *Unified Patent Protection in Europe. A Commentary* (edited by Winfried Tilmann and Clemens Plassmann), Oxford University Press (2018), pp. 533 and 538, available at: <https://academic.oup.com/book/41092/chapter/350018499>.

¹⁴ Bostyn, S. et al., Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering. European Commission, 2016, p.47, available at: <https://ec.europa.eu/docsroom/documents/18604/attachments/1/translations/>.

¹⁵ Bostyn, S. et al., *ibid*, p.47.

24. The legislative rationale for these provisions is explicitly stated in Recitals 52 and 53 of the Directive. Recital 52 addresses the need for guaranteed access to patented inventions by the breeder where a plant variety represents significant technical progress of considerable economic interest:

“Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;”

25. Recital 53 provides a symmetrical justification for access to protected plant varieties, where the patented invention embodies such technical progress:

“Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;”

26. These provisions aim to resolve dependency issues between overlapping intellectual property rights, namely, patents and plant variety rights, by enabling the acquisition or exploitation of one right where such exploitation would otherwise infringe the other, provided that the dependent use represents significant technical progress of considerable economic interest. By allowing for the grant of non-exclusive compulsory licenses, the mechanism ensures that holders of either right are not prevented from making effective use of their titles due to the existence of a prior conflicting right.

27. In addition, with respect to the policy objectives of the cross-licensing provision in patent law of France, it is explained that it is to “encourage patent owners to grant a license voluntarily”.¹⁶

3. International Legal Framework of the Exceptions Regarding Farmers’ and/or Breeders’ Use of Patented Inventions

28. No international treaty expressly addresses the exceptions regarding farmers’ and/or breeders’ use of patented inventions. However, Article 30 of the TRIPS Agreement outlines general principles regarding the exceptions to the exclusive rights conferred by a patent, which the WTO Members may provide. It states:

“Exceptions to 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.”

29. Since Article 30 is a permissive (“may”) provision, Members are permitted, but not obliged, to provide such limited exceptions to patent rights. Any exception, including those relating to farmers’ and/or breeders’ use of a patented invention, must be consistent with the conditions set out in Article 30.

¹⁶ See France’s response to Question 97(a) in the Questionnaire, available at: <https://www.wipo.int/scp/en/exceptions/>.

30. The WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Product* case¹⁷ provided some guidance with respect to the interpretation of this provision, the summary of which has been provided elsewhere.¹⁸ However, as the exception under discussion was not the specific focus of the dispute, the compliance of this exception with Article 30 of the TRIPS Agreement was not discussed.

31. Nevertheless, a number of countries provide some form of exceptions regarding farmers' and/or breeders' use of patented inventions under their national patent laws.¹⁹ Legislative debates in some of those countries have offered insight into the compatibility of the relevant provisions with the TRIPS Agreement. For example, in France, a document submitted to the *Assemblée Nationale* on Article L613-5-3²⁰, concerning the breeders' use exception, stated, *inter alia*, that the TRIPS Agreement "does not preclude the introduction of such a derogation in national patent law".²¹

32. Some commentators have also expressed their views on the consistency of the exceptions under discussion with Article 30 of the TRIPS Agreement. For instance, Dr. Viola Prifti observes that the breeding exemption, which permits the use of patented biological material for the purpose of developing new plant varieties, has been considered consistent with the three-step test under Article 30. However, she also notes that a 'comprehensive breeding exemption', which allows not only the use of the material for breeding but also the commercialization of the resulting new plant variety, faces several obstacles in complying

¹⁷ WTO document WT/DS114/R.

¹⁸ For the summary of the case, see document SCP/13/3, pp. 21 and 22, and document SCP/28/3, pp. 6-8.

¹⁹ For the analysis of the national laws, see Section 5 of this document. In addition, see the Appendix to this document.

²⁰ See the *Rapport Assemblée Nationale* n°1936, which can be found at: <https://www.assemblee-nationale.fr/12/rapports/r1936.asp>.

²¹ Specifically, to justify this finding, the rapporteur of the Senate's Economic Affairs Committee observed that:

- Article 30 authorizes "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 7 provides that "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.";
- Article 8.2 states that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." The underlined portions reflect emphasis as found in the original French document submitted to the *Assemblée Nationale*. See *ibid*.

with Article 30 of the TRIPS Agreement “since it erodes the basic principles of patent law.”^{22,23}

33. With respect to Article 27 of the Agreement on a Unified Patent Court (UPCA), titled ‘Limitations of the effect of a patent’ which provides for, *inter alia*, the breeders’ use (in paragraph (c)), farmers’ use (in paragraphs (i) and (j)) and exhaustion principle for biological material (in paragraph (l)), in a book edited by Winfried Tilmann and Clemens Plassmann it is also concluded that the “provisions are consistent with Art 30 TRIPS[...] that leaves it to the discretion of the Contracting States to provide for 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, also taking into account the legitimate interests of third parties. [...]”²⁴

34. As regards compulsory cross-licensing between patents and plant variety rights, there is no international treaty provision expressly regulating this specific matter. Where a patent is used without the consent of the right holder, including situations where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, such use must comply with the general conditions stipulated in Article 31 of the TRIPS Agreement (e.g. case-by-case decision, adequate remuneration, supply predominantly of the domestic market, and use being non-exclusive).²⁵ By contrast, a situation where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right is not specifically addressed in the TRIPS Agreement. In Europe, this is regulated under the CVPR Regulation, which is directly applicable in EU Member States.²⁶

²² Dr. Viola Prifti further noted that “the objectives and principles of TRIPS, however, leave considerable room for states to promote public interest in plant breeding. Special circumstances, such as food crisis, may induce states to resort to general principles instead of applying strict rules. [...] This interpretation is particularly relevant for accommodating the divergent interests of countries. Identifying a coherent relationship between national plant-breeding interests and TRIPS objectives might result in different answers. Special solutions might be needed for Europe as opposed to, for example, the United States. The air of vagueness surrounding article 30 gives good reasons for adopting flexible solutions in patent law.” See Viola Prifti “The Breeding Exemption in Patent Law: Analysis of Compliance with Article 30 of the TRIPS Agreement”, *The Journal of World Intellectual Property*, 2013, Vol. 16, no. 5-6, pp. 218-239.

²³ In a book edited by Carlos M. Correa and Abdulqawi A. Yusuf, it was also concluded that “farmers’ use exception adopted under EU law seems to comply with requirements of Article 30”. Carlos M. Correa and Abdulqawi A. Yusuf, “Intellectual Property and International Trade. The TRIPS Agreement,” Third edition, 2016, p.315. Similarly, Juan I. Correa concludes with respect to breeders’ use exception that “a limited breeders’ exemption would not have major difficulties to overcome the requirements of TRIPS while the full exemption could experiment some difficulties with regard to the second and third steps of article 30: “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”. See Correa, Juan I., “Breeder’s Exemption in Patent Law: Towards a TRIPS Compliant Exemption”, 2019. WIPO Academy, University of Turin and ITC-ILO - Master of Laws in IP - Research Papers Collection - 2017-2018.

²⁴ See Chapter V, Sources of Law and Substantive Law in *Unified Patent Protection in Europe. A Commentary* (edited by Winfried Tilmann and Clemens Plassmann), Oxford University Press (2018), p.30. In contrast to the above views, Nuno Pires de Carvalho stated that “[...] exceptions to breeders’ rights that, in light of Article 30 of the TRIPS Agreement, would not be accepted in the context of patents [...]”. He is also of the view that Article 11 of Directive 98/44/EC of the European Parliament and of the Council of July 6, 1988 (relating to farmers’ use exception), is inconsistent with Article 30 of the TRIPS agreement as it is not “limited” and that the provision also violates Articles 1.1 and 28 of the TRIPS Agreement. See Nuno Pires de Carvalho, “The TRIPS Regime of Patent Rights”, 2010, pp. 310 and 311, Kluwer Law International.

²⁵ For a detailed analysis of Article 31 of the TRIPS Agreement, see document SCP/30/3.

²⁶ See Article 29(5a) and (6) of the CPVR Regulation.

4. Exceptions Regarding Farmers' and/or Breeders' Use of Patented Inventions under Regional Instruments

35. In Europe, two regional instruments include provisions governing exceptions for farmers' and/or breeders' use of patented inventions: the European Union (EU) Biotech Directive, and UPCA.²⁷ In addition, relevant provisions are found in Decision № 486 of September 14, 2000 of the Commission of the Andean Community.

4.1 EU Directive 98/44/EC (The Biotech Directive)

Compulsory cross-licensing

36. At the EU level, Article 12 of the Biotech Directive addresses compulsory cross-licensing in cases of dependency, that is, situations where a patent or a plant variety right (PVR) cannot be exploited without infringing a prior patent or a prior PVR. The provision states:

“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 in as much 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.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

[...]²⁸

37. In general, in order to give legal effect to EU Directives, Member States must transpose them into their national laws. While provisions on compulsory cross-licensing can be found in the national legislation of EU Member States, the transposition and the implementation of Article 12 of the Biotech Directive has not been uniform. Specifically, an

²⁷ The Agreement on a Unified Patent Court of June 1, 2023.

²⁸ Council Regulation (EC) No 2100/94 on Community plant variety rights was amended by Regulation (EC) No 873/2004 to align it with Directive 98/44/EC (the Biotech Directive), specifically with regard to compulsory cross-licensing between patents and plant variety rights.

analysis of relevant national provisions reveals textual differences among Member States.²⁹ However, there is no recorded information indicating that the provision has ever been applied, i.e., that any such compulsory license has ever been requested. Moreover, to date, there appears to be no case law regarding the interpretation of compulsory cross-licensing provisions at the national level.³⁰

38. Discussions within the EU and among various academic circles point to challenges regarding the applicability and effectiveness of the compulsory cross-licensing provision in the Biotech Directive.³¹ One of the key difficulties lies in the lack of clear interpretation of what constitutes “*significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety*” in Article 12(3)(b) of the Biotech Directive.³²

39. In December 2015, the European Parliament adopted a resolution requesting clarification of certain provisions of Directive 98/44/EC, including the issue of cross-licensing between patents and plant variety rights. In response, the European Commission issued a Notice in 2016 providing interpretative guidance on requested matters.³³ With respect to the issue of cross-licensing, the European Commission observed that demonstrating significant technical progress may be more challenging in the case of plant varieties than for patents. It further clarified that, pursuant to Article 12(3) of the Directive, compulsory cross-licenses

²⁹ For analysis of national law provisions, see Section 5 of this document.

³⁰ See, e.g., Daria Kim 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 International, 73(4), 2024, p. 331; See also Bostyn, S., et al., “Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering. European Commission.”, 2016, p.58.

³¹ Regarding academic discussions, see, e.g., Daria Kim, who notes that a “breeder is unlikely to embark on a multi-year, costly breeding program to develop a new variety and obtain a PBR in the presence of significant legal uncertainty as to whether the variety will fulfil the requirement of ‘significant technical progress of considerable economic interest’”. Daria Kim et al., *ibid*, pp., 331 and 334; See also Christoph Antons, who summarizes the opinions of different authors regarding the difficulties of application of cross-licensing provisions under the terms prescribed by European laws. Antons, Christoph, “Article 27(3)(B) Trips and Plant Variety Protection in Developing Countries”, August 2, 2016. Hanns Ullrich, Reto M. Hilty, Matthias Lamping and Josef Drexl (eds.), TRIPS plus 20: From Trade Rules to Market Principles, Heidelberg-New York-Dordrecht-London: Springer, 2016, p.16; See also ALLEA (All European Academics) Statement on Measures to Ease the Impact of the IP System on New Genomic Techniques for Crop Development. The Statement notes: “the existing cross-licensing regime in Article 12 of the EU Biotechnology Directive is not considered workable in practice, predominantly because the meaning of one of the basic requirements is unclear: “the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety”. In addition, compulsory licensing happens on a case-by-case basis and the most likely outcome is uncertainty, which is expected to result in considerable innovation slowdown.” February 2024, p.9. See also Bostyn, S., who concludes that “[a] regime for mandatory licensing for dependency is highly needed in the context of breeding activities where genome editing patents are present. The current regime is not useful and should be replaced with a proper functioning regime.” Patenting Plants, plant variety protection and inclusion of plant breeders: is it achievable? in, Sappa, C. (ed.), Research Handbook on Intellectual Property and Inclusivity, Edward Elgar, 2024, p. 341.

³² Another difficulty lies in the lack of clear guidance on how to interpret the terms “acquiring” or “exploiting” a plant variety right in Article 12(1) of the Biotech Directive. It is unclear whether this refers only to the phase when the breeder is applying for the plant variety right after breeding is complete, which risks wasted investment if no license is granted, or also includes early breeding activities, which could lead to paying for a license that ultimately proves unnecessary if no new variety is developed. See Bostyn, S., et al., “Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering. European Commission.”, 2016, p.56.

³³ Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003.

would only have to be granted in cases where the new variety represents a “genuine agricultural achievement”.

40. Furthermore, the European Commission notes the difficulty in applying these criteria when analyzing the subject matter covered by two distinct protection regimes, such as patents and *sui generis* system:

“The double condition relating to technical progress and economic value might be cumbersome for a plant variety right holder to demonstrate. This wording was inspired by Article 31(l) of TRIPs, which deals with the situation in which a patent cannot be exploited without infringing another patent. However, the way plant varieties are assessed by plant variety offices differs significantly from the approach taken by patent offices: while plant variety offices make sure that the new variety is distinct (from other varieties of common knowledge), uniform, stable and new in comparison with existing varieties, patent offices merely focus on technical teaching arising from the invention from a theoretical point of view. In addition, it is difficult to predict before the placing on the market of a new plant variety whether it will be an economic success.”³⁴

41. The Commission further notes, however, that notwithstanding these challenges, compulsory cross-licensing is not expected to pose a major issue for protected varieties because of the compulsory breeder’s exemption provided on the one hand in Article 27(c) of the Unified Patent Court Agreement, and on the other in Article 15(c) of the Regulation on Plant Variety Rights,³⁵ ensuring free access to the widest possible source of genetic material and thus stimulating innovation.^{36, 37, 38}

³⁴ As regards the interpretation of analogous criteria found in Article 31(l) of the TRIPs Agreement, some authors have also noted the lack of clarity. See. e.g., Daria Kim 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 International, 73(4), 2024, p. 334; see also Hanns Ullrich, “Patent Dependency under European and European Union Patent Law – A Regulatory Gap”, Max Planck Institute for Innovation and Competition Research Paper No 23-04, 2023.

³⁵ Article 15(c) of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (the CPVR Regulation) states that ‘acts done for the purpose of breeding or discovering and developing other varieties’ are excluded from the scope of the right.

³⁶ The Commission further acknowledges that “[s]ome uncertainty could however arise when a patent claim targets native traits, because breeders could then be prevented from developing new varieties.”

³⁷ The Expert Group which was set up to assist and advise the Commission in its reporting requirements under Article 16, paragraph (c) of the Biotech Directive found no known cases of compulsory cross-licenses being granted or requested, with no public data available. They could not agree on whether the system under Article 12 functions effectively but noted the threshold for obtaining such a license appears very high. They noted that no evidence was presented showing that breeders are particularly disadvantaged under the current regime. Some experts argued that condition (b) of Article 12(3) is effectively impossible to meet because of the different nature of patent and plant variety protection, while others saw little difference from other rarely used compulsory licensing systems and found no reason for special treatment of breeders. In conclusion, although all experts agreed that the wording of Article 12 is impractical, an overwhelming majority (all but two) recommended that no action be taken. See Bostyn, S., et al., *supra* note 14.

³⁸ The Position Statement prepared in the context of the European Commission’s July 2023 proposal to ease marketing authorization requirements for certain NGT-derived plants notes another issue: “[...] the wording of Art. 12(2) makes it difficult for a breeder – the holder of a PVR – to get a cross-licence for an NGT technology. It is unclear how a new plant variety can be considered a ‘significant technical progress’ compared with a biotechnological invention that is not an NGT plant but a genome-editing method and/or a research tool.” See Daria Kim et al., *supra* note 31, p.331.

Exhaustion of rights

42. Article 10 of the Biotech Directive clarifies how the exhaustion principle applies to patented biological material, which by its nature can reproduce itself, when it is placed on the market by the patent holder or with their consent. The provision states:

“The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.”

43. Article 10 establishes a specific exhaustion rule tailored to the unique characteristics of biological material. It is designed to balance the patentee’s exclusive rights with the practical realities of biological propagation, ensuring that once the patented material has been placed on the market with the consent of the right holder, certain acts of propagation or multiplication that necessarily result from its intended use fall outside the scope of patent protection.

44. According to Article 2(1)(a) of the Directive, “biological material” is defined as material containing genetic information and capable of reproducing itself or being reproduced in a biological system. The scope of patent protection for such material is set out in Articles 8 and 9 of the Directive. Article 8(1) provides that 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. Article 8(2) states that 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 provides that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material³⁹ in which the product is incorporated and in which the genetic information is contained and performs its function.

45. Article 10 limits the scope of protection conferred by Articles 8 and 9, allowing farmers and breeders to use patented biological material for propagation or multiplication if that was the intended purpose of the sale. However, exhaustion does not extend to acts involving further cycles of reproduction beyond the scope of the initially authorized use.⁴⁰

³⁹ Save as provided in Article 5(1).

⁴⁰ S. Bostyn explained in this regard that a person who used a patented yeast to make beer would *prima facie* infringe the patent in the yeast. This is because the process of making beer necessarily involves the multiplication of the yeast organisms. However, if the patented yeast were sold in a home brew shop for the purpose of beer-making it would provide “defense” for the defendant. However, if the defendant propagated the yeast and offered it for sale, the defense would not apply. Similarly, it has been suggested that the “defense” would allow farmers to sow a patented seed, to harvest and sell the resulting crop, for example, to sell the wheat for flour, but farmers would not be allowed to sell the seed to other farmers for the purpose of propagating new crops. S. Bostyn, “The Patentability of Genetic Information Carriers” 1999, and R. Nott, “You Did It: The European Biotechnology Directive at Last” 1998, cited in Lionel Bently, Brad Sherman, *Intellectual Property Law*, Oxford University Press, 2001, at 510.

Farmers' use

46. Article 11 of the Biotech Directive sets out the farmers' use exception, or what is also known as "the farmers' privilege" or "farm saved seed exemption". This exception allows farmers to use the patented product of their harvest for propagation or multiplication on their own farm, and to use protected livestock for agricultural purposes. Specifically, Article 11 states:

"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.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity."

47. According to paragraph 1 of the provision, farmers are allowed to save seeds and use the product of their harvest for propagation or multiplication by them on their own farm under the conditions set out under Article 14 of the CPVR Regulation which provides for Community plant variety rights as "as the sole and exclusive form of Community industrial property rights for plant varieties".⁴¹

48. Article 14 of the CPVR Regulation reads:

"1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right."

49. Paragraphs 2 and 3 of Article 14 of the CPVR Regulation state that the farmers' privilege exists only for certain defined categories of agricultural plant species – namely fodder plants, cereals, potatoes, and oil and fibre plants – with "no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding".

50. Further, according to paragraph 3 of that provision, the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing.

⁴¹ Article 1 of the CPVR Regulation.

51. Furthermore, the farmers' use exception is subject to payment of an equitable remuneration to the holder, from which small farmers are exempted.⁴² Other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area.⁴³

52. Finally, the CPVR Regulation provides that monitoring compliance with the provisions relating to the farmers' use shall be a matter of exclusive responsibility of holders. Farmers shall provide the relevant information to the holders at their request. Relevant information may equally be provided by official bodies involved in the monitoring of agricultural production, if such information has been obtained through the ordinary performance of their tasks, without additional burden or costs. This provision shall be understood in accordance with domestic or Community provisions on personal data protection.⁴⁴

53. Article 14(3) of the CPVR Regulation provides that the conditions to give effect to the agricultural exemption set out in Article 14(1), and to safeguard the legitimate interests of both the breeder and the farmer, shall be established through implementing rules. Pursuant to this mandate, the European Commission adopted Commission Regulation (EC) No 1768/95 of 24 July 1995, which lays down the specific implementing rules governing the agricultural exemption provided under the CPVR Regulation. Specifically, Commission Regulation (EC) No 1768/95 sets out the detailed conditions, limitations, and obligations applicable to the agricultural exemption under Article 14(1) of the CPVR Regulation, including provisions concerning the rights and obligations of the holder and the farmer (e.g., clarification of what constitutes an "own holding" within the meaning of Article 14(1)), and the determination of the level of remuneration due to the holder.⁴⁵

54. Thus, the scope of the farmers' use exception in the EU Biotech Directive is directly linked to the framework established by the CPVR Regulation. Due to this legislative connection, legislative developments and judicial interpretations within the CPVR system could, *mutatis mutandis*, be applicable when analysing the scope of the exception under the Biotech Directive. While the Court of Justice of the European Union has addressed Article 14 of the CPVR Regulation in a limited number of cases relating to plant variety rights,⁴⁶ that provision has not, to date and to the best of our knowledge, been subject of judicial consideration in the context of patent infringement proceedings, either at the EU or national level.

55. Regarding the interpretation of Article 14 of the CPVR Regulation, it is relevant to consider that the European Union, as a member of the International Union for the Protection

⁴² Small farmers shall be considered to be: "- in the case of those of the plant species referred to in paragraph 2 of this Article to which Council Regulation (EEC) No 1765/92 of 30 June 1992 establishing a support system for producers of certain arable crops (...) applies, farmers who do not grow plants on an area bigger than the area which would be needed to produce 92 tonnes of cereals; for the calculation of the area, Article 8 (2) of the aforesaid Regulation shall apply, - in the case of other plant species referred to in paragraph 2 of this Article, farmers who meet comparable appropriate criteria". Article 14.3 of the CPVR Regulation.

⁴³ The actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned. Article 14.3 of the CPVR Regulation.

⁴⁴ Article 14.3 of the CPVR Regulation.

⁴⁵ Commission Regulation (EC) No 1768/95 of 24 July 1995 as amended by Commission Regulation (EC) No 2605/98 of 3 December 1998, can be found at: <https://cpvo.europa.eu/en/about-us/law-and-practice/legislation-in-force>.

⁴⁶ Please see the PVR case-law database, which contains decisions and judgments of, including, the National Courts of EU Member States, the Court of Justice of the European Union, and the Boards of Appeal of the CPVO. The database can be found at: <https://cpvo.europa.eu/en/about-us/law-practice>.

of New Varieties of Plants (UPOV), must ensure compliance with the provisions of the UPOV Convention. Accordingly, guidance issued by UPOV concerning the analogous exception under Article 15(2), as revised in the 1991 Act,⁴⁷ may be instructive in interpreting the scope of Article 14 of the CPVR Regulation.^{48, 49}

56. As regards the scope of the farmers' use exception concerning breeding stock under Article 11(2) of the EU Biotech Directive, it is clear from the text of the provision that farmers who purchase patented breeding stock or animal reproductive material with the patent holder's consent are authorized to use it for their own agricultural purposes, including on-farm breeding to maintain their production. However, this exception does not extend to the sale or commercial distribution of offspring or reproductive material for breeding purposes within a commercial reproduction activity. To date, no case law has been identified, either at the EU or national level, relating to Article 11(2) of the EU Biotech Directive. In practice, the extent and conditions of this derogation is subject to determination under national laws, regulations, and practices, pursuant to Article 11(3) of the Biotech Directive.

4.2 Agreement on a Unified Patent Court (UPCA)

57. Article 27 of the UPCA sets out a list of exceptions to the rights conferred by a patent, including breeders' use in paragraph (c), farmers' use in paragraphs (i) and (j), and exhaustion of rights in paragraph (l). In particular, Article 27 of the UPCA states:

"27. Limitations of the effects of a patent

The rights conferred by a patent shall not extend to any of the following:

[...]

⁴⁷ Article 15(2) of UPOV Convention states: "[Optional exception] Notwithstanding Article 14[...], each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii)".

⁴⁸ See, e.g., *Explanatory Notes on Exceptions to the Breeder's Right under the 1991 Act of the UPOV Convention* (document UPOV/EXN/EXC/1), which provides guidance on, *inter alia*, the optional exception in Article 15(2) of the 1991 Act. The Guide is available at: https://www.upov.int/edocs/expndocs/en/upov_exn_exc.pdf. In addition, the UPOV website FAQ offers explanations on questions such as "Can farmers, for instance, be allowed to exchange seeds of protected varieties freely within the local community?" and "Is it possible for subsistence farmers to exchange propagating material of protected varieties against other vital goods within the local community?" See: <https://www.upov.int/about/en/faq.html#QF60>. It should be noted, however, that the binding obligations on UPOV members are those set out in the text of the relevant Act of the UPOV Convention, and these explanatory materials must not be interpreted in a manner inconsistent with the applicable Act.

⁴⁹ While the above discussion reflects official legal sources, some non-official commentary has also addressed the scope of Article 14 of the CPVR Regulation. For example, the Swedish Academy of Agriculture and Forestry noted that "In the EU context of Farmers' privilege, the farmers are given the right to produce, process and use seed from their own harvest of PVR protected varieties of cereals, oilseeds, pulses and potatoes, but not to sell seed to neighbors and others". "Plant variety rights and patents on plants – their application on NGT plants and plant varieties in the EU", 11 November 2024, p. 4, available at: <https://www.ksla.se/wp-content/uploads/2024/11/Plant-variety-rights-and-patents-Plant-Node.pdf>. In addition, with regard to legal scholars' comments on Article 14 of the CPVR Regulation, it is stated that, as the provision "only applies in relation to farmers who use the product of their harvest for propagating purposes on their own holding [...], the sale of the product of the harvest, by one farmer to another, will not empower the latter to use this product for propagating purposes on his holding: it would be an infringing act pursuant to Article 13." Würtenberger, G., van der Kooij, P. A. C. E., Kiewiet, B., & Ekvad, M., *European Union plant variety protection* (3rd ed.). Oxford University Press, 2021, p.150.

- (c) *the 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^[...];*

- (j) *the use by a farmer of protected livestock for an agricultural purpose, provided that the breeding stock or other animal reproductive material were sold or otherwise commercialised to the farmer by or with the consent of the patent proprietor. Such use includes making the animal or other animal reproductive material available for the purposes of pursuing the farmer's agricultural activity, but not the sale thereof within the framework of, or for the purpose of, a commercial reproductive activity;"*

[...]

- (l) *the acts allowed pursuant to Article 10 of Directive 98/44/EC^[...]."*

58. The text of this provision indicates that the scope of the farmers' use exceptions and the exhaustion of rights under the UPCA corresponds directly to the EU Biotech Directive provisions discussed above. Article 27(i) explicitly cross-refers to Article 14 of the CPVR Regulation, aligning it with the Biotech Directive's farmers' use provision. Meanwhile, paragraph (l) refers directly to the acts permitted under Article 10 of the Biotech Directive.

59. As regards the breeders' use exception in paragraph (c) of Article 27 of the UPCA, it is clear from the wording of that paragraph that the exception covers the use of biological material⁵⁰ specifically for breeding or for discovering and developing other plant varieties. This exception is purpose-bound: the permitted acts must have the objective of breeding or developing new varieties. Its scope also appears broader than a standard "experimental use" exception, as it explicitly includes use for breeding, i.e., not only research "on" the patented material, but also research "with" it.⁵¹

60. As of May 2025, there have been no specific cases or decisions directly interpreting the above provisions of the UPCA. Article 20 of the UPCA explicitly requires the Unified Patent Court to apply EU law in its entirety and to respect its primacy. Accordingly, the above exceptions under the UPCA must be interpreted consistently with the corresponding provisions of the Biotech Directive and relevant jurisprudence of the Court of Justice of the

⁵⁰ The UPCA does not provide the definition of the term "biological material". However, in the Biotech Directive, the term means "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system". See Article 2(1)(a) of the Biotech Directive.

⁵¹ It should be noted that under many national patent laws, the scope of the experimental use or research exemption is limited to research 'on' the patented subject matter, as opposed to research 'with' it. In other words, the patented subject matter can typically be used without a license only to study or improve the invention itself, and not as a research tool to create and develop, for example, a new plant variety. For further information on the scope of the research exemption, see document SCP/29/3.

European Union.⁵² Although it does not represent an official interpretation, reference may be made to academic commentary for illustrative purposes only. In particular, a volume edited by Winfried Tilmann and Clemens Plassmann⁵³ provides the following commentary on these provisions:

On paragraph (c) (breeders' use):

“By Art 27(c), the UPCA provides for a separate privilege element for the use of biological material for the purpose of breeding, or discovering and developing plant varieties; the provision goes beyond the experimental privilege according to Art 27(b) and is oriented on Art 15(c) of the Community Plant Variety Rights Regulation. [...] The purpose of the provision is to prevent plant research from being excessively hampered by the effect of patents for biological material.[...] In that respect, Art 27(c) UPCA, similar to lit I [...], allows for the purpose-tied use of biological material [...].

According to the wording of the provision, any kind of use is privileged. There is no limitation to particular experimental acts as provided for under Art 27(b) UPCA. In particular, a breeder may do research not only on but also with the patent-protected biological material.[...] It is not a condition that such material must have been placed on the market by the entitled person themselves; rather, it suffices if information relating to the biological material is made available.[...] Use, of course, is permissible only if it takes place for the purpose of breeding, or discovering and developing other plant varieties within the meaning of Art 5(2) Community Plant Variety Rights Regulation. In that respect, the provision contains a definitive element. Breeding or development relates to the creation of another plant variety through human intervention, whereas discovery means finding a new variety without human intervention.[...] Not covered by the plant research privilege is the exploitation of the newly acquired material.”

On paragraph (i) (farmers' use):

“[...] Art 27(i) UPCA provides for a limitation of patent effects for use of the product of harvest for propagation (sexual reproduction) or multiplication (asexual reproduction). The purpose of the provision is to safeguard agricultural production. As a consequence, the prerequisite for the exemption is that the act of use is performed by a farmer. It thus has to be a person who works in the area of primary production and who in this context specifically engages in the production of plant and/or animal products with the aid of the forces of nature on an area farmed for such purpose. Regarding the extent and conditions of the use, Art 27(i) UPCA makes reference to Art 14 Regulation (EC) No 2100/94[...] (Plant Variety Rights Reg). Given that mention is also made there of small farmers, it may be concluded from this that the size of the farming operation is not relevant.

The product of harvest privilege, on account of the reference to Art 14 Plant Variety Rights Reg, does not cover any product of harvest but only the fodder plants, cereals, potatoes, as well as oil and fibre plants specifically listed in Art 14(2) Plant Variety Rights Reg. The plant propagating material concerned must have been sold or otherwise commercialized, for example through sale to a wholesaler or intermediate

⁵² It should be noted however that, unlike the farmers' use and exhaustion provisions, the breeders' use exception in Article 27(c) of the UPCA does not have a corresponding provision in the Biotech Directive. Its interpretation will therefore likely need to be developed within the framework of the UPCA itself.

⁵³ Chapter V, Sources of Law and Substantive Law in *Unified Patent Protection in Europe. A Commentary* (edited by Winfried Tilmann and Clemens Plassmann), Oxford University Press (2018), pp. 533 and 538, available at: <https://academic.oup.com/book/41092/chapter/350018499>.

dealer, to the farmer by or with the consent of the patent proprietor for agricultural use. The product of harvest privilege relates only to the farmer's product of harvest gained from the plant propagating material, as is clear from the wording of Art 27(i) UPCA ('product of his harvest').

Use is reserved to the farmer 'by him in his own holding'. That does not exclude the possibility of the farmer having relevant acts of use performed by his own personnel. However, the involvement of third parties, for example service providers, has to be regarded as not permissible, because that would not constitute an act performed 'by him' (the farmer). Here, the wording of Art 27(i) UPCA deviates from Art 14(1) Plant Variety Rights Reg which does not stipulate such restriction. The quantitative extent of the acts of use is irrelevant (Art 14(3) Plant Variety Rights Reg)."

On paragraph (j) (farmers' use as regards breeding stock):

"Likewise, the rights of a patent, pursuant to Art 27(j) UPCA, do not extend to use by a farmer of protected livestock for an agricultural purpose [...], provided that the breeding stock or other animal reproductive material were sold or otherwise commercialized to the farmer by or with the consent of the patent proprietor. As in the case of Art 27(i) UPCA, the purpose pursued here is to safeguard agricultural production. The term livestock includes animals that are bred or kept for the production of food, wool, skin, or fur or for other farming purposes (Art 2(1) Directive 98/58 EC^[...]). Accordingly, the use privilege covers the aforementioned agricultural purposes as well as making the agricultural livestock or other animal reproductive material available for the purpose of pursuing the farmer's agricultural activity. However, the privilege does not cover the sale of livestock or the reproductive material by the farmer for the purpose or within the framework of a commercial reproductive activity. The reason is that this would overstep the privilege purpose of safeguarding agricultural production.

On paragraph (l) (exhaustion of rights):

"[...] Of course, if the biological material is placed on the market by the patent proprietor himself or with his consent in the patent's domestic territory, i.e. within the territory of the CMSs [...], exhaustion, pursuant to Art 10 Biotech Dir, to which Art 27(l) UPCA refers, occurs not only with reference to the biological material (initial material) but also in respect of the material derived therefrom by means of propagation or multiplication (reproductive material). The prerequisite, of course, is that the biological material was (also) placed on the market for the purpose of reproduction, i.e. not (only) for consumption purposes. Where the specific purpose is not expressly stated or implied from a contractual agreement, the objective circumstances in which it was placed on the market are controlling. It does not matter where the reproduction occurs. The only decisive factor is that a form of propagation (sexual reproduction) or multiplication (asexual reproduction) has occurred. That said, the effect of exhaustion is limited: it occurs only with reference to the further use of the reproductive material, but not if the reproductive material is used for further propagation or multiplication. For further reproduction, therefore, biological material must once again be acquired from the patent proprietor."

4.3 Andean Community Decision N° 486

61. The Andean Community Decision N° 486, which is applicable to the Member States of the Andean Community, comprising Bolivia, Colombia, Ecuador, and Peru, provides a

breeders' use exception in Article 53(e), while Article 54 addresses the exhaustion rule with respect to biological material. In general, the Andean Community Decisions have direct effect as the domestic IP legislation of the Member States.

62. The provisions state:

"53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

[...]

(e) where the patent protects biological material, that can be reproduced, other than plants, using that material as the basis with which to obtain viable new material, except where to do so requires repeated use of the patented subject matter.

54.

[...]

Where the patent protects biological material, that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in accordance with the first paragraph above, provided that the reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market, and provided that the material derived from such use is not used for multiplication or propagation purposes."

63. It follows from the wording of Article 53(e) that the patentee's exclusive rights are limited by permitting third parties to use the patented biological material as a basis for obtaining "viable new material". However, the exception does not apply where "repeated use" of the patented subject matter is required.

64. Regarding the exhaustion principle in Article 54, the formulation is similar to that discussed above in regional European instruments, as it limits the extent of patent rights after the patented material has been placed on the market by the patentee or with its consent. It allows reproduction, multiplication, or propagation necessary for the intended use for which the material was sold, provided that the resulting material is not used for further multiplication or propagation beyond that scope.

65. As no interpretive guidance has been developed to date regarding Articles 53(e) and 54 of Andean Community Decision N° 486, it remains to be seen what the exact boundaries of these provisions are for its Member States.

5. National Implementation of the Exceptions Regarding Farmers' and/or Breeders' Use of Patented Inventions

66. In total, 54 countries have been identified to provide one or more of the four types of exceptions relating to breeders' and farmers' use of patented inventions through specific statutory provisions in their respective IP or patent legislation. The Appendix to this document contains the relevant legal provisions from those countries.

67. Compared with other types of exceptions and limitations to patent rights, this represents a smaller number of countries that have introduced provisions specifically addressing the use of patented inventions by farmers and breeders. This may be due to the flexibility provided under Article 27(3)(b) of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement), which allows Members of the World Trade Organization (WTO Members) to exclude plants, animals, essentially biological processes for the production of plants or animals, as well as plant varieties from patentable subject matter. Depending on how this provision has been implemented at the national/regional level, the need to establish specific exceptions for farmers or breeders regarding the use of plant or animal inventions may not arise.

68. Furthermore, national laws may differ in terms of the scope of rights conferred by a patent on self-reproducible biological material, namely, the extent to which a patent on such material extends to propagated material possessing the same characteristics as the patented material. Moreover, certain uses by farmers may fall under the general “private and non-commercial use” exception, while the use of patented inventions by breeders to develop new plant varieties may fall within the scope of the “research or experimental use” exception. As a result, the need to establish exceptions or limitations addressing such uses by farmers and breeders through specific provisions may not be recognized in all jurisdictions. The extent to which the general principle of patent exhaustion applies to the subsequent propagation or multiplication of biological material may also vary across jurisdictions, further influencing whether specific exceptions for farmers or breeders are deemed necessary.

Table: List of countries whose national or regional legislation contains provisions on farmers’ and/or breeders’ use of patented inventions

Countries	Total number
Albania, Andorra, Armenia, Austria, Belgium, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Cabo Verde, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liberia, Lithuania, Luxembourg, Malta, Mexico, Montenegro, Netherlands (Kingdom of the), Nicaragua, North Macedonia, Norway, Oman, Poland, Portugal, Peru, Republic of Moldova, Romania, San Marino, Sao Tome and Principe, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.	54

69. With respect to the scope of the relevant provisions in national laws, most countries have not developed any judicial interpretation concerning the four types of exceptions related to breeders’ and farmers’ use of patented inventions. In a few other countries, a small number of court cases have addressed one or more of these exceptions. The following subsections provide information on various aspects of these exceptions in different countries, based primarily on the analysis of national legal provisions.

Exhaustion of rights

Formulation and scope of the exception

70. Provisions concerning the application of the exhaustion principle to patented biological material have been identified in 42 countries.

71. Many national laws adopt a formulation similar to that found in the relevant provision of Estonian law (EU Biotech Directive–based model), which states:

“The following acts do not constitute infringement of the exclusive right of the proprietor of a patent:

[...]

7) the propagation or multiplication of biological material placed on the market by the proprietor of the patent or with the proprietor’s consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the biological material obtained is not subsequently used for other propagation or multiplication.”⁵⁴

72. A different formulation with substantively the same effect can be found, e.g., in Nicaraguan law, which states:

“Where the patent protects biological material capable of reproduction, the patent shall not extend to material obtained by multiplication or propagation of the material that is brought on to the market as provided in the first paragraph of this Article insofar as the multiplication or propagation is the necessary consequence of the use of the material for the purposes for which it was brought on to the market, and the material resulting from that use is not used for multiplication or propagation purposes.”⁵⁵

73. Based on the texts of national legal provisions in most countries, the following common key legal elements can be identified in relation to this exception:

- (i) Exhaustion triggered by authorized sale: the exhaustion applies only where the biological material has been put into market by the patent holder or with its consent.
- (ii) Permitted use – purpose-bound propagation: the exception allows propagation or multiplication, but only when it necessarily results from the intended use of the material as marketed. In other words, the permitted use is tied to the purpose for which the material was marketed.
- (iii) Restriction to one cycle of propagation: the material derived from the permitted act may not be used for further propagation or multiplication. This suggests that the exhaustion does not extend to reuse or continued reproduction, thereby preserving the patent holder’s control beyond the first cycle.⁵⁶

74. These elements are particularly common in the laws of EU Member States that have implemented the EU Biotech Directive.

75. Some differences in the formulation of national legal provisions, however, have been identified in some other countries. For example, in Brazil, Article 43.VI of Law No. 9.279 states:

⁵⁴ Sections 16(7) of the Patents Act of Estonia (consolidated text of August 31, 2023).

⁵⁵ Articles 47 of the Law No. 354 on Patents, Utility Models and Industrial Designs of Nicaragua.

⁵⁶ For example, Polish law expressly states that the protection conferred by a patent shall not extend to biological material obtained by means of a “single act of propagation or multiplication of biological material placed on the market [...]”. See Article 93(1) of the Act of June 30, 2000, on Industrial Property (as amended up to Act of March 9, 2023) of Poland.

“The provisions of the previous Article do not apply:

[...]

*VI. to third parties who, in case of patents related to living material, use, place in circulation, or market a patented product that has been legally introduced into commerce by the patentholder or the holder of a license, provided that the patented product is not used for commercial multiplication or propagation of the living material in question”.*⁵⁷

76. Based solely on its wording, one may reasonably conclude that the Brazilian approach differs from the EU Biotech Directive–based model primarily in its focus on the intended purpose of use (i.e., whether it is commercial), rather than on the biological behavior of the material (i.e., whether it is being propagated or multiplied). Provision allows third parties to use, circulate, or market patented living material placed on the market by the right holder, provided it is not used for commercial propagation or multiplication. Accordingly, one could argue that the exception potentially permits certain non-commercial activities involving the material.⁵⁸

77. In contrast, the Mexican approach appears to be more restrictive. Under the exhaustion rule, third parties are permitted to use, circulate, or commercialize the patented invention only for purposes “other than multiplication or propagation”, after it has been lawfully introduced into commerce by the patent owner or with its consent. On its face, the provision appears to exclude any form of reproduction or propagation, irrespective of its commercial or non-commercial nature, and does not seem to allow even a single act of propagation after the product has been lawfully introduced into commerce.⁵⁹

78. With respect to the territorial scope of exhaustion, the laws of some countries do not specify the particular market into which the biological material must be introduced.⁶⁰ In contrast, other countries’ laws explicitly refer to introduction into the domestic market,⁶¹ or the market of a Member State of the European Union or a Contracting Party to the European Economic Area Agreement.⁶²

Farmers’ use

Formulation and scope of the exception

79. Provisions concerning farmers’ use have been identified in 45 countries. In most of these jurisdictions, two distinct types of exceptions typically appear: one relating to plant

⁵⁷ Article 43.VI of Law No. 9.279 of May 14, 1996.

⁵⁸ However, in a 2019 decision, the Brazilian Superior Court of Justice (STJ) clarified that this provision must be interpreted in light exhaustion rule which does not apply when the patented product is used for the multiplication or commercial propagation of the living material in question. See relevant case law in paragraphs 96-99 of this document.

⁵⁹ Article 57. VII of the Federal Law on the Protection of Industrial Property of Mexico states “*Un tercero que, en el caso de patentes relacionadas con productos que consistan en materia viva, utilice, ponga en circulación o comercialice la invención patentada, para fines que no sean de multiplicación o propagación, después de que ésta haya sido introducida lícitamente en el comercio por el titular de la patente, o la persona que tenga concedida una licencia,*”.

⁶⁰ See, e.g, the provisions of law of Brazil and Mexico.

⁶¹ See, e.g, the provisions of laws of Armenia, Bosnia and Herzegovina.

⁶² For detailed discussion on the types of exhaustion doctrines and their legal implications, see document SCP/34/3.

reproductive material and the other to animal reproductive material. Not surprisingly, the wording of the relevant provisions found in many European countries closely mirrors that of either Article 11 of the EU Biotech Directive or Article 27(i) and (j) of the UPCA, as discussed above.

80. For example, Section 3b of the Patent Act of Finland reflects the EU Biotech Directive style. The provision states:

“By way of derogation from the provisions of section 3 a, subsections (1) to (3), 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 Council Regulation (EC) No 2100/94 on Community plant variety rights.

By way of derogation from the provisions of section 3 a, subsections (1) to (3), the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.”

81. The UPCA-style formulation is exemplified by the applicable law of Ireland, which states:

“10. (1) Regulations 7 and 8 shall not extend to—

(a) the use by a farmer of the product of his harvest for propagation or multiplication by him on his own farm, where there has been a sale or other form of commercialisation of plant propagating material to the farmer by the proprietor of the patent or with the consent of the proprietor of the patent for agricultural use, subject to conditions corresponding to the derogation set out in Article 14 of the Council Regulation, and

(b) the use for an agricultural purpose by a farmer of protected livestock, where there has been a sale or other form of commercialisation of breeding stock or other animal reproductive material to the farmer by the proprietor of the patent or with the consent of the proprietor of the patent.

(2) The use for an agricultural purpose by a farmer of protected livestock referred to in paragraph 1(b) includes making the animal or other animal reproductive material available for the purposes of pursuing the agricultural activity of the farmer but not sale within the framework or for the purpose of a commercial reproduction activity.”

82. Some non-European countries have also incorporated language similar to that of the above-mentioned European instruments. For example, Armenia and San Marino follow the EU Biotech Directive-style, while Albania has adopted a formulation closer to the UPCA model.⁶³

⁶³ For the full text of the relevant national law provisions, see the Appendix.

83. In some countries that have implemented the above-discussed European framework, differences can be observed in the formulation of the relevant provisions at the statutory level. For example, the national laws of Croatia, Bulgaria, the Czech Republic, and Norway, concerning farmers' use of plant reproductive material, do not explicitly reference Article 14 of the CPVR Regulation.

84. Other variations in wording also appear in the legislation of certain European countries. For instance, Section 8 of the Czech Republic's Act No. 206/2000 Coll. permits farmers to reuse harvested material for agricultural purposes, provided there is no commercial exploitation. However, the wording of this provision does not explicitly restrict the use to acts performed "by the farmer" or "on his own farm."⁶⁴ Likewise, Section 3b of Norway's Patents Act does not limit propagation or multiplication to being carried out personally by the farmer, but only specifies that it must occur "on his own farm".⁶⁵

85. Other particularities observed in the wording of national provisions. For example, in Sweden, an additional condition is applied with respect to farmers' use of patented inventions: "[t]he right under the first paragraph may not be exercised to a greater extent than is reasonable with regard to the needs of the farmer and the interests of the patent holder."⁶⁶ In Switzerland, the law expressly clarifies under the farmers' use exception, as provided in their law, farmers are required to obtain the consent of the patentee if they wish to give the product of their harvest, or animal or animal reproductive material, to third parties for reproduction purposes. In addition, the relevant provision states that "contractual agreements which limit or revoke the farmers' privilege in the area of food and feed production are null and void."⁶⁷

86. Furthermore, the Industrial Property Code of Italy does not appear to contain a farmers' use provision concerning animal reproductive material, limiting the exception to "patented material of plant origin".⁶⁸ In France, the provision relating to animal reproductive material states that "the sale or any other form of commercialisation of breeding stock or other animal reproduction material to a farmer by the holder of the patent, or with his consent, implies authorization to use, *if necessary on payment of a fee*, the protected livestock for an agricultural purpose".⁶⁹ Few countries' statutes make reference to secondary legislation, such as implementing regulations, that would further define the scope of farmers' use in relation to animal reproductive material.⁷⁰

87. While the laws of EU Member States refer to the CPVR Regulation to define the scope and conditions of the farmers' use exception for plant reproductive material, legislation in many non-EU countries that include such an exception often do not provide comparable detail regarding its scope, conditions, or beneficiaries, at least at the level of the statute.

88. For example, the statutory provisions of Botswana do not set out specific limitations on the scope of farmers' use, potentially allowing broader use in practice, unless such details

⁶⁴ See Sections 8 and 9 of the Act No. 206/2000 Coll., of June 21, 2000, on the Protection of Biotechnological Inventions of the Czech Republic.

⁶⁵ It should be noted, however, that these observations are based solely on the statutory wording of national provisions. It is possible that implementing regulations or administrative guidance in these countries may provide further details regarding, for example, limitations on scope, beneficiaries, or permitted crops.

⁶⁶ Section 10, Chapter 3, of the Patents Act of Sweden.

⁶⁷ Art. 35a of the Patent Act of 25 June 1954, of Switzerland.

⁶⁸ Art. 170-bis, paragraph 5 of the Industrial Property Code of Italy.

⁶⁹ Art. L613-5-2 of the Intellectual Property Code of France. [emphasis in *Italic* is added]. The European legal instruments, as discussed above, do not refer to fee payments with respect to the provision on animal livestock.

⁷⁰ See the provisions of the laws of Hungary, Iceland, Spain, and Türkiye in the Appendix.

are found in secondary legislation. Specifically, Section 25(1) of the Industrial Property Act states:

“25. (1) The rights conferred by a patent shall not extend to –

[...]

(d) use by a farmer in the harvest of a farm produce for propagation or multiplication by the farmer on the farmer’s holding, where there has been a sale of plant propagating material to the farmer by the patentee or with the patentee’s consent for agricultural use;

(e) use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the patentee or with the patentee’s consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention;”

89. According to the applicable law of Türkiye, only small farmers, as defined under the relevant legislation, are entitled to use, on their own land, reproductive material derived from a product that was legitimately obtained from the patentee, with the patentee’s consent, or through other lawful commercial means, for the purpose of further production on that same land.⁷¹

90. In Liberia, the exception allows a farmer not only to use the product of their harvest for propagation or multiplication on their own holding, but also to exchange it with other farmers within the context of traditional or communal practices, provided that the plant material used to produce the harvest was put on the market in accordance with the applicable conditions set out in the law.⁷²

Accidental or unavoidable use

91. A few countries’ laws, such as those of Germany, Austria, and Switzerland, contain specific provisions addressing the accidental or technically unavoidable acquisition of patented biological material. These provisions generally clarify that accidental use - such as the presence of patented material in a field without intentional introduction - is not considered an infringement, thereby reducing the legal uncertainty for farmers in such cases. Specifically, the relevant provisions of these countries state that the scope of patent protection does not extend to biological material obtained in the course of agricultural activity “by chance or in a technically unavoidable manner”. Accordingly, a farmer cannot be held liable “if he has grown seeds or planting material not subject to this patent protection”.⁷³

Case law on exhaustion and farmers’ use

92. In the United States of America, the question of patent exhaustion has been addressed in the context of farmers saving and replanting patented seed. Although there is no express statutory provision on this issue, courts have consistently held that the doctrine of patent exhaustion applies only to the specific article sold, not to subsequent reproductions of that

⁷¹ Article 85 of the Industrial Property Law, Law № 6769 of December 22, 2016 of Türkiye.

⁷² Section 13.11 b) vii. of the Liberia Intellectual Property Act, 2016.

⁷³ See Section 22c (4) of the Patent Act of Austria, Section 9c (3) of the Patent Act of Germany, and Art. 9 para. 1 let. f Patents Act of Switzerland.

article, particularly in the case of self-replicating biological materials, such as genetically modified seeds.

93. This principle was definitively articulated by the U.S. Supreme Court in *Bowman v. Monsanto Co.*, 569 U.S. 278 (2013),⁷⁴ where the Court held that:

*“Patent exhaustion does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder’s permission. [...] the doctrine restricts the patentee’s rights only as to the “particular article” sold [...]; it leaves untouched the patentee’s ability to prevent a buyer from making new copies of the patented item.”*⁷⁵

94. The Court emphasized that although Bowman had lawfully acquired the seeds, his act of planting and harvesting them constituted an unauthorized “making” of the patented invention. Therefore, exhaustion did not apply, and infringement was established.

95. Earlier rulings by the Federal Circuit, including *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004), reached the same conclusion. The court held:

*“The restrictions in the Technology Agreement are within the scope of the patent grant, for the patents cover the seeds as well as the plants. The “first sale” doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been sold. The price paid by the purchaser “reflects only the value of the ‘use’ rights conferred by the patentee.” [...] The original sale of the seeds did not confer a license to construct new seeds, and since the new seeds were not sold by the patentee they entailed no principle of patent exhaustion.”*⁷⁶

⁷⁴ Facts of the case: Monsanto invented and patented Roundup Ready soybean seeds, which contain a genetic alteration that allows them to survive exposure to the herbicide glyphosate. It sells the seeds subject to a licensing agreement that permits farmers to plant the purchased seed in one, and only one, growing season. Growers may consume or sell the resulting crops but may not save any of the harvested soybeans for replanting. Petitioner Bowman purchased Roundup Ready soybean seed for his first crop of each growing season from a company associated with Monsanto and followed the terms of the licensing agreement. But to reduce costs for his riskier late-season planting, Bowman purchased soybeans intended for consumption from a grain elevator; planted them; treated the plants with glyphosate, killing all plants without the Roundup Ready trait; harvested the resulting soybeans that contained that trait; and saved some of these harvested seeds to use in his late-season planting the next season. After discovering this practice, Monsanto sued Bowman for patent infringement. Bowman raised the defense of patent exhaustion, which gives the purchaser of a patented article, or any subsequent owner, the right to use or resell that article. The District Court rejected Bowman’s defense and the Federal Circuit affirmed. *Bowman v. Monsanto Co.*, 569 U.S. 278 (2013), p.1, available at: <https://supreme.justia.com/cases/federal/us/569/11-796/case.pdf>.

⁷⁵ *Bowman v. Monsanto Co.*, 569 U.S. 278 (2013), pp.1 and 2.

⁷⁶ Facts of the case: In *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002), the defendant, a soybean farmer, purchased Roundup Ready® genetically modified seeds from an authorized distributor and entered into Monsanto’s Technology Agreement. The agreement allowed him to plant the purchased seeds for a single growing season but expressly prohibited saving and replanting harvested seeds. McFarling nonetheless saved second-generation seeds and replanted them in subsequent seasons without authorization. Monsanto sued for patent infringement and breach of contract. McFarling raised several defenses, including patent exhaustion (first sale doctrine), and a claim that his actions were protected under the Plant Variety Protection Act (PVPA). The Federal Circuit rejected all of these defenses, emphasizing that Monsanto’s rights under the utility patent prevailed over the PVPA’s farmer’s privilege, and that patent exhaustion did not extend to reproduction of patented seeds. *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed.Cir 2002), available at: <https://law.justia.com/cases/federal/appellate-courts/F3/302/1291/559968/>.

96. McFarling argued, *inter alia*, that the contractual prohibition against using the patented seed to produce new seed for planting violates section 2543 of the Plant Variety Protection Act (PVPA),⁷⁷ which permits farmers to save seeds of plants registered under the PVPA. In this respect, the court held:

“The PVPA and the Patent Act are complementary forms of statutory protection of plant ‘breeders’ rights.” Utility patents under Title 35 provide rights and privileges that differ from those provided by Plant Variety Protection certificates.” [...] the Court held that utility patents are available to plants and seeds that meet the requirements of patentability, independent of and in addition to rights under the PVPA. The Court observed that one of the differences between the two statutes is that “there are no exemptions for research or saving seed under a utility patent.” [...] It is thus established that the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patent Act.”⁷⁸

97. Similarly, in *Monsanto Co. v. Scruggs*, (2006), the Federal Circuit reaffirmed that saving and replanting patented seeds without a license exceeds the scope of permissible use under exhaustion, as it amounts to the creation of new patented material.⁷⁹

98. A similar approach was adopted by the Supreme Court of Canada in *Monsanto Canada Inc. v. Schmeiser* (2004). While the Court did not frame the issue explicitly in terms of ‘seed saving’, it implicitly held that saving and replanting patented seeds without the patent holder’s authorization constitutes unauthorized use under Canadian patent law.⁸⁰

⁷⁷ Current Sec. 113. ‘Right To Save Seed; Crop Exemption’ of the PVPA states “Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 111, it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 127 that the actions of the purchaser constitute an infringement. (7 U.S.C. 2543.)”

⁷⁸ This position was reaffirmed in *McFarling II*, 363 F.3d 1336 (Fed. Cir. 2004), where the court declined to reconsider its earlier ruling and stated that the PVPA does not demonstrate congressional intent to preempt restrictions contained in utility-patent licenses. In *McFarling III*, Nos. 05-1570, -1598 (Fed. Cir. Feb. 13, 2007), the court again declined to revisit the issue, confirming that the PVPA does not entitle farmers to infringe patents by replanting saved seed without a license. Thus, across all three decisions, the Federal Circuit consistently held that the PVPA does not override patent rights conferred under the Patent Act.

⁷⁹ Specifically, the Court stated: “The doctrine of patent exhaustion is inapplicable in this case. There was no unrestricted sale because the use of the seeds by seed growers was conditioned on obtaining a license from Monsanto. Furthermore, the “first sale’ doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been sold.” See *Monsanto v. McFarling*, 302 F.3d 1291, 1299 (Fed. Cir. 2002). Without the actual sale of the second generation seed to Scruggs, there can be no patent exhaustion. The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.” *Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006).

⁸⁰ In *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, the defendant, a Canadian farmer, grew canola plants that contained a patented gene conferring resistance to glyphosate (Roundup®). Schmeiser claimed that the genetically modified seed had unintentionally arrived on his land, but he nonetheless saved and replanted the resulting seeds without obtaining a license from Monsanto. While Monsanto’s license would have permitted planting the seeds for a single growing season only, Schmeiser replanted without

[Footnote continued on next page]

99. In practice, the jurisprudence in both the United States and Canada establishes that a purchaser of patented seeds may plant them once, consistent with their intended use (often defined in licensing agreements or product labeling), but may not save, reuse, or replicate them.

100. In Brazil, a comparable case was brought before the courts. The plaintiff challenged Monsanto's practice of collecting royalties on genetically modified soybeans at the post-harvest stage, arguing that it violated farmers' rights under Brazil's Plant Variety Protection Act (Law No. 9.456/1997), which allowed farmers to save seeds from their harvest for replanting and to sell their produce without additional payments. The plaintiffs claimed Monsanto's IP rights were exhausted once it had licensed the genetically modified technology to seed producers.

101. While a lower civil court ruled in favor of the farmers, the Superior Court of Justice (STJ), in 2019, issued a decision in favor of Monsanto. The STJ concluded that the farmers' rights to save seeds under the Plant Variety Protection Act do not apply in cases involving patented genetically modified seeds.⁸¹

102. With respect to exhaustion, the STJ stated:

"However, and herein lies the fundamental point of the present controversy, the final part of paragraph VI. of Art. 43 of the Industrial Property Law expressly provides that there will be no exhaustion in the event that the patented product is 'used for multiplication or commercial propagation of the living matter in question'.

Clearly, the legislative option was to make it clear that exhaustion, when it comes to patents related to living matter, only affects the circulation of those products that can be classified as non-reproducible living matter, a circumstance that does not coincide with the object of the appellants' claim."

[...]

In this line of thought, to understand that the farmers represented by the appellants have the right to reserve the RR soybean product (which contains technology patented by the defendants) for replanting and subsequent marketing, as well as to donate or exchange these seeds, is tantamount to emptying the normative content of the provision in question, making it a dead letter, which is inadmissible from a technical-legal point of view." [non-official translation]

103. Thus, in Brazil, according to the STJ decision, saving, replanting, donating, or exchanging such seeds constitutes multiplication or propagation for commercial purposes, which is excluded from the exhaustion doctrine under Brazilian law.

authorization. The Supreme Court did not determine how the gene came to be present but held that his act of saving and replanting the seeds constituted unauthorized "use" of the patented invention under the Patent Act. *Monsanto Canada Inc. v. Schmeiser* (2004), available at: <https://decisions.scc-csc.ca/scc-csc/scc-csc/en/item/2147/index.do>.

⁸¹ Superior Court of Justice decision No. 1.060.428 of October 9, 2019 (Brazil) (Superior Tribunal de Justiça), cited in: Peschard, K., & Randeria, S. (2020). Taking Monsanto to court: legal activism around intellectual property in Brazil and India. *The Journal of Peasant Studies*, 47(4), 792–819, available at: <https://doi.org/10.1080/03066150.2020.1753184>.

Breeders' use

Formulation and scope of the exception

104. Provisions concerning breeders' use have been identified in the patent laws of 18 countries. While they exhibit a shared underlying rationale - to facilitate innovation through further breeding - they differ in their formulation and scope.

105. A degree of convergence is evident in the legislative approach of several European countries. For instance, Germany, France, Sweden, the Netherlands, and Switzerland adopt formulations that link the exception specifically to the development of new plant varieties:

106. Article L613-5-3 of the Intellectual Property Code of France provides:

"Rights conferred by the Articles L613-2-2 and L613-2-3 shall not extend to the deeds performed in order to create or discover and develop other plant varieties."

107. Similarly, paragraph 2a of Section 11 of the Patent Act of Germany states:

"The effect of a patent does not extend to [...] the use of biological material for the purpose of breeding, discovering and developing a new plant variety."

108. By contrast, countries such as Brazil, Mexico, Nicaragua and the Dominican Republic use more detailed statutory exemptions. These provisions often incorporate specific qualifiers, such as absence of commercial intent or limitations on repeated use, which introduce narrower or more conditional exceptions.

109. For example, Article 43(V) of the Industrial Property Law of Brazil states:

"The provisions of the previous Article do not apply: [...] to third parties who, in the case of patents related to living material, use the patented product, without economic intent, as an initial source of variation or propagation to obtain other products."

110. Article 57(VI) of the Industrial Property Law of the Federal Law on the Protection of Industrial Property of Mexico states:

"The right conferred by a patent shall have no effect against: [...] a third party that, in the case of patents related to living matter, uses the patented invention as an initial source of variation or propagation to obtain other products, unless such use is made repeatedly." [non-official translation]

111. Similarly, Article 30(f) of the Industrial Property Law of the Dominican Republic states:

"A patent shall not confer the right to prevent: [...] where the patent protects biological material that is capable of being reproduced, the use of the material as an initial basis for obtaining a new viable biological material, except where the patented material must be used repeatedly in order to obtain the new material;"

112. Based on the wording of the relevant provisions, it could be assumed that the scope of the breeding exception in the latter group of countries may be narrower than in the former.

Brazil explicitly restricts the exception to non-commercial (no economic intent) uses. In the Dominican Republic, Mexico, and Nicaragua, the exception is qualified by a restriction on repeated use of the patented material.

113. Furthermore, countries like the Dominican Republic, Brazil, Mexico, and Nicaragua use the terminology of “initial source” or “starting point” to define the scope of allowed use.⁸² These formulations emphasize the right to use patented material as a basis for further development.

114. In addition, while France, Germany, the Netherlands,⁸³ Sweden,⁸⁴ and Switzerland,⁸⁵ with respect to the purpose of the exception, specifically refer to the breeding or production, discovery and development of “new plant varieties”, the laws of the Dominican Republic, Brazil, and Mexico use broader terms such as obtaining “viable biological material”, or “other products” suggesting a potentially wider scope of biological innovation beyond plant varieties.

115. The law of Italy⁸⁶ additionally refer to the use of biological material “for cultivation,” which could imply a broader range of permitted activities beyond breeding *per se*.

116. In Oman, the breeding exception explicitly includes the development of “essentially derived varieties”, indicating alignment with the terminology contemplated under the UPOV Convention.⁸⁷

117. A further formulation nuance found in the national law of Italy, which merges the breeder’s use into broader exception for experimental use.⁸⁸

118. The submission from the Russian Federation explains that, although the Civil Code of the Russian Federation does not contain specific provisions concerning the use of patented inventions for agricultural and/or breeding purposes, Article 1359(2) of the Civil Code provides that, breeders, *inter alia*, may conduct scientific research on a product or method that incorporates the invention, or perform experiments *with such products or methods* without infringing patent rights.⁸⁹ [emphasis added]

119. Likewise, the submissions from China and the Republic of Korea referred to the general research or experimental use exception with reference to farmers’ and breeders’ use of patented inventions.⁹⁰

⁸² As regards Nicaragua, see Article 46(c) of the Law No. 354 on Patents, Utility Models and Industrial Designs.

⁸³ As regards the Netherlands, see Article 54c of the National Patent Act 1995.

⁸⁴ See Sections 8, Chapter 3 of the Patents Act of Sweden.

⁸⁵ See Article 9(e) of the Patent Act of Switzerland.

⁸⁶ See Article 68, paragraph 1, letter a-bis, of the Industrial Property Code of Italy.

⁸⁷ See Section 11(4)(c) of the Law on Industrial Property Rights of Oman.

⁸⁸ The provision states: “Art. 68. Limitations of patent rights

1. The exclusive power attributed by the patent right does not extend, whatever the object of the invention: [...] (a-bis) to acts carried out on an experimental basis relating to the object of the patented invention, or the use of biological material for cultivation purposes, or the discovery and development of other plant varieties;”.

⁸⁹ See a response from the Russian Federation to C.9260, dated January 31, 2025, published on the SCP Electronic Forum website at: https://www.wipo.int/en/web/scp/electronic-forum/meetings/session_37/comments_received.

⁹⁰ Specifically, in the submission of China it is stated: “Article 75(4) of the Patent Law of the People's Republic of China provides that where the relevant patent is used specially for the purposes of scientific research and experimentation, it shall not be deemed as infringement of the patent right.”, The submission of the Republic of Korea referred to Article 96 of the Korean Patent Act which stated: “(1) The effects of a

[Footnote continued on next page]

120. In contrast, the response from El Salvador noted that, while Article 208 of the Intellectual Property Act sets out certain limitations to the rights of the patent holder, allowing use for private and non-commercial purposes as well as for research or teaching, those provisions do not expressly permit farmers to reuse protected seeds or allow plant breeders to use them in breeding programs without the authorization of the patent holder.⁹¹

121. With respect to the scope of the breeders' exemption in Switzerland, it is explained that both plant variety protection law and patent law provide for an exemption allowing further breeding. However, unlike under plant variety protection, the commercialization of a new variety incorporating a patented trait requires the patent holder's consent, typically through a license, due to the replicability of patented innovations and the need to recover R&D costs.⁹²

122. Regarding the breeders' use provision in the Netherlands' patent law, the preparatory works clarify that "actual access to the material protected by patent law for breeding purposes only arises after the material has been placed on the market."⁹³

Compulsory cross-licensing

Formulation and scope of the exception

123. As discussed above, provisions concerning compulsory cross-licensing typically concern situations where either: (i) a plant breeder cannot acquire or exploit a plant variety without infringing a prior patent, or (ii) a patent holder cannot exploit a biotechnological invention without infringing a prior plant variety protection right.

124. Such provisions have been identified in the patent laws of 37 countries, most of which are European jurisdictions. In those countries, provisions are generally formulated to model after Article 12 of the EU Biotech Directive and they adopt the same structural elements. These include the following key conditions:

- The plant variety or the invention must constitute significant technical progress of considerable economic interest in comparison to the invention claimed in the patent or the protected plant variety;
- The license must be non-exclusive and subject to payment of an appropriate royalty; and
- A cross-license must be made available to the other party under reasonable terms.

patent shall not extend to the following: 1. Practice of a patented invention for the purpose of research or testing (including research and testing for obtaining permission for items of medicines or reporting items of medicines under the Pharmaceutical Affairs Act or for registering pesticides under the Pesticide Control Act)". See the submissions published on the SCP Electronic Forum website, *ibid*.

⁹¹ See the submission from El Salvador published on the SCP Electronic Forum website, *ibid*.

⁹² The reference is made to Art. 6 let. c of the Plant Varieties Protection Act and Art. 9 para. 1 let. e of the Patents Act, respectively. See the webpage of the Swiss Federal Institute of Intellectual Property (IPI) at: <https://www.ige.ch/en/law-and-policy/national-ip-law/patent-law/revision-transparency-on-patents-in-plant-breeding/plant-breeding-and-patents>.

⁹³ House of Representatives of the States General, Amendment of Article 53b of the Dutch Patent Act 1995 in connection with the introduction of a limited breeding exemption, Memorandum in Response to the Report, Parliamentary year 2012–2013, 33 365 (R 1987), no. 7, p.6.

125. In a few countries, the breeder's use is addressed by applying the standard patent dependency rules, not by a separate breeder-specific clause.⁹⁴

126. Comparative analysis of national provisions reveals several variations in formulation, including differences in the conditions for grant, scope of rights affected, and procedural requirements, though it is possible that some of these aspects are further specified in secondary legislation or administrative regulations. For example, in some countries, the relevant provisions do not include conditions relating to technical progress or economic importance.⁹⁵ The law of Latvia generally states "the owner of the plant variety is entitled to qualify for a cross-licence with justified conditions for the use of the protected invention".⁹⁶ In Iceland, a compulsory license shall be granted if the plant variety holder demonstrates that the variety involves two separate conditions, namely "technically important progress" and leads to "considerable financial benefit" in comparison to the patented invention.⁹⁷ The law of the Czech Republic applies such compulsory licensing not only to plant varieties but also to animal variety rights.⁹⁸

127. Other particularities are also identified in the national provisions. For example, Estonia allows for compulsory licensing when a patent hinders the grant of plant variety rights and does not address the situation when patents hinder "exploitation" of plant variety rights. Belgium's provision reflects Article 12 of the EU Biotech Directive but also adds an additional requirement that such a license must be granted "mainly for the supply of the national market".⁹⁹

6. Challenges Faced by the Member States in Implementing the Exceptions

128. In response to Note C. 9260, dated 31 January 2025, which invited Member States to submit input for the preparation of the draft reference document on the exceptions concerning farmers' and/or breeders' use of patented inventions, including any implementation challenges, only a limited number of countries provided submissions. Among those, none reported specific challenges encountered in implementing the exceptions under discussion.

121. In addition, based on the responses to the 2011 Questionnaire on Exceptions and Limitations to Patent Rights submitted by Member States, it appears that, at that time, the exceptions relating to farmers' and breeders' use of patented inventions had not raised any significant implementation issues at the national level.¹⁰⁰

⁹⁴ See, e.g., Article 82 of the Industrial Property Act of Poland, which references the general patent dependency provision by stating: "6. The provision of paragraph (1)(iii) shall apply accordingly where a plant breeder is not able to exercise his right to the protected plant variety [...]"

⁹⁵ See, e.g., relevant provisions of laws of Estonia, Romania, São Tomé and Príncipe, and Serbia.

⁹⁶ Section 54 of the Patent Law of Latvia.

⁹⁷ Article 46 a) of the Patents Act № 17/1991 of Iceland.

⁹⁸ Section 9 of the Act No. 206/2000 Coll., of June 21, 2000, on the Protection of Biotechnological Inventions of the Czech Republic.

⁹⁹ Article XI.37. § 1er of the Law of April 19, 2014 of Belgium.

¹⁰⁰ Most of the Member States that replied to the question on whether any challenges had been encountered in relation to the practical implementation of the exceptions in question responded negatively, or provided no answer to this question. See the responses to the Questionnaire at:

<https://www.wipo.int/scp/en/exceptions/>. Only response from Mexico stated that as the exception that allowed third parties to use the patented product as an initial source of variation or propagation to obtain other products related to "the traditional practice of its farmers", "due to the imminent approval of

[Footnote continued on next page]

129. Although the ambiguity and uncertainty of national law provisions haven't been explicitly identified by Member States as implementation challenges, as discussed elsewhere,¹⁰¹ such issues, *inter alia*, may affect the practical utilization of the exceptions by relevant stakeholders, including farmers and breeders.^{102, 103}

7. Results of National/Regional Implementation of the Exceptions

130. No information has been submitted by Member States regarding the socio-economic effects resulting from the implementation of any of the four types of exceptions to patent rights relating to farmers' and breeders' use discussed in this document. Furthermore, there appears to be a general lack of empirical studies examining how the implementation of these exceptions affects agricultural innovation or impacts farmers and plant breeders in practice. More broadly, even studies that provide conclusive evidence on the overall effects of the patent system on the agricultural sector appear to be scarce.

131. The limited availability of empirical studies on the exceptions in question may be partly attributed to the issue of patentability of plant- and animal-related inventions, which falls outside the scope of this document. In essence, Article 27(3)(b) of the TRIPS Agreement permits WTO Members to exclude from patentable subject matter plants and animals (other than micro-organisms), as well as essentially biological processes for their production (other than non-biological and microbiological processes). However, Members are required to provide protection for plant varieties either by patents, by an effective *sui generis* system, or by a combination of both.^{104,105} This flexibility regarding the patentability of such inventions may partly help explain why exceptions relating to farmers' and breeders' use of patented inventions, as discussed in this document, are reflected in the laws of fewer countries

commercial transgenic crops", there has been a great concern about the interpretation of the exception as regards "transgenic plants and possible contamination by pollen of traditional crops".

¹⁰¹ See document SCP/36/6.

¹⁰² In Europe, certain issues regarding the wording of specific provisions in the Biotech Directive were discussed, among other matters, by the Expert Group established to provide the European Commission with technical and legal expertise on the application of Directive 98/44/EC. See: Bostyn, S. et al., Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering. European Commission, 2016, p.47, available at: <https://ec.europa.eu/docsroom/documents/16686/attachments/1/translations>.

¹⁰³ Certain challenges concerning the implementation of the compulsory cross-licensing system in Europe have been discussed in legal academic literature. See footnote 28 of this document.

¹⁰⁴ Additionally, Article 27.2 of the TRIPS Agreement, allows Members to exclude from patentability inventions the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including, *inter alia*, to protect animal or plant life or health, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

¹⁰⁵ While a full analysis of the implementation of these provisions under the national laws and interpretation of those various national provisions would go beyond the scope of this document, it should be noted that the exact scope of the exclusions relating to plants and animals in national laws may require thorough understanding of other provisions of the relevant national law. For example, even if there is no explicit provision excluding plants and animals or biological material that exists in nature from patentability, patents may be refused because they are considered to be discoveries or lack novelty. Similarly, with respect to parts of plants and animals (cells, genes etc.), in some countries, they may be excluded from patentable subject matter, while in some other countries, they may be considered as a particular type of chemical substance, if isolated and purified from their natural environment. In the latter case, whether such an invention would obtain patent protection or not depends on other conditions of patentability, such as novelty, inventive step (non-obviousness), industrial applicability (utility) and the disclosure requirement. Thus, exclusion clauses by themselves do not fully indicate how broadly plant- or animal-related inventions are protected under a country's patent regime.

compared to other exceptions previously examined by the SCP.¹⁰⁶ The limited availability of empirical studies on the exceptions in question may also be attributed to the inherent difficulty of obtaining data on their use, as in most jurisdictions, such uses are not registered or otherwise recorded. In the case of cross-compulsory licenses, as stated above, there are no reported examples of actual use. Moreover, in jurisdictions where regulatory frameworks restrict or prohibit the commercialization of genetically modified or gene-edited plants, the practical need or demand for such patent exceptions may be muted - thereby discouraging the legislative adoption of such exceptions.

132. With respect to farmers use exception, while no empirical studies appear to assess the socio-economic impact of such exception specifically under patent law, some research has been documented in the context of the analogous exception under plant variety protection, particularly within the EU framework. Given that Article 11 of the EU Biotech Directive and Article 27(i) of the UPCA both link the scope of the farmers' use exception to Article 14 of the CPVR Regulation, these studies may provide indicative insights.¹⁰⁷

133. Though not economic in nature, some legal scholars have proposed that countries that do not currently provide farmers' or breeders' use exceptions under their patent laws could consider adopting similar frameworks to those found in European law.^{108,109}

134. In 2022, following public consultations, the U.S. Department of Agriculture (USDA) published a report highlighting concerns and recommendations related to intellectual property rights for plant-related innovations. Key concerns expressed by stakeholders included: (i) limited access to consolidated information on existing IP rights; (ii) inadequate prior art searches during patent examination, leading to potentially invalid patents; and (iii)

¹⁰⁶ As discussed above, the four exceptions discussed in this document (breeders' use, farmers' use, exhaustion of rights, and compulsory cross-licensing) are based on distinct legal concepts. While their policy objectives may overlap in promoting access and innovation, the implementation challenges and practical effects of each exception may differ and should likely be assessed individually.

¹⁰⁷ For example, CPVO – EUIPO study (2022), "Impact of the Community Plant Variety Rights System on the EU Economy and the Environment" provides an overview of existing literature on the economic effect of the farmers' use exception under plant variety protection system in Europe. However, after reviewing the available literature, the study concludes that "[...] this area is still work in progress. [...] it seems that functioning of farmers' seed network and their economic contribution to agricultural output is still beset by lack of research, especially in terms of interdisciplinary evaluations of their social, institutional, and economic functioning", p. 53 and 54.

¹⁰⁸ For example, Romero and Correa suggest that although the European legal model may not be directly transplantable, it offers useful elements for addressing challenges posed by the extension of patent protection to plants and plant materials. They note that the EU farmers' use exception, available without remuneration for certain crops and categories of farmers, could be expanded in developing countries to cover all farmers and crops, thereby avoiding burdens that could impact livelihoods and food security. Similarly, the breeders' use exception under European law, which allows the use of patented material for developing new varieties (though not their commercialization), is cited as a possible model to support innovation. The authors also highlight the Swiss approach, which prohibits contractual derogation of the farmers' use exception, as a legal safeguard worth considering. Romero T., and Correa C., "Patenting of Plants and Exceptions to Exclusive Rights: Lessons from European Law", South Centre, September, 2021; See also Antons C., who also suggests that farmers' use exception should be considered in developing countries. Antons C., "Article 27.3.b TRIPS and Plant Variety Protection in Developing Countries", draft of a chapter published in Hanns Ullrich, Reto M. Hilty, Matthias Lamping and Josef Drexler (eds.), TRIPS plus 20: From Trade Rules to Market Principles, Heidelberg-New York-Dordrecht-London: Springer, 2016, p.20.

¹⁰⁹ While not related to the EU context, in 2002, the Canadian Biotechnology Advisory Committee (CBAC) similarly recommended that Parliament amend the Patent Act to include a farmers' privilege allowing the saving and replanting of seeds from patented plants under certain conditions. The current Canadian Patent Act does not contain a statutory farmers' use exception. Relevant jurisprudence, including *Monsanto Canada Inc. v. Schmeiser*, as discussed above, confirms that farmers do not have an automatic right to reuse patented genetic traits without the patent holder's consent. CBAC report is available at: <https://publications.gc.ca/collections/Collection/C2-598-2001-2E.pdf>.

restrictive licensing practices that undermine research and breeding exemptions. In response, a new inter-agency Working Group on Competition and Intellectual Property was proposed to enhance patent quality, improve IP transparency, gather stakeholder input, and explore the introduction of research or breeders' exemptions under U.S. utility patent law.¹¹⁰

135. In Europe, in the context of recent regulatory discussions on New Genomic Techniques (NGTs), transparency has also emerged as a key concern, particularly regarding the patent landscape for plant-related innovations. Under the Council's negotiating mandate, applicants for Category 1 NGT¹¹¹ plants will be required to provide information on any relevant existing or pending patents, which will be published in a publicly accessible database managed by the European Commission, in order to ensure greater transparency and legal certainty for breeders and farmers.^{112,113} In parallel, the Commission is also expected to conduct a study to assess the impact of patents on innovation, breeders' and farmers' access to NGT-derived plant reproductive material, and on the competitiveness of the EU plant breeding sector.¹¹⁴

136. In the absence of empirical evidence, it remains difficult to draw definitive conclusions regarding the impact of implementing farmers' and breeders' use exceptions in patent laws. Nevertheless, patents are widely regarded as an important mechanism for stimulating investment in biotechnology, particularly in plant breeding, where innovation requires significant time and resources. At the same time, exceptions such as those for farmers' and breeders' use adopted in various jurisdictions aim to strike a balance between the rights of patent holders and broader public interests, including food security, innovation, and sustainable agriculture. However, there is a notable lack of empirical research evaluating the practical effects of these exceptions, underscoring the need for further interdisciplinary studies to assess whether they are achieving their intended policy objectives. Additionally, strengthening patent quality and enhancing transparency, particularly in relation to plant-related inventions, are essential to ensuring that the patent system functions effectively and equitably in support of innovation and public welfare in the agricultural sector.

[Appendix follows]

¹¹⁰ USDA, "More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs", March 2023.

¹¹¹ Two distinct pathways for NGT plants to be placed on the market are being discussed: (i) *Category 1 NGT plants* - those that could occur naturally or through conventional breeding methods. They would be exempt from the rules currently set out in the GMO legislation and would not require product labelling, although seeds produced through these techniques would have to be labelled; and (ii) *Category 2 NGT plants* - all other NGT plants, for which the rules under GMO legislation would apply, including a risk assessment and authorization prior to being placed on the market, as well as labelling requirements. See: <https://www.consilium.europa.eu/en/press/press-releases/2025/03/14/new-genomic-techniques-council-agrees-negotiating-mandate/>.

¹¹² For more information on discussions on NGTs, see the European Commission website: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/protection-biotechnological-inventions_en, and the Council of the European Union press release: <https://www.consilium.europa.eu/en/press/press-releases/2025/03/14/new-genomic-techniques-council-agrees-negotiating-mandate/>.

¹¹³ To promote transparency and enable breeders to make informed decisions about whether to use a given variety for breeding purposes, the European seed industry association, Euroseeds, has developed a database called PINTO, where companies list their commercial varieties that are covered by patents. For more information, see: <https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/>.

¹¹⁴ The study may not directly address the specific exceptions discussed in this document, but it could nonetheless provide useful insights into certain related issues, particularly those concerning access to patented plant material and transparency in the context of NGT-related innovation. The study should conclude in the second half of 2025.